Original Research Article

# Efficacy of Bromfenac in prevention of macular edema following cataract surgery in a tertiary care hospital in Salem district

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## Abstract

**Background:** Postoperative inflammation continues to be a cause of patient discomfort, delayed recovery, and in some cases, suboptimal visual results. Topical nonsteroidal anti-inflammatory drugs (NSAIDs) and steroid are commonly used in the management and prevention of noninfectious ocular inflammation following cataract surgery. **Methods:** A prospective study was carried out in 120 patients, In Department of ophthalmology over a period of six months from 2018 November to 2018 April a tertiary care hospital at Salem, Tamil Nadu. A suitable data collection form was designed to collect and document the data. The patients are to be selected as per selection criteria and their consents will be taken. Data were collected from the case sheets of medical records. Patients were selected in between the age of at least 18 and almost 80 are scheduled for routine cataract surgery. Patients were randomized to receive Loteprednol Etabonate or prednisolone acetate 4 times daily in addition to Bromfenac 0.09% and Moxifloxacin 0.6% after surgery. Visual acuity, IOP, and anterior chamber cell and flare intensity were assessed over 3 weeks after cataract surgery. **Results:** In patients who were treated with bromfenac the number of patients without significant macular thickness is 60 and with significant macular thickness is In patients who were treated with placebo the number of patients without significant macular thickness is 57 and with significant macular thickness is 3. This proves that the use of bromfenac as a post-operative treatment for the patients is much effective in the prevention of macular edema. The number of patients with raised IOP in different follow up visits on day-1 is 16,1,7and 2,in week-1 is 1,0,0,1, in week-2 is 1,0,0,1, in week-4 is 1,0,0,1,and in week-6 and week-8 is zero patients. This proves that use of bromfenac will not have any effect on IOP, because the number of patients with raised IOP on week-8 with different SLE findings was found to be nil when compared with day 1. **Conclusion:** From this study, we have concluded that bromfenac was found to be effective in the prevention of macular edema as none of the patients who were subjected to bromfenac developed macular edema. It can be considered to be safe and no complications developed in patients subjected to bromfenac following cataract surgery.

**Keywords:** Bromfenac Solution, Macular Edema, Intraocular Pressure, Visual Acuity.

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## INTRODUCTION

Macular edema (ME) is a frequent complication of uveitis (mainly intermediate, posterior, and pan-uveitis) Cystoid Macular Edema (CME) is defined as retinal thickening of the macula due to a disruption of the normal blood-retinal barrier; this causes leakage from the perifoveal retinal capillaries and accumulation of fluid within the intracellular spaces of the retina, primarily in the outer plexiform layer.[1] A common outcome related to ME is visual impairment. In a recent large survey of Rothova, an important VA decrease (in more than 1/5 of the uveitis patients) was caused by cystoid ME (CME), and mainly in

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chronic forms of CME and in elderly subjects; a clinically significant CME developed in more than one-third of all the examined patients.[2] Inflammatory ME is multifactorial and recognizes a variety of inducing mechanisms, among which is inner blood-retinal barrier inflammatory disruption, inflammation of retinal vessels or vasculitis, vitreous tractive syndrome, dysfunction of RPE and choroidal or choriocapillaris inflammation are the leading causes.[3] The pathophysiology of uveitic CME is partially unknown and it is mainly related to damaged tissue inflammatory response with the activation of arachidonic acid cascade and the release of inflammatory mediators (prostaglandins, thromboxanes, leukotrienes, metalloproteinases, nitric oxide, interleukins, VEGF, TMNF-a, etc.) both from the cyclooxygenase and lipoxygenase pathways.[4] These inflammatory-derived substances induce a pathologic hyperpermeability of retinal vessel walls with consequently a fluid, protein, and other macromolecules extravasation into the retinal interstitium.[5] Local anti-inflammatory therapy may be associated with systemic carbonic anhydrase inhibitors (acetazolamide) and/or with oral steroids.[6] Other therapeutic options for recalcitrant and resistant cases of uveitic ME are posterior sub-Tenon corticosteroid injections, systemic corticosteroids (intravenous followed by oral administration), intravitreal steroids, and anti-VEGF drugs, intravitreal delivery steroid systems, systemic (or intravitreal) steroid-sparing immunosuppressive drugs (the most used of which are methotrexate, cyclosporine A, azathioprine, and mycophenolate mofetil), interferon-a (and in multiple sclerosis-associated uveitic CME, and interferon-b), somatostatin analogues (octreotide-LAR), and systemic or intravitreal biologic drugs (mainly anti-TNF agents[7]

## METHODS

A prospective study was carried out in 120 patients, In Department of ophthalmology over a period of six months from 2018November to2018 April a tertiary care hospital at Salem, Tamil Nadu. A suitable data collection form was designed to collect and document the data. The patients are to be selected as per selection criteria and their consents will be taken. Data were collected from the case sheets of medical records. Patients were selected in between the age of at least 18 and almost 80 are scheduled for routine cataract surgery. Patients were randomized to receive Loteprednol Etabonate or prednisolone acetate 4 times daily in addition to Bromfenac 0.09% and Moxifloxacin 0.6% after surgery. Visual acuity, IOP, and anterior chamber cell and flare intensity were assessed over 3 weeks after cataract surgery.

**STATISTICAL ANALYSIS:** Statistical analysis was performed by the SPSS program for Windows, version 17.0 (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.). Continuous variables are presented as a mean ± standard deviation, and categorical variables are presented as absolute numbers and percentage. Data were checked for normality before statistical analysis using a Shapiro-Wilk test. Normally distributed continuous variables were compared using ANOVA.

## RESULTS

A total of 120 cases of cataract surgery patients were collected and analyzed. The Cataract patients were classified according to their gender to know which group is more prone to the Cataract. Out of the selected 120 cataract patients, 61(50.83%) were male and 59(49.17%) patients were female. From this, males are more in numbers than females. The total number of patients according to the eye in which the surgery has done was calculated. The details were calculated separately for male and female patients. Surgery was done for 26 male and 36 female patients in the right eye and 35 male and 23 female patients underwent surgery in the left eye. From this analysis, we found that cataract surgery has done more in the right eye than the left eye.

**Table 1:** Differential diagnosis of patients

| S. No. | Diagnosis | Male | Female | Total no. Of patients | Percentage (%) |
|---|---|---|---|---|---|
| 1 | Immature cataract | 52 | 51 | 103 | 85.8 |
| 2 | Mature cataract | 4 | 8 | 12 | 10 |
| 3 | Posterior cataract | 1 | 0 | 1 | 0.83 |
| 4 | Traumatic cataract | 1 | 0 | 1 | 0.83 |
| 5 | Hyper mature cataract | 1 | 0 | 1 | 0.83 |
| 6 | Nuclear Sclerosis Grade | 2 | 0 | 2 | 1.67 |
| | **Total** | **61** | **59** | **120** | **100** |

Table 1 Shows: Immature cataract patients were more in 120 patients which were 85.8 %, another differential diagnosis was found to fewer patients which is less statistically significant

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**Table 2:** Choice of drug administration

| S.no. | Drugs administered | No. of male patients | No. of a female patient |
|---|---|---|---|
| 1 | Placebo | 28 | 32 |
| 2 | Bromfenac | 32 | 28 |

Table: 2 shows We have classified the total number of patients on the basis of the drug administered that is bromfenac and placebo. The details were calculated separately for male and female patients.

**Table 3:** Pre-operative intra-ocular pressure in patients undergoing cataract surgery

| IOP value | Number of male patients | Number of female patients | Total number of patients |
|---|---|---|---|
| 10-13 | 19 | 24 | 43 |
| 14-17 | 22 | 22 | 44 |
| 18-21 | 20 | 12 | 32 |
| 22-25 | 00 | 00 | 00 |
| 25 above | 00 | 01 | 01 |
| Total | 61 | 59 | 120 |

Table :3 shows the pre-operative intraocular pressure was calculated in patients undergoing cataract surgery. The details were calculated separately for male and female patients. The IOP values of patients were classified as 10-13, 14-17, 18-21, 22-25and above 25

**Table 4:** Post-operative intra-ocular pressure in patients who underwent cataract surgery

| IOP Value | 1 day | 1st week | 2nd week | 4th week | 6th week | 8th week |
|---|---|---|---|---|---|---|
| 10-13 | 46 | 60 | 66 | 60 | 57 | 55 |
| 14-17 | 44 | 43 | 45 | 45 | 60 | 62 |
| 18-21 | 27 | 17 | 09 | 15 | 03 | 03 |
| 22-25 | 2 | 0 | 0 | 0 | 0 | 0 |
| 25 above | 1 | 0 | 0 | 0 | 0 | 0 |
| **Total** | **120** | **120** | **120** | **120** | **120** | **120** |

Table: 4 The post-operative intraocular pressure was calculated in patients who underwent cataract surgery. The IOP values of patients were classified as 10-13, 14- 17, 18-21, 22-25 and 25 above.

**Table 5:** Different ranges of SLE findings post-operative cataract surgery

| SLE findings | No of patients Day 1 | No of patients Week 1 | No of patients Week 2 | No of patients Week 4 | No of patients Week 6 | No of patients Week 8 |
|---|---|---|---|---|---|---|
| Normal | 94 | 118 | 118 | 118 | 120 | 120 |
| SK+ | 16 | 1 | 1 | 1 | 0 | 0 |
| DM folds | 1 | 0 | 0 | 0 | 0 | 0 |
| Air in AC | 7 | 0 | 0 | 0 | 0 | 0 |
| K oedema | 2 | 1 | 1 | 1 | 0 | 0 |
| Total | 120 | 120 | 120 | 120 | 120 | 120 |

Table: 5 shows the postoperative range of SLE findings was calculated in patients underwent cataract surgery. The details were calculated among the total number of patients along with their follow up visits in the next weeks. The SLE findings of patients were classified as normal, SK+, DM folds, Air in AC, Corneal edema (K edema).

**Table 6:** Comparison of patients with significant macular thickness after administered with bromfenac and placebo

| Drugs used | Total number of patients | No of patients without significant macular thickness | No of patients with significant macular thickness |
|---|---|---|---|
| Bromfenac | 60 | 60 | 0 |
| Placebo | 60 | 57 | 3 |

Table: 6 shows The comparison of patients with significant macular thickness after administered with the post-operative treatment of placebo and bromfenac. The patients were grouped into patients who are taking bromfenac and placebo. The details were calculated among the total number of patients without significant macular thickness and number of patients with macular thickness after using bromfenac and placebo.

## DISCUSSION

In India, most of the cataract patients belong to age group sixty years and above. In our setting cataract is found at above the age of fifty years generally. That's why this age bar was included in the study. Both sexes were included to avoid bias in the study result. A one-eyed person was excluded as the previous pathology of the affected eye might lead to catastrophe in the existing functioning eye.[8] Patients with postoperative complications like severe uveitis, endophthalmitis, and corneal edema might not be affected properly by our study drugs and not only that they would require some other special intervention. The efficacies of the drugs used in this study were assessed by comparing the IOP, signs of inflammation, including conjunctival hyperemia, ocular pain, and aqueous cells and flare.[9] The main effectiveness criterion was the rate of anterior chamber cell decrease. The previous studies have demonstrated that ocular rebound inflammation may develop secondary to rapid tapering or abrupt discontinuation of topical ocular steroid use and is best prevented with gradual tapering. The mechanisms by which rebounds in ocular disease may follow steroid withdrawal are still uncertain. Topical corticosteroids are commonly used as a routine treatment over several weeks to reduce the inflammatory reaction after cataract surgery.[10] In a group in which prednisolone acetate 1% was used, we found that there was a normal IOP in all patients in all four visits. In this study in the prednisolone group, we found that ocular pain, conjunctival hyperemia, aqueous cells, and aqueous flare all were 100% relieved by the end of the 4 th week.[11] Kim SJ et.al study, it was found that diclofenac sodium 0.01% ophthalmic solution was as effective, safe, and well-tolerated overall as prednisolone acetate 1.0% ophthalmic suspension.[12] Equi R, study, they have found that ketorolac tromethamine 0.5% and diclofenac sodium 0.1% may be as effective and safe as prednisolone acetate 1% in controlling inflammation following cataract extraction. In a group in which bromfenac 0.09% was used, we found that IOP remains in the normal range in all visits in 100% of patients. In our study, we found that bromfenac 0.09% was effective in controlling postoperative ocular pain and inflammation which was similar to study done by Donnenfeld *et al.*,[9] who found that bromfenac 0.09% ophthalmic solution was effective for the rapid resolution of ocular pain after cataract surgery[13] Lobo CL et.al found that bromfenac has a more rapid onset of anti-inflammatory activity than diclofenac on measuring aqueous flare levels; they had noted that at each time, flare was lower in the bromfenac group than in the diclofenac group. In the group in which ketorolac 0.5% was used, we found normal IOP among all patients in all four visits. We also found that ketorolac 0.5% was more effective in controlling ocular pain as compared to nepafenac 0.1%, bromfenac 0.09%, and prednisolone 1%.[14] Although we found that ketorolac was effective and safe in controlling postoperative inflammation, el- Mentes J, found that ketorolac tromethamine 0.5% and diclofenac sodium 0.1% may be as effective and safe as prednisolone acetate 1% in controlling inflammation following cataract extraction.[15]

## CONCLUSION

The following events have been identified during postmarketing use of bromfenac ophthalmic solution 0.09% in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The events, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to topical bromfenac ophthalmic solution 0.09%, or a combination of these factors, include corneal erosion, corneal perforation, corneal thinning, and epithelial breakdown From this study, we have concluded that bromfenac was found to be effective in the prevention of macular edema as none of the patients who were subjected to bromfenac developed macular edema. It can be considered to be safe and no complications developed in patients subjected to bromfenac following cataract surgery.

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