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Research Article

Effects of Bromfenac Ophthalmic Solution on Intraocular Pressure after Phacoemulsification Surgery

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Abstract:

Background: Cataract surgery is one of the commonest surgeries. Changes in intraocular pressure (IOP) might occur after surgery and some post-operative medications might affect it.

Objectives: To evaluate the effects of the non–steroidal anti–inflammatory drug Bromfenac 0.09% ophthalmic solution on intraocular pressure after phacoemulsification and to report any side effects of the drug.

Method: It was a prospective study done at Jenna ophthalmic center, Baghdad- Iraq from May 2023 to January 2024 involving adult patients with cataract prepared for phacoemulsification with intraocular lens implantation. The patients were divided into two groups: **Group I:** received 0.09% Bromfenac ophthalmic solution twice daily in addition to Moxifloxacin 0.5% ophthalmic drops every 6 hours and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6 hours post-operatively. **Group II:** received only Moxifloxacin 0.5% every 6 hours and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6 hours without the administration of Bromfenac 0.09% ophthalmic drops post-operatively. The intraocular pressure was measured pre-operatively and 6 weeks post-operatively by Goldman applanation tonometry.

Results: Eighty-seven eyes of 87 patients are enrolled in the study. The preoperative mean of intraocular pressure in group I and group II were 16.6 ± 2.37 mmHg, and 17.1 ± 3.33 mmHg respectively (not significantly different), while the postoperative mean of intraocular pressure in group I and group II, were 16.0 ± 2.32 mmHg and 16.7 ± 2.9 mmHg respectively. There were no significant changes in IOP post-operatively in either group, and the only side effect reported was punctate epithelial corneal erosion in five patients in group I.

Conclusion: The effect of Bromfenac 0.09% ophthalmic solution administration postoperatively on IOP in cataract patients was insignificant. The medication resulted in punctate epithelial erosion in some patients.

Keywords: Bromfenac; Cataract; Goldman application tonometry; Intraocular Pressure; Phacoemulsification.

Introduction

A cataract is a degenerative alteration in the metabolism of the lens of the eye (1) that leads to opacification and cloudiness of the lens (2) which is normally crystalline and transparent (3). Most of the time, cataracts are associated with the aging process. (4). Although cataracts are nearly always curable through surgery, they remain one of the most prevalent causes of visual impairment globally, including Iraq (4,5). Phacoemulsification has been demonstrated to decrease IOP after surgery in many studies (6). Elevation of intraocular pressure (IOP) from the individual's normal level has consistently been considered to be one of the most important risk factors in glaucoma. It has also been demonstrated that lowering IOP would be protective. (7) Postoperative treatment of cataract surgery usually includes topical drops, such as antibiotics, steroids, and non-steroidal anti-inflammatory drugs (NSAIDs). Topical preparations are the dosage forms Those are Most frequently chosen for the treatment of ocular diseases. They are a non-invasive method of administration (8). Non-steroidal anti-inflammatory Drugs (NSAIDs) primarily inhibit cyclooxygenases I and II. These enzymes are involved in the cascade of arachidonic acid, which leads to a decrease in the synthesis of prostaglandins (9).

Bromfenac is a brominated NSAID that possesses potent in-vitro anti-inflammatory properties and prevents the conversion of arachidonic acid to cyclic endoperoxides, which are precursors of prostaglandins (PG), by binding to and inhibiting the activity of cyclooxygenase II (cox-2) and it is the only available brominated ophthalmic NSAID that is currently available (10). The lipophilicity of Bromfenac is enhanced by the presence of bromine in its chemical structure, which facilitates its penetration into the cornea, vitreous fluid, and intraocular tissue. Additionally, the duration of the compound's analgesic and anti-inflammatory activity is increased by bromination at the fourth position of the phenyl ring (11). The United States Food and Drug

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Administration (FDA) has approved the administration of Bromfenac 0.09% twice daily for the prevention of ocular pain and the treatment of postoperative inflammation in patients undergoing cataract surgery (12), but this inhibition of inflammation might affect the change of IOP after the surgery.

Several studies have demonstrated that PGs, including endogenous PGs stimulated by latanoprost, contribute to reducing IOP and NSAIDs including Bromfenac, inhibit cyclooxygenase activity, thereby suppressing the production of endogenous PGs. However, there are no reports indicating that Bromfenac sodium hydrate affects IOP. (13).

The rationale of this study is to understand the dual aspects of Bromfenac use: Its impact on IOP regulation and its safety profile. By addressing these aims, the research provided valuable insights that can inform clinical practice, improve postoperative outcomes, and guide future studies on NSAIDs in ophthalmology. This study aimed to evaluate the effects of the non–steroidal anti-inflammatory drug Bromfenac 0.09% ophthalmic solution on IOP after phacoemulsification surgery. Moreover, tried to report the adverse effects of 0.09% Bromfenac ophthalmic solution on our patients.

Patients and Methods

This study was a prospective study that was done at Jenna Ophthalmic Center, Baghdad, Iraq, from May 2023 to January 2024. It enrolled 87 eyes from 87 Iraqi patients diagnosed with cataract. Ethical and scientific approvals were obtained from the scientific committee of the Department of Pharmacology / College of Medicine, University of Baghdad. The study was conducted following the Helsinki Treaty. Written informed consent was obtained from all participants.

Inclusion Criteria

1. Patients 18 years of age or older.
2. Patients diagnosed with cataract.
3. Normal IOP at preoperative assessment (10- 21 mmHg).

Exclusion Criteria

1. Patients who have glaucoma, ocular hypertension, pseudo exfoliation syndrome, or any optic nerve disease.
2. Patients with ocular diseases that might influence intra-ocular pressure such as history of uveitis, intraoperative complications, and traumatic cases.
3. Patients who have undergone previous ocular surgery in the same eye such as vitrectomy or corneal surgery.
4. Patients who developed serious adverse effects from other drugs or had complications intraoperatively or postoperatively unrelated to Bromfenac.
5. Patients taking antiglaucoma medications.
6. Patients lost to follow-up.
7. Patients with an allergy to one of the postoperative medications.

Participants

Eighty-seven Iraqi adult patients aged ≥ 18 years with senile or iatrogenic cataract were enrolled in this study. All patients underwent a comprehensive ophthalmic examination, including review of their medical history, visual acuity testing, slit-lamp examination and IOP measurements. None of the enrolled patients had a history of previous ocular surgery, any ocular condition (glaucoma, uveitis, retinal disorders, central corneal opacities, etc.), or systemic disorders affecting vision.

Those patients have undergone phacoemulsification surgery with intraocular lens (IOL) implantation and were divided into two groups. They were randomly assigned to group I or group II using simple randomization where a random number generator was used to create a sequence, ensuring an equal probability of being assigned to either group.

Group I: Consisted of 45 patients who received 0.09% Bromfenac ophthalmic solution twice daily in addition to Moxifloxacin 0.5% ophthalmic drops every 6 hours and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6 hours.

Group II: Consisted of 42 patients who received only Moxifloxacin 0.5% every 6 hours and Dexamethasone phosphate 0.1% ophthalmic drops every 4-6 hours.

Neither group received any preoperative eye drops. Topical NSAIDs may sometimes be used preoperatively to reduce intraoperative miosis. This was not part of the protocol for either group in our study. All patients began their assigned postoperative regimens immediately after surgery.

All the above drugs were used for 6 weeks with gradual tapering of steroids.

Phacoemulsification surgery was performed by two experienced surgeons on all patients with no intraoperative complications. The IOP was measured immediately before the phacoemulsification surgery to establish a baseline reading for each patient and then 6 weeks post-operatively by the same observer in both groups using Goldmann Applanation Tonometry with two measurements of IOP with the mean value recorded. All patients were followed up at one day, one week, and six weeks for any complications or side effects of any drug.

The central corneal thickness (CCT) was measured as part of routine postoperative evaluation, but we did not specifically adjust IOP readings based on CCT changes.

Statistical analysis

Microsoft Excel 2019 and the Statistical Package for the Social Sciences (SPSS, Version 25) were used for data entry and analysis. Frequencies and percentages were calculated. Continuous variables were displayed as mean±standard deviation. The paired *t*-test was used to compare preoperative and postoperative IOP in each group. The Chi-square test was used to test for associations. In all analyses, $p < 0.05$ was used to indicate statistical significance.

Results

Demographically, the two study groups were comparable in terms of age, gender, diabetes mellitus, and hypertension. The mean age of group I was 66.4 ± 8.70 years ranging from 45 years to 86 years. More than half of the cases 25 (55.5%) were males, 27 (60%) had diabetes and 20 (44.4%) had hypertension. Group II had a mean age was 61.3 ± 9.30 years ranging from 40 years to 76 years. Twenty cases 22 (47.6%) were males, 14 (33.3%) had diabetes and 19 (45.2%) had hypertension, Table 1.

Table (1): Distribution of the two study groups by demographic features

Variables	Category	Study groups – No. (%)		
		Group I	Group II	*p*-value
Age group (Years)	40-49	1 (2.2)	5 (11.9)	0.344
	50-59	9 (20.0)	12 (28.5)	
	60-69	17 (37.7)	17 (40.4)	
	70 +	18 (39.9)	8 (19.0)	
Gender	Male	25 (55.5)	20 (47.6)	0.746
	Female	20 (44.4)	22 (52.3)	
Diabetes Mellitus	No	18 (40.0)	28 (66.6)	0.508
	Yes	27 (60.0)	14 (33.3)	
Hypertension	No	25 (55.5)	23 (54.7)	0.474
	Yes	20 (44.4)	19 (45.2)	

The mean preoperative IOP in group I and group II were 16.6 ± 2.37, and 17.1 ± 3.33 mmHg respectively (p-value = 0.365). The mean postoperative IOP in group I and group II were 16.0 ± 2.32 and 16.7 ± 2.90 mmHg respectively (p-value = 0.266), table 2.

Table (2): Mean±SD intraocular pressure in the two groups pre- and post-operatively

Intraocular pressure (mmHg)	Group I (n=45)	Group II (n=42)	P-value
Preoperative	16.6 ± 2.37	17.1 ± 3.33	0.365
Postoperative	16.0 ± 2.32	16.7 ± 2.90	0.266

There were 41 patients with diabetes, with a pre-operative mean IOP of 16.4 ± 2.37 and 17.1 ± 3.10 mmHg in group I and group II, respectively (p-value = 0.463). The mean postoperative IOP was 15.8 ± 2.22 and 16.5 ± 2.80 mmHg in group I and group II, respectively (p-value = 0.375), Table 3.

Table (3): Mean±SD intraocular pressure in the two groups pre- and post-operatively in diabetes patients

Intraocular pressure (mmHg)	Group I (n=27)	Group II (n=14)	P-Value
Pre-op	16.4 ± 2.37	17.1 ± 3.10	0.463
post-op	15.8 ± 2.22	16.5 ± 2.80	0.375

There were 39 patients with hypertension. The mean pre-operative IOP was 17.0 ± 2.42 and 17.9 ± 3.70 mmHg in groups I and II, respectively (p-value = 0.395). The mean postoperative IOP was 15.8 ±1.9 and 17.0 ± 3.10 mmHg in groups I and II, respectively (p-value = 0.282), Table 4.

Table (4): Mean±SD intraocular pressure in the two groups pre- and post-operatively in hypertensive patients

Intraocular pressure (mmHg)	Group I (n=20)	Group II (n=19)	P-Value
Pre-op	17 ± 2.42	17.89± 3.70	0.395
post-op	15.8±1.9	17 ±3.1	0.282

There were 45 males in this study with a mean pre-operative IOP of 16.8 ± 2.54, and 17.2 ± 3.29 mmHg in group I and group II respectively (p-value = 0.714). The mean post-operative IOP was 16.1 ± 2.20 and 16.7 ± 3.00 mmHg in group I and group II respectively (p-value =0.466), figure 1.

There were 42 females with a mean pre-operative IOP of 15.8 ± 2.32 and 16.8 ± 2.87 mmHg respectively in group I and group II (p-value = 0.842). The mean post-operative IOP was 15.8 ± 2.60 and 16.5 ± 2.78 mmHg respectively in group I and group II (p- value = 0.584), figure 2.

Five patients developed Punctuate Epithelial Erosions (PEE) post-operatively in group I while there were no patients with corneal changes in group II and no other side effects were reported.

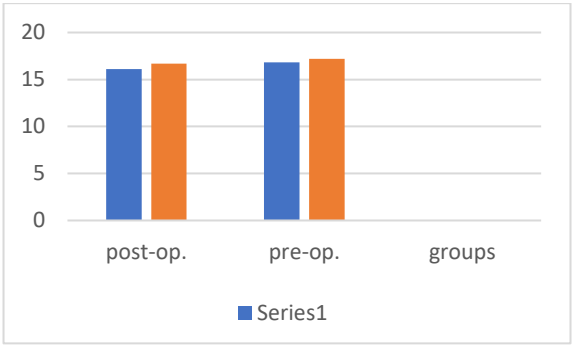

Figure (1): Mean IOP in the two groups pre- and post-operatively in males

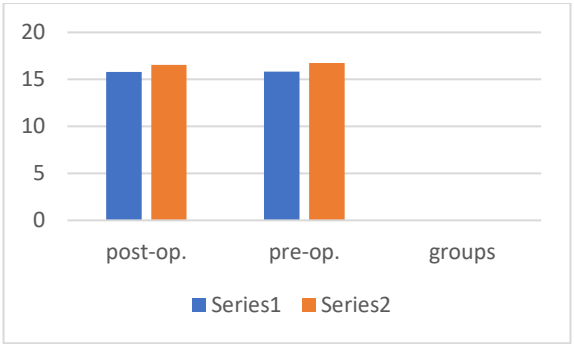

Figure (2): Mean IOP in the two groups pre- and post-operatively in females

Discussion

The present study investigated the effects of Bromfenac ophthalmic drops on IOP in patients undergoing phacoemulsification cataract surgery. The IOP in both groups showed a slight decrease after surgery. Interestingly, this reduction was observed across all subgroups, including diabetic and hypertensive patients, as well as male and female participants. However, this change was not statistically significant. The observation suggests that

Bromfenac may not directly affect the change of IOP, as a comparable reduction was noted in the group that did not receive Bromfenac (group II). The observed small decrease in IOP in both groups can be attributed to the phacoemulsification operation itself. The conclusions of Baek et al. corroborate the notion that phacoemulsification results in an initial decrease in IOP, which subsequently regresses in both healthy individuals and glaucoma patients during long-term follow-up (6). However, Baek didn't use Bromfenac drops in his study, other studies also support this finding. Hoffman et al reported that phacoemulsification itself has been associated with a long-term lowering of IOP (14). and Issa et al. reported a sustained reduction in IOP following phacoemulsification, independent of anti-inflammatory drugs (15).

The absence of a significant effect of Bromfenac on IOP in our study aligns with previous findings on NSAIDs. Kashiwagi et al study showed that NSAIDs, including Bromfenac, are primarily utilized for their potent anti-inflammatory and analgesic properties and they act by inhibiting cyclooxygenase enzymes (COX-1 and COX-2), thereby reducing prostaglandin synthesis. While prostaglandins are known to influence aqueous humor dynamics, the inhibitory action of NSAIDs does not appear to translate into a direct modulation of IOP (13). In fact, there are no report showing that Bromfenac drops can influence IOP. The study of Kashiwagi et al confirmed that Bromfenac drops itself did not influence IOP (13). Additionally, research has shown that Bromfenac does not significantly affect IOP in patients with well-controlled diabetes. Tobimatsu et al compared the effects of Bromfenac and betamethasone on IOP in diabetic patients and found no significant differences between the two treatments, suggesting that Bromfenac does not adversely impact IOP in this population (16).

Five patients from group I had Punctate Epithelial Erosions (PEE). PEE is a tiny collection of ocular surface cells that sustain injury as a result of insufficient tear production (17). Many studies reported corneal toxicity from NSAID especially when combined with steroid (12, 18).

Limitations: This study has some limitations. First, the sample size was relatively small, which may limit the generalizability of the findings. Second, the follow-up period was short, restricting the ability to assess long-term effects. Additionally, potential confounding factors, such as variations in postoperative care and patient adherence to prescribed medications, were not controlled. Future studies with larger sample sizes and extended follow-up periods are recommended to validate these findings.

Conclusion

The effects of Bromfenac 0.09% ophthalmic solution on intraocular pressure in postoperative cataract patients were insignificant. The medication did result in punctate epithelial erosion in some patients.

Authors' declaration:

We confirm that all the Figures and Tables in the manuscript belong to the current study. Besides, the Figures and images, which do not belong to the current study, have been given permission for re-publication attached to the manuscript. The project was approved by the local ethical committee in the Department of Pharmacology / College of Medicine / University of Baghdad According to the code number (03-32) on 17/9/2024.

Conflicts of Interest: None

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Authors' contributions:

Study conception & design:(Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein). Literature search: (Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein). Data acquisition: (Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein). Data analysis & interpretation: (Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein). Manuscript preparation: (Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein). Manuscript editing & review: (Enas S. Abdullah, Samara M. Ali, Zaid R. Hussein).

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تأثيرات محلول العين برومفيناك على ضغط العين لدى مرضى إعتام عدسة العين الخاضعين لعملية استحلاب العدسة

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الخلاصة:
الخلفية: جراحة الساد هي واحدة من أكثر العمليات الجراحية شيوعًا وقد تحدث تغيرات في ضغط العين بعد جراحة الساد وقد تؤثر بعض الأدوية بعد الجراحة عليها.
الأهداف: تقييم تأثيرات محلول برومفيناك ٠.٠٩٪ المضاد الالتهابات غير الستيرويدي على ضغط العين بعد جراحة استحلاب العدسة والإبلاغ عن أي تأثيرات جانبية للدواء.
المنهجية: أجريت هذه الدراسة في مركز جنة للعيون في بغداد – العراق وكانت مدة الدراسة من أيار ٢٠٢٣ إلى كانون الثاني ٢٠٢٤ وشملت مرضى بالغين مصابين بإعتام عدسة العين الناتج عن التقدم في السن او لأسباب طبية، وخضعوا لجراحة إعتام عدسة العين عن طريق استحلاب العدسة مع زراعة عدسة داخل العين، وتم تقسيمهم إلى مجموعتين: المجموعة الأولى: الذين تلقوا محلول برومفيناك٠.٠٩٪ للعين مرتين يوميًا بالإضافة إلى قطرات موكسيفلوكساسين ٠.٥٪ للعين كل ٦ ساعات وقطرات ديكساميثازون فوسفات ٠.١٪ للعين كل ٤-٦ ساعات بعد الجراحة. المجموعة الثانية: الذين تلقوا فقط موكسيفلوكساسين ٠.٥٪ كل ٦ ساعات وقطرات ديكساميثازون فوسفات٠.١٪ للعين كل ٤-٦ ساعات دون إعطاء قطرات برومفيناك ٠.٠٩٪ للعين بعد الجراحة. تم قياس ضغط العين قبل الجراحة وبعد 6 أسابيع من الجراحة باستخدام مقياس جولدمان توتر العين.
النتائج: تم تسجيل سبعة وثمانين عينًا لـ ٨٧ مريضًا في الدراسة. كان متوسط ضغط العين قبل الجراحة في المجموعة الأولى والمجموعة الثانية ١٦.٦ ± ٢.٣٧ملم زئبق و ١٧.١± ٣.٣٣ ملم زئبق على التوالي (لا يختلفان بشكل كبير)، بينما كان متوسط ضغط العين بعد الجراحة في المجموعة الأولى والمجموعة الثانية ١٦.٠± ٢.٣٢ ملم زئبق و١٦.٧± ٢.٩ملم زئبق على التوالي (القيمة الاحتمالية = ٠.٢٦٦). لم تكن هناك تغييرات كبيرة في ضغط العين بعد الجراحة في كلتا المجموعتين، وكان التأثير الجانبي الوحيد المبلغ عنه هو تآكل القرنية الظهاري النقطي في خمسة مرضى في المجموعة الأولى.
الإستنتاجات: وجدت هذه الدراسة أن تأثيرات محلول برومفيناك ٠.٠٩٪ للعين على ضغط العين في مرضى إعتام عدسة العين بعد الجراحة كانت غير فعالة. أدى الدواء إلى تآكل ظهاري منقط في بعض المرضى.
مفتاح الكلمات: برومفيناك؛ إعتام عدسة العين؛ قياس ضغط العين بطريقة جولدمان؛ ضغط العين؛ استحلاب العدسة.