

To compare the effectiveness of prednisolone versus bromfenac in controlling the ocular inflammation after cataract surgery

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Abstract

Aim: Comparison of topical Bromfenac versus topical Prednisolone acetate to control post cataract surgery ocular inflammation.

Materials and Methods: Effectiveness and safety of topical Bromfenac(0.09%) and topical Prednisolone acetate (1%) was evaluated in patients of cataract surgery in controlling inflammation. Two groups of patients each having 100 patients were enrolled in this study. Both the groups were comparable in baseline parameters. Patients in each group were followed for one month after cataract surgery. Visual acuity, post-operative inflammation was evaluated by detailed slit-lamp examination in both groups at first day, one week and one month after the surgery.

Results: The two groups had no statistically significant difference in post-operative inflammation and were well tolerated.

Conclusion: Bromfenac(0.09%) is an effective drug in controlling ocular inflammation after un-complicated cataract surgery having effect comparable to topical Prednisolone acetate(1%) with minimal side effects.

Keywords: Bromfenac, Cataract, Inflammation, Prednisolone.

Introduction

Cataract is opacification of natural intraocular lens usually occurring in older age resulting in partial decrease in vision or complete blindness in advanced cases. Treatment is removal of opaque lens and implantation of artificial transparent lens including newer foldable lens with advanced technology of phacoemulsification. Intraocular inflammation occurs after cataract surgery which may vary from mild to severe in intensity. Clinical features of inflammation are photophobia, watering, swelling, pain, tenderness, and decreased vision. In post-operative period inflammation is treated with topical steroid including Prednisolone acetate(1%) along with antibiotics. Steroids have side effects of elevation of intraocular pressure(IOP) that may lead to irreversible optic nerve damage. Steroids also delay wound healing and increase susceptibility to ocular infection. Bromfenac, a non-steroidal anti-inflammatory drug(NSAID) has also been shown to control post-operative ocular inflammation effectively with less frequent dosing and fewer side effects.^(1,2,3)

After cataract surgery, ocular inflammation occurs due to disruption of blood-aqueous barrier and cellular infiltration of aqueous humor.⁽⁴⁾ Surgical trauma during cataract surgery causes a cascade of inflammatory events from the release of arachidonic acid and production of prostaglandins by activation of cyclo-oxygenase(COX) enzymes. Prostaglandins released from the ocular tissue in response to surgical trauma are responsible for intra-ocular inflammation.⁽⁵⁾ Ocular clinical features include pain, hyperemia, miosis, light sensitivity and cystoid macular edema in response to prostaglandin release. Although usually self-limited,

post-operative ocular inflammation after cataract surgery can be associated with many complications including corneal edema, IOP spikes, cystoid macular edema (CME) and posterior capsule opacification.⁽⁶⁾ Corticosteroids interfere with release of arachidonic acid and inhibit production of all chemical mediators including prostaglandins. Steroids prevent formation of PG's through inhibition of enzyme phospholipase A2 and release of arachidonic acid while non-steroidal anti-inflammatory drugs (NSAID) prevent PG's synthesis by inhibition of enzyme cyclo-oxygenase.⁽⁷⁾ Corticosteroids are highly effective and are gold standard for treatment of ocular inflammation.⁽⁸⁾

NSAID are effective in preventing and treating CME after cataract surgery along with pain and ocular inflammation. Wittpenn et al found that with steroid use alone the incidence of macular edema is 12%.⁽⁹⁾ The investigators found that the incidence of CME postoperatively detected by OCT in patients randomized to Diclofenac sodium (NSAID) decreased significantly.⁽¹⁰⁾

In this study comparison was done to evaluate the efficacy of topical corticosteroid drug Prednisolone acetate(1%) with topical Bromfenac(0.09%) in controlling intraocular inflammation occurring in post-operative period after cataract surgery .

Materials and Methods

This study was conducted on 200 patients undergoing cataract surgery by phacoemulsification technique with foldable intraocular lens. Patients were above age of 50 years.

Exclusion criterion:

- Glaucoma

- History of Uveitis or any intraocular inflammation.
- Known sensitivity to any drug or similar medications.
- Corneal opacity and any macular pathology.
- Complicated cataract.
- Complication during cataract surgery.
- Any other eye medication used for some other ocular disease.
- Diabetes mellitus.

Written and Informed consent was taken from all patients before surgery. Detailed ophthalmic examination including intraocular pressure(IOP) by applanation tonometry, fundus examination and slit-lamp examination was performed. Detailed ocular and medical history was taken, routine pre-anaesthetic check-up was done. Cataract surgery was done with Phacoemulsification under local/topical anaesthesia with foldable intraocular lens implantation. Post operatively visual acuity and detailed slit lamp examination was done. Any signs of inflammation in anterior chamber were noted. Posterior segment examination was done to assess any inflammation in vitreous and any cystoid macular oedema. Intraocular pressure (IOP) was measured with applanation tonometry. Patients were randomly divided into two groups. Simple random sampling method was used for randomization. Patients in both groups were started topical antibiotic Moxifloxacin (0.5%) four times a day for four weeks. Patients in Group I were started on Prednisolone acetate(1%) eye drops four times a day for one week ,then thrice a day for three weeks. Patients in Group II were started on Bromfenac (0.09%) eye drops twice a day for four weeks. Patients were examined on day 1, day 7 and day 30 postoperatively. Visual acuity, Slit lamp examination, fundus examination and intraocular pressure was recorded on each visit.

Post-operative iritis was graded in three categories-

- Mild- Just detectable aqueous flare or 5-10 aqueous cells.
- Moderate- Moderate aqueous flare. Clear iris details or 11-20 aqueous cells.
- Severe- Moderate aqueous flare, hazy iris details or 21-50 aqueous cells.

Statistical analysis was done to see statistical significance. Chi square test for qualitative data was applied. Baseline comparison of quantitative data between two groups was made using the independent sample t-tests after comparing homogeneity of variances. Alpha error for significance was set at $p < 0.05\%$.

Results

The mean age in the Prednisone acetate group (Group I) was 65 years and in the Bromfenac group(Group II) was 66 years. Group I included 52(52%) males and 48(48%) females and group II

included 50(50%) males and 50(50%) females.

Best Corrected Visual Acuity: The average best corrected visual acuity (BCVA) was 6/9 in both the groups.

Post-operative ocular inflammation

Although one patient in group II remained with persistent post-operative inflammation even after one month of surgery but still in both groups no significant difference was present($p > 0.5$).

Table 1: Post-operative ciliary congestion

Group	Day 1	Day 7	Day 30
Prednisolone Group I	14	2	0
Bromfenac Group II	16	3	1

Table 2: Post-operative iritis in Prednisolone acetate group I

Grades of Iritis	Post-Operative Days		
	Day 1	Day 7	Day 30
Mild	14	5	0
Moderate	2	1	0
Severe	1	0	0
Total	17(17%)	6(6%)	0

Table 3: Post-operative iritis in Bromfenac group II

Grades of Iritis	Post-Operative Days		
	Day 1	Day 7	Day 30
Mild	15	6	1
Moderate	2	2	0
Severe	1	0	0
Total	18(18%)	8(8%)	1(1%)

Discussion

Two groups were almost similar in age and gender distribution. The average best corrected visual acuity (BCVA) was 6/9 in both the groups. Hence no significant difference was present in both groups regarding final visual outcome after cataract surgery. As per our study no patient on topical Prednisolone acetate had persistent post-operative inflammation after one month as compared to 1 patient in Bromfenac group. However, the difference was not statistically significant.

Different NSAIDs are being tried topically after cataract surgery and Bromfenac(0.09%) is one of the NSAIDs approved for effective control of inflammation. Bromfenac is most potent and it is 3.7 times more potent than Diclofenac, 6.5 times than Amfenac, 18 times than ketorolac in inhibiting COX-2 enzymes.^(2,11) Bromine in Bromfenac make it more lipophilic and enhances ocular penetration and hence increases effectiveness. In regard to dosing, Bromfenac requires only twice a day instillation and hence is more

convenient. Bromfenac requires less dosing, almost same effectiveness in controlling inflammation when compared to steroids. Bromfenac has extra advantage of no side effect of steroid including rise of IOP, secondary infection and delayed wound healing. Indeed, corticosteroid induced ocular hypertension and steroid induced glaucoma is a leading drawback of topical corticosteroid therapy.⁽¹²⁾

Studies comparing NSAIDs with corticosteroids have demonstrated no significant difference in the results between these treatments.^(13,14) However, NSAID treatment appears to be more effective than topical corticosteroids in re-establishing the blood-aqueous barrier.⁽¹⁵⁾ The beneficial effects of NSAIDs over corticosteroids include stabilization of IOP, provision of analgesia and reduction of the risk of secondary infections.⁽¹⁶⁾

Conclusion

Bromfenac (0.09%) is an effective drug in controlling ocular inflammation after un-complicated cataract surgery having effect comparable to topical Prednisolone acetate(1%) with minimal side effects and less dosing schedule leading to better compliance. Moreover, as it is a clear solution no shaking is required prior to its instillation as is required in Prednisolone acetate.

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