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Comparison of the Safety and Efficacy of Topical Prednisolone Acetate (1%) with Topical Bromfenac (0.09%) in Controlling Ocular Inflammation After Cataract Surgery.

KEYWORDS: Cataract surgery, comparative study, prednisolone acetate, bromfenac, iritis.

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ABSTRACT *Aim: To compare the effectiveness of topical bromfenac as an alternative to topical prednisolone acetate in controlling inflammation after cataract surgery.*

Material and Methods: The effect of topical bromfenac (0.09%) following cataract surgery was evaluated and compared to routine corticosteroid prednisolone acetate (1%) in a comparative prospective interventional study .Both the groups were comparable in baseline parameters.50 patients in each group were followed up post operatively for one month. Visual acuity, post-operative inflammatory response for the two drugs with respect to ciliary congestion and iritis was graded at Post operative day 1,7 and 30.

Results: The two groups did not show statistically significant difference in improvement for any of the variables. There were no side effects for topical bromfenac and it was well tolerated.

Conclusion: Bromfenac is as effective as topical prednisolone acetate in controlling inflammation after cataract surgery.

INTRODUCTION:

Cataract surgery is the most commonly performed ophthalmic surgery. Post-operative medication regimens following cataract surgery have included an antibiotic drop and a topical steroid to control inflammation. Steroids, however, are associated with certain side effects including delayed wound healing, susceptibility to infection and an elevation in intraocular pressure (IOP) that may lead to irreversible optic nerve damage. Bromfenac, a non-steroidal anti-inflammatory drug (NSAID) has also been shown to control pain and inflammation in the post-operative period and may be associated with higher rates of compliance (given less frequent dosing) and fewer side effects.[1-3]

In this study we aim to compare the efficacy of topical corticosteroid drops Prednisolone acetate (1%) with topical anti-inflammatory drops Bromfenac (0.09%) in controlling ocular inflammation after cataract surgery.

MATERIAL AND METHODS:

This was a comparative prospective interventional study. All the patients from age 50-80 yrs. attending the outdoor patients department from February 2014-May 2014 were included in the study. Patients diagnosed with cataract Who were suitable for clear corneal Phacoemulsification

Exclusion Criteria:

- Use of an eye medication or drops within 48 hours of the scheduled cataract surgery, other than the study medication or procedural solution required for surgery.
- Known sensitivity to any of the ingredients in the study medications or similar medications.
- Corneal oedema in either eye.
- Complicated cataract surgery including use of iris hooks or iris stretchers.
- History of previous intraocular surgery in the study eye.
- A history of uveitis, iritis or intraocular inflammation.
- Macular pathology of the retina.
- Presence of glaucoma.
- Diabetes mellitus.
- History of steroid related intra ocular pressure (IOP) rises in the study.

informed consent was taken from all patients before surgery. Authors adhered to the tenets of the Declaration of Helsinki during the study.

After general ophthalmologic examination, specific ophthalmic investigations like slit lamp bio microscopic examination, intraocular pressure on non-contact tonometry was done. Comprehensive investigations were undertaken including patient's age, gender, medical and ocular history .Routine investigations and pre anaesthetic check-up were done.

Cataract surgery was performed under peribulbar anaesthesia by temporal clear corneal Phacoemulsification surgery with rigid 5.25 post chamber intra ocular lens implantation. All surgeries were performed by a single surgeon. Identical material was used for all surgeries. All phacoemulsification procedures were performed using Stop and Chop technique.

Post-operatively visual acuity and detailed slit lamp examination were performed. Presence of any signs of inflammation in the anterior chamber were noted. Fundus examination to rule out inflammation in vitreous and cystoid macular oedema was done. Intra ocular pressure was recorded.

Post-operatively patients were randomly divided into two groups. Patients in Group I were started on a combination of Moxifloxacin (0.5%) and Prednisolone acetate (1%) eye drops four times a day for one week ,then thrice a day for a week, then twice a day for a week and finally once a day for a week.. Patients in Group II were started on a combination of Moxifloxacin (0.5%) and Bromfenac (0.09%) eye drops twice a day for four weeks.

Patients were examined on Day 1, Day 7 and Day30 post-

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operatively. At each visit visual acuity, slit lamp examination, detail fundus examination and intra ocular pressure were recorded.

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.

STASTICAL ANALYSIS:
The following tests were used for statistical significance:

- Chi square test for qualitative data.
- Baseline comparisons of quantitative data between groups were made using the independent sample t-test after comparing homogeneity of variances.

Alpha for significance was set at p<0.05%.

Table 1: Post- operative ciliary congestion.

	Post operative days		
	D1	D7	D30
Prednisolone acetate Group I	14 (28%)	2(4%)	0
Bromfenac Group II	12(24%)	1(2%)	0

Table 2: Post-operative iritis (Presence of aqueous flare or cells)
Predacetate Group (Group 1)

Grades of iritis	Post-operative days		
	D1	D7	D30
Mild	12(24%)	5(10%)	0
Moderate	2(4%)	1(2%)	0
Severe	0	0	0
Total	14(28%)	6(12%)	0

Bromfenac Group (Group 2)

Grades of iritis	Post-operative days		
	D1	D7	D30
Mild	14(28%)	7(14%)	0
Moderate	1(2%)	0	0
Severe	0	0	0
Total	16(30%)	7(14%)	0

RESULTS:
The mean age in the prednisolone acetate group (Group I) was 66.42 years and in the bromfenac group (Group II) was 66.04 years.

Group I included 24 males (48%) and 26 females (52%), while Group II consisted of 22 males (44%) and 28 females (56%).The two groups were similar in gender distribution.

Best Corrected Visual Acuity
The average best corrected visual acuity (BCVA) in both groups was 6/9.There was no statistically significant difference in BCVA between the two groups

Post- operative inflammation
Inflammatory scores were examined at day 1, 7 and at one month post- operatively for all patients. 50 eyes were examined in each group for presence of ciliary congestion and iritis.

None of these parameters showed any statistically significant difference in anti-inflammatory activity between the two topical medications. (p>0.05)

DISCUSSION:
Inflammation after cataract surgery is due to disruption of Blood-Aqueous Barrier (BAB) and cellular infiltration of aqueous humor. Surgical trauma from cataract surgery causes a cascade of inflammatory events from the release of arachidonic acid and production of prostaglandins by the activation of cyclo -oxygenase (COX)-1 and (COX)-2 enzymes. Prostaglandins released from the ocular tissue in response to surgical trauma are the main chemical mediators responsible for intra-ocular inflammation.[4] Clinical symptoms of prostaglandin release are pain, hyperaemia, miosis, light sensitivity and decreased vision from CME.[5] Corticosteroids, when used properly, interfere with the release of arachidonic acid and inhibit the production of all by-products, including prostaglandins. They are currently considered the gold standard for the treatment of ocular inflammation.[6]

Steroidal agents prevent formation of PG's through inhibition of enzyme phospholipase A_2 and release of arachidonic acid while non-steroidal anti-inflammatory drugs (NSAID's) prevent PG synthesis by inhibition of enzyme cyclo-oxygenase.[7]The results of the present found no statistically significant difference in controlling post-operative inflammatory reaction between prednisolone acetate and bromfenac at any observation time.

Besides their indicated use in controlling pain and ocular inflammation, many surgeons have also explored NSAIDs in preventing or even treating CME as an off-label use. Wittpenn et al [8] found that with steroid use alone the incidence of macular swelling is 12%.Additionally ,in one of the first studies to document the beneficial effects of topical NSAIDs with cataract surgery, the investigators found that patients using topical steroids had a 12% incidence of developing post-operative CME detected by OCT, while patients randomised to diclofenac sodium pre-operatively and post operatively avoided the development of macular thickening.[9]

Although there are many choices when it comes to using NSAID topically, bromfenac (0.09%) is the only NSAID approved for cataract surgery using once a day dosing. Bromfenac is also the most potent of the approved ophthalmic NSAIDs.It is 3.7 times more potent than diclofenac, 6.5 times more potent than amfenac and 18 times more potent than ketorolac at inhibiting the COX-2 enzyme.[2, 10] Bromine in bromfenac makes the drug more lipophilic and therefore more effective at penetrating ocular tissues, enhancing its inhibitory nature.

A recent electronic monitoring study of patients after cataract surgery revealed that any dosage more frequent than twice daily would significantly decrease compliance.[10]In that study, compliance was only 50.2% overall and 20% of patients only took 25% of their required drops. Certainly, therapy three or more times a day drastically reduces patients' and/or their families' ability to apply the entire prescribed drug into the operative eye.

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Since topical bromfenac drops are not needed to be tapered during the treatment period as against the tapering regimen required for the topical prednisolone therapy the twice daily topical bromfenac regimen is very easy for the patients and their relatives to follow while it helps in improved compliance.

Most of the published studies so far have been done on Caucasian patients. Our study is probably the first study done on Indian patients with brown irises.

In conclusion, considering the adverse effects of topical corticosteroids like rise of IOP, delayed wound healing, secondary infection and equal effectiveness of topical NSAID's like bromfenac, this study recommends the use of bromfenac 0.09% to control inflammation after uneventful cataract surgery.

The drawback of this study is that the trial has been conducted in patients with uncomplicated cataract surgery. It is not known whether bromfenac is equally effective in treating inflammation associated with complications of cataract surgery.

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