International Journal of Community Medicine and Public Health
Trivedi HR et al. Int J Community Med Public Health. 2020 Apr;7(4):1375-1381
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: http://dx.doi.org/10.18203/2394-6040.ijcmph20201440

Original Research Article

Topical bromfenac versus prednisolone: post cataract surgery safety and efficacy

Harish R. Trivedi, Harsha Maheshwari*

Department of Ophthalmology, Government Medical College, Bhavnagar, Gujarat, India

Received: 14 December 2019
Revised: 01 March 2020
Accepted: 02 March 2020

***Correspondence:**
Dr. Harsha Maheshwari,
E-mail: drharshamaheshwari@gmail.com

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ABSTRACT

Background: Cataract surgery can result in postoperative inflammation which increases the risk of complications like increased intraocular pressure (IOP), uveitis and cystoid macular oedema. We aim to evaluate the effectiveness of topical non-steroidal anti-inflammatory drug bromfenac and topical prednisolone in controlling intraocular inflammation after uncomplicated cataract surgery and compare intraocular pressure (IOP) differences, degrees of anterior chamber inflammation and macular oedema between two different treatments.
Methods: 100 patients undergoing manual small incision cataract surgery with PMMA posterior chamber intraocular lens implantation were randomly assigned to receive either Bromfenac (0.09%) eye drops or prednisolone acetate (1%) eye suspension as their postoperative anti-inflammatory medication with 50 cases in each group. The patients were examined at the day 1, day 7, day 15, and day 30 after surgery. Postoperative inflammation was evaluated subjectively by intraocular pressure, slit-lamp assessment of signs of inflammation in the form of aqueous cells and flare and optical coherence tomography to rule out post-operative macular oedema.
Results: Both the drugs are equally effective in controlling post-operative inflammation and post-operative cystoid macular oedema.
Conclusions: Bromfenac (0.09%) is an effective drug in controlling ocular inflammation after un-complicated cataract surgery having effect similar to topical Prednisolone acetate (1%) with minimal side effects and less frequent dosing.

Keywords: Bromfenac, Cataract, Inflammation, Prednisolone

INTRODUCTION

The word 'cataract' dates from the middle ages and has been derived from the Greek word 'katarraktes' which means 'waterfall'. This term was coined assuming that an 'abnormal humour' developed and flowed in front of the lens to decrease the vision. A cataract is the clouding of the lens that may occur because of protein denaturation in the lens.[1] 'Age-related cataract' also called as senile cataract is the commonest type of acquired cataract affecting equally persons of either sex usually above the age of 50 years. It is the leading cause of avoidable blindness worldwide, accounting for nearly half (47.8 %) of all cases of blindness.[2] According to world health organisation an estimated 20 million people worldwide are blind from bilateral cataract.[3] WHO defines 'blindness as visual acuity of less than 3/60, or a corresponding visual field loss to less than 10°, in the better eye with the best possible correction. It is estimated that over 90% of the world's visually impaired live in developing countries.[4]

No medical treatment, can yet prevent the formation or progression of cataract in the lens of the otherwise healthy adult eye therefore sight restoring cataract surgery remains the mainstay of treatment and is undoubtedly one of society's most cost- effective medical interventions.

From around 1.2 million cataract surgeries per year in the 1980s, the cataract surgical output increased to 3.9 million per year by 2003.[5,6] Recent data from the world health organization (WHO) shows that there is a 25% decrease in blindness prevalence in India.[7]

The surgical methods have improved significantly over the years, thus lowering the risk of complications and raising patients' and surgeons' expectations of a successful visual outcome.

Various methods of cataract surgery have been adopted while phacoemulsification is the preferred cataract surgical method in developed countries, manual small incision cataract surgery is gaining strong popularity in many developing world settings where the backlog of cataract blindness persists due to the lack of health-care resources, funding, and eye surgeons.

Like other types of surgery, cataract surgery induces a surgical inflammatory response. Post-operative ocular inflammation after cataract surgery can be associated with many complications including corneal oedema, uveitis, increased intraocular pressure (IOP), cystoid macular oedema (CME) and posterior capsule opacification.[8]

CME occurs because of fluid accumulation occurring a few weeks to months after cataract surgery. The cause of CME is believed to be an increased vascular permeability induced by inflammatory mediators such as prostaglandins. There is a tendency toward a higher prevalence of CME in patients with increased postoperative inflammation.[9]

The prevalence of CME varies from study to study depending on how CME is defined. By using fluorescein angiography, prevalence of CME of up to 20% has been reported.[10] Only 2% were diagnosed with CME when loss of visual acuity was required to establish the diagnosis.[11]

Management of inflammation is thus a mainstay in modern cataract surgery. Currently, 2 drug groups are available to control ocular inflammation: steroids and nonsteroidal anti-inflammatory drugs (NSAIDs).

Corticosteroids inhibit the release of arachidonic acid from phospholipids by inhibiting the enzyme phospholipase-A2, and hence decrease in the production of proinflammatory prostaglandins by inhibiting enzyme cyclo-oxygenase, and LTs and related cytokines by inhibiting enzyme lipo-oxygenase.[12]

Non-steroidal anti-inflammatory drugs prevent PG's synthesis by inhibition of enzyme cyclo-oxygenase.[13]

Although topical corticosteroids are a vital component of the treatment of postoperative inflammation, their prolonged use can produce side effects, such as elevated IOP, cataract formation (in phakic individuals), and lowered resistance to infection.[14] Bromfenac is an NSAIDs approved to treat postoperative inflammation and reduce ocular pain following cataract surgery.[15]

Therefore, keeping in mind the side effects of steroid therapy, in our study a comparison of NSAIDs and corticosteroids is done which will help in determining the efficacy of these two anti-inflammatory agents in controlling inflammation and post-operative CME after routine cataract surgery.

METHODS

This is a prospective, randomised, interventional hospital based comparative study. Duration of study from March 2018 to 2019.

Inclusion criteria

Patients 20 to 70 years of age of both sexes giving written and informed consent. Patients who underwent uneventful and uncomplicated cataract surgery done with manual SICS method.

Exclusion criteria

Known cases of 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, patients taking corticosteroids or NSAIDs for any systemic illness, known cases of diabetes mellitus, and high myopia.

After getting ethical approval from institutional review board in March 2018 the study was carried out in department of ophthalmology, government medical college and Sir T. Hospital, Bhavnagar. Written and informed consent was taken from all patients. Detailed ophthalmic examination including visual acuity of the patients tested with a Snellen's chart and BCVA was recorded, IOP by non-contact tonometer, fundus examination and slit lamp examination to reveal the hardness of nucleus was performed. central macular thickness of all the patients was measured using optical coherence tomography (OCT) and recorded. Detailed ocular and medical history were taken and pre-anaesthetic check-up was done. Cataract surgery was done with manual small incision cataract surgery method under peribulbar block containing bupivacaine (0.5%) and lignocaine (2%) in a ratio of 2:1 mixed with hyaluronidase 5 IU/ml with PMMA intraocular lens implantation. Post operatively visual acuity and detailed slit lamp examination was done. IOP was measured with non-contact tonometer. Any signs of inflammation in

anterior chamber were noted. Posterior segment examination was done to assess cystoid macular oedema and CMT was recorded. Patients were randomly divided into two groups. 50 patients receiving bromfenac (0.09%) eye drops two times a day for 4 weeks were grouped as Group A and remaining 50 receiving prednisolone acetate (1%) eye drops four times a day for 4 weeks as Group B. All 100 patients were started on moxifloxacin (0.5%) eye drops four times a day for 4 weeks. All patients were examined and assessed on the day 1, 7,15 and 30 postoperatively. BCVA, IOP, intraocular inflammation assessment as anterior chamber cells and flare was recorded at each visit. Aqueous cells will be counted in an oblique slit-lamp beam,1mm long and 1mm wide with maximal light intensity and magnification and graded as per 'standardization of uveitis nomenclature'.

Table 1: The SUN working group grading scheme for anterior chamber cells.

Grade	Cell count
0	0
0.5	1-5 (trace)
1	6-15
2	16-25
3	26-50
4	>50

Table 2: The SUN working group grading scheme for anterior chamber flare.

Grade	Flare count
0	Complete absence
1	Very slight (barely detectable)
2	Moderate (iris and lens clear)
3	Marked (iris and lens hazy)
4	Intense (fibrin clot)

Macular OCTs were obtained and central macular thickness recorded at the 1-week and 1-month visits using TOPCON 3D OCT maestro machine. Statistical analysis was done**.** All data were collected and tabulated in microsoft excel sheet as per available database and details of participant, data are summarized as mean standard deviation (SD) and as percentage wherever required. All statistical calculations were done using Graph PAD INSTAT 3.0 software (California USA). Nonparametric tests (Mann-Whitney test) were applied when the collected data were in non-gaussian distribution and unpaired t test was applied data distribution was parametric. P value <0.05 was considered statistically significant.

RESULTS

The prospective study comprises of 100 patients divided into two groups of 50 each. In Group A 72% patients were female and 28% were male as compared to 66% females and 34% males in Group B. It was observed that Group A has mean age of 58.82 years with a standard deviation of 5.329 and Group B has mean age of 58.34 years with standard deviation of 5.479 (Table 3).

Table 3: Age and gender distribution between the groups.

Demographic details	Group A	Group B
Age (mean±SD)	58.52±5.329	58.34±5.479
Female (%)	36 (72)	33 (28)
Male (%)	14 (28)	17 (66)

Table 4: Comparison of intraocular pressure.

Intraocular pressure (mm/hg)	Group A (mean±SD)	Group B (mean±SD)	P value
Pre-operative	14.64±1.626	14.760±1.975	
Day 1	14.960±2.330	15.360±2.363	0.4036
Day 7	14.680±1.942	15.460±2.233	0.0665
Day 15	14.420±1.785	15.000±2.466	0.2191
Day 30	14.080±1.510	14.960±2.312	0.0413

Table 5: Comparison of CMT.

CMT (OCT) (µm)	Group A (mean±SD)	Group B mean±SD)	P value
Pre-operative	189.98±15.000	188.40±11.735	
Day 7	188.54±14.194	186±11.798	0.3763
Day 30	186.64±12.378	185.34±11.617	0.5894

Best corrected visual acuity

All patients under the study had BCVA 6/6 at the 30th day.

Intraocular pressure

In Group A, the difference in mean IOP pre operatively and IOP at day 1 is statistically not significant as the P value is 0.7194 but at day 30 the reduction in mean IOP is significant with a p value 0.0444. In group B post-operative values of mean IOP at day 1 and day 30 when compared to pre-operative mean IOP values is not significant. P values 0.2166 and 0.7351 respectively. The difference between mean IOP at day 1, day 7 and day 15 was not significant in both the groups under our study. Further, it was observed that the comparison of IOP was statistically significant only at day 30 with a higher mean in Group B and p value 0.0413 (Table 4).

Anterior chamber inflammation

It was observed that at day 1, 4% patients in each group had no anterior chamber cells, 66% patients of group A

and 68% in group B has 1 to 5 cells and 6 to 15 cells in 30% and 28% patients in group A and B respectively. At the end of one week 96% patients has no anterior chamber cells at all in group B as compared to 86% in group A. By the end of 15 days both the groups showed no cells in the anterior chamber (Figure 1). It was observed that all patients in both the groups had no signs of anterior chamber flare at any day post-surgery (Figure 2).

Central macular thickness

In both groups the difference between mean values of CMT pre op and values at day 30 was not significant. P values 0.2275 and 0.1931 in group A and B respectively. Also, the difference between mean values of CMT at day 7 and 30 in both the groups was not statistically significant (Table 5).

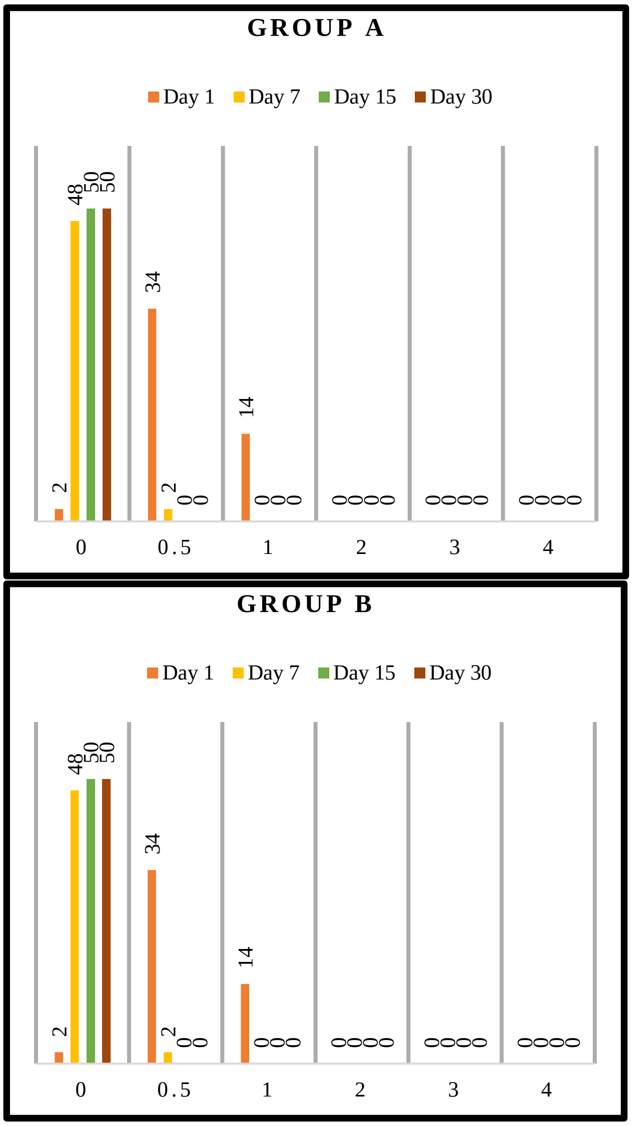

Figure 1: Diagram showing grading of anterior chamber cells in patients on day 1,7,15, and 30 post operatively in Group A, B.

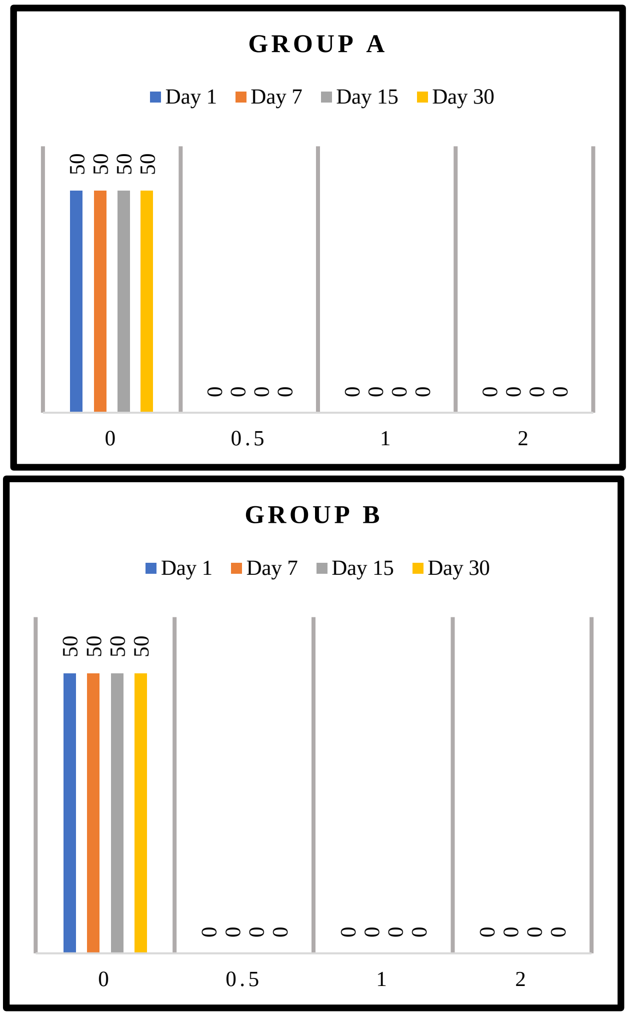

Figure 2: Diagram showing grading of anterior chamber flare in patients on day 1,7,15, and 30 post operatively in Group A, B.

DISCUSSION

Cataract is responsible for 62.6% of all cases of blindness in India.[16] The 3.5 million cataract surgeries in India in 2000 are estimated to result in 0.32 million persons having blindness averted over their lifetime. To eliminate cataract blindness in India, an estimated 9 million good-quality cataract surgeries are needed every year during 2001-2005, increasing to over 14 million surgeries needed every year during 2016-2020 on persons most likely to go blind from cataract.[17] Like any other surgery cataract surgery is associated with complications such as corneal oedema, uveitis, increased IOP, cystoid macular oedema (CME) and posterior capsule opacification. We performed a prospective study to compare the efficacy of topical steroid prednisolone acetate with topical NSAID bromfenac after cataract surgery. The efficacies of the drugs used in this study were assessed by comparing the IOP, signs of inflammation, and central macular thickness in both the groups.

In our study we found that there is no statistically significant rise in IOP post operatively in both the groups when compared to respective pre-operative values. However, there is a statistically significant difference in mean IOP when two groups are compared to each other at day 30, with higher mean in steroid group. Steroid induced rise in IOP is usually associated with steroid responders which we did not identify as we excluded all the patients having history of glaucoma, diabetes, high myopia.[18] Pleyer et al in their study concluded that dexamethasone and prednisolone acetate, and the newer corticosteroid difluprednate are more likely to result in clinically significant increases in IOP as compared to fluorometholone, rimexolone, and loteprednol etabonate.[19]

Duong et al, recently conducted a post-operative inflammation study, where they looked at three groups: a bromfenac-alone group, bromfenac plus steroid and a steroid-alone group. The only group which did not show a post-operative pressure spike was the NSAID-only group.[20]

In our study, criterion for signs of inflammation was the grade of anterior chamber cell and flare. A progressive decrease in anterior chamber cell count after the 1st postoperative day was found on slit-lamp examination, suggesting that the inflammatory reaction was controlled in both the groups and by the end of one month all patients had no signs of anterior chamber inflammation.

Topical corticosteroids are commonly used as a routine treatment over several weeks to reduce the inflammatory reaction after cataract surgery.[21] Various topical steroids have been used of which prednisolone and dexamethasone are most common. Several studies have shown prednisolone to be more effective.

Misra et al conducted a study of 60 patients and showed that topical 1% prednisolone acetate is more effective than topical 0.1% dexamethasone sodium in controlling postoperative inflammation and in early visual rehabilitation in uneventful cataract surgeries in Indian eyes.[22] Schoenwald et al also showed in experimental animals that prednisolone acetate suspension reaches the higher corticosteroid levels in anterior chamber amongst the other drugs used.[23] Kessel et al studied that topical NSAIDs are more effective in controlling postoperative inflammation after cataract surgery.[24] Donnenfeld et al found that bromfenac 0.09% ophthalmic solution was effective for the rapid resolution of ocular pain after cataract surgery.[25]

Twice-daily formulation was approved in 2005 in the US as bromfenac ophthalmic solution 0.09% (Xibrom®; ISTA pharmaceuticals Inc., Irvine, CA, USA) for the treatment of postoperative inflammation following cataract extraction. 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. Clinical symptoms of prostaglandin release are pain, hyperaemia, miosis, light sensitivity, and decreased vision from CME.[26] Corticosteroids, when used properly, interfere with the release of arachidonic acid and inhibit the production of all by products, including prostaglandins. They are associated with numerous adverse events, including inhibition of the immune system, delayed wound healing, and increased IOP.[27] In contrast, NSAIDs irreversibly inhibit the COX enzymes, thereby halting the production of prostaglandins.

Different NSAIDs are being tried topically after cataract surgery. All NSAIDs act by blocking the cyclooxygenase (COX) enzymes, COX-1 and COX-2, thereby reducing or blocking the production of prostaglandins. The COX-2 enzyme is more prevalent in the inflammatory response than COX-1, and thus the potency of inhibition of COX-2 tends to determine the clinical efficacy of the NSAID.[28,29] 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.[30,31] Bromine in bromfeanc make it more lipophilic and enhances ocular penetration and hence increases effectiveness.

Another delayed complication of cataract surgery is post-operative cystoid macular oedema. In our study, both the drugs were equally effective in preventing post-operative macular oedema and none of the patient developed CME. The difference between mean values of CMT at day 7 and 30 in both the groups was not statistically significant. Also, there was no significant difference in pre-operative and day 30 values of CMT in each group. In a study conducted by Natung et al, it was found that the mean central subfield thickness (CST) of all subjects was 240.40±18.26 μm, and mean macular thickness was 287.87±18.07 μm.[32]

This pathology is associated with the blood-retinal barrier disruption induced by prostaglandins (PG) and other inflammatory mediators. Macular thickness, as assessed by OCT in patients without PCME, peaks at approximately 4 to 6 weeks postoperatively.[33] Multiple studies have shown the benefits of NSAIDs in preventing CME. Maria et al showed bromfenac is the best tolerated and is more effective than diclofenac and nepafenac in reducing CME after phacoemulsification.[34]

Jeong et al showed that 0.1% bromfenac sodium hydrate ophthalmic solution had a similar effect to 1% prednisolone acetate ophthalmic solution on preventing CME after cataract surgery.[35] This indicates that topical NSAID can be considered along with topical steroids in order to prevent CME after cataract surgery. Also, in our study, the best corrected visual acuity (BCVA) at the end of one month was 6/6 in both the groups. Hence, no significant difference was present in both groups regarding final visual outcome after cataract surgery. Both the drugs were effective in controlling post-operative inflammation and no increase in CMT was

present. The IOP was higher in Prednisolone group when compared to bromfenac at day 30. Corticosteroids are well known for their anti-inflammatory action. But they may cause increase in IOP, delaying wound healing, and suppress immune function, which are all undesired and completely avoided with the use of NSAIDs like bromfenac which reduces the need of long term follow up as with the use of prednisolone.

In our study, all patients of cataract surgery had excellent post-operative management of inflammation as well as prevention of CME, with both prednisolone and bromfenac. Although, IOP was higher in patients randomised to prednisolone as compared to the bromfenac group, there was no rise in IOP when compared to pre-operative values. So, bromfenac is advantageous in controlling post-operative rise in IOP and reduces the need of long term follow up as with the use of prednisolone.

CONCLUSION

Bromfenac (0.09%) is an effective drug in controlling ocular inflammation after un-complicated cataract surgery having effect similar to topical prednisolone acetate (1%) with minimal side effects and less dosing schedule leading to better compliance. So, bromfenac is a better alternative to prednisolone as it is as potent in its anti-inflammatory effects as steroids, with fewer side effects, better tolerability and requires only twice a day instillation and hence is more convenient.

ACKNOWLEDGEMENTS

I express my deepest sense of gratitude and indebtedness to my guide, Dr. Harish R. Trivedi, associate professor, department of ophthalmology, Sir T. hospital and government medical college, Bhavnagar, whose keen insight and extensive knowledge in the subject has been a source of inspiration, encouragement and guidance to me. Without his inspiring teaching, valuable guidance, great suggestions and sustained devotion; this work wouldn't have been completed.

I am very much thankful to Dr. Nilesh V. Parekh, professor and head of ophthalmology department, Sir T. hospital and government medical college, Bhavnagar, for constant support, inspiration and motivation. Whose assistance, stimulating suggestion and encouragement helped me in all the time of research work.

I am grateful to our college's respected Dean, Dr. Hemant Mehta, government medical college, Bhavnagar, Dr. Vikas Sinha, superintendent, Sir T. hospital, Bhavnagar and also to all members of ethical review board, government medical college, Bhavnagar to commence this thesis in our institution. I am very much thankful to Dr. Neepa R. Gohil, assistant professor of our department who has been a continuous source of motivation, guidance and support.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Review Board

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Cite this article as: Trivedi HR, Maheshwari H. Topical bromfenac versus prednisolone: post cataract surgery safety and efficacy. Int J Community Med Public Health 2020;7:1375-81.