e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2022; 14(3); 607-612

Original Research Article

Randomized Comparative Assessment of the Effectiveness of Prednisolone versus Bromfenac in Controlling the Ocular Inflammation after Cataract Surgery

Rajesh Kumar[1], Arun Kumar Sinha[2]

[1]Senior Resident, Department of Ophthalmology, Bhagwan Mahavir Institute of Medical sciences, Pawapuri, Nalanda, Bihar, India.
[2]Prof & Head, Department of ophthalmology, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India.

Received: 15-02-2022 / Revised: 20-03-2022 / Accepted: 30-03-2022
Corresponding author: Dr. Rajesh Kumar
Conflict of interest: Nil

Abstract

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

Material & Methods: This study was conducted in Department of Ophthalmology, Bhagwan Mahavir Institute of Medical sciences, Pawapuri, Nalanda, Bihar, India and private hospital for 1 year. 250 patients underwent small incision cataract surgery and phacoemulsification. Patients were above age of 50 years.

Results: Post-operative congestion was seen in 35 cases on day 1 followed by 6 and 1 on day 7 and day 30 respectively. 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).

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

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 organization 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]

Topical steroids commonly used might increase IOP, inhibit wound healing, and increase the risk of infection. [5-6] In addition, they require a complex tapering schedule and rebound inflammation. Currently, there is a growing interest in seeking alternative drugs such as nonsteroidal anti-inflammatory drugs (NSAIDs). [5] They have advantages such as stable IOP, lower risk of infection, and the additional benefit of analgesia. The use of NSAIDs in uneventful phacoemulsification without any high-risk factors is still controversial.

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%. [7] The investigators found that the incidence of CME postoperatively detected by OCT in patients randomized to Diclofenac sodium (NSAID) decreased significantly. [8]

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 postoperative period after cataract surgery.

Material & Methods:

This study was conducted in Department of Ophthalmology, Bhagwan Mahavir Institute of Medical sciences, Pawapuri, Nalanda, Bihar, India and private hospital for 1 year.

250 patients underwent small incision cataract surgery and phacoemulsification. 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-anesthetic check-up was done.

Small incision Cataract surgery and Phacoemulsification was done under local/topical anesthesia 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 edema. 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 64.5 years and in the Bromfenac group (Group II) was 65.8 years. Group I included 75 males and 53 females and group II included 65 males and 60 females.

Post-operative congestion was seen in 35 cases on day 1 followed by 6 and 1 on day 7 and day 30 respectively. [Table 1]

Post operative iritis in Prednisolone acetate group I was present in 21 cases on day 1 while there were no cases after a month. The average best corrected visual acuity (BCVA) was 6/9 in both the groups. [Table 2]

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 3]

Table 1: Post-operative ciliary congestion

Group	Day 1	Day 7	Day 30
Prednisolone Group I	16	2	0
Bromfenac Group II	19	4	1
Total	35	6	1

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

Grades of Iritis	Post-Operative Days		
	Day 1	Day 7	Day 30
Mild	17	6	0
Moderate	3	1	0
Severe	1	O	0
Total	21	7	0

Table 3: Post-operative iritis in Bromfenac group II

Grades of Iritis	Post-Operative Days		
	Day 1	Day 7	Day 30
Mild	16	7	1
Moderate	3	3	0
Severe	1	0	0
Total	20	10	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.

The major drawbacks of steroids include raised IOP, delayed wound healing, increased risk of infection, and complex tapering regimen. Due to these drawbacks, NSAIDs have been explored to reduce

inflammation. [9-10] However, NSAIDs have been reported to be more effective in re-establishing the blood–aqueous barrier as measured by anterior ocular fluorophotometry. [5]

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. [11]

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. [12-13] 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. [14-15] Bromine in bromfeanc make it more lipophilic and enhances ocular penetration and hence increases effectiveness.

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. [16] 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. [17] Kessel et al studied that topical NSAIDs are more effective in controlling postoperative inflammation after cataract surgery. [18] Donnenfeld et al found that bromfenac 0.09% ophthalmic solution was effective for the rapid resolution of ocular pain after cataract surgery. [19]

Bromine in Bromfeanc makes 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. [20]

Studies comparing NSAIDs with corticosteroids have demonstrated no significant difference in the results between these treatments. [21-22] However, NSAID treatment appears to be more effective than topical corticosteroids in re-establishing the blood– aqueous barrier. [23] The beneficial effects of NSAIDs over corticosteroids include stabilization of IOP, provision of analgesia and reduction of the risk of secondary infections. [24,25]

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.

References:

1. Tsui PH, Huang CC, Zhou Q, Shung KK. Cataract measurement by estimating the ultrasonic statistical parameter using an ultrasound needle transducer: an in vitro study. Physiol Meas. 2011; 32:513-22.
2. Resnikoff S, Pascolini D, Etyaale D. Global data on visual impairment in the year 2002. Bull World Health Organ. 2004; 82:844-51.
3. Baltussen R, Sylla M, Mariotti SP. Cost-effectiveness analysis of cataract surgery: a global and regional analysis.

Bull World Health Organ. 2004; 82:338-45.
4. Thylefors B. A simplified methodology for the assessment of blindness and its main causes. World Health Stat Q. 1987; 40:129-41.
5. O'Brien TP. Emerging guidelines for use of NSAID therapy to optimize cataract surgery patient care. Curr Med Res Opin 2005; 21:1131–7.
6. Heier JS, Topping TM, Baumann W, Dirks MS, Chern S. Ketorolac versus prednisolone versus combination therapy in the treatment of acute pseudophakic cystoid macular edema. Ophthalmology 2000; 107: 2034-8; discussion 2039.
7. Wittpenn JR, Silverstein S, Heier J, et al. A randomized, masked comparison of topical ketorol 0.4% plus steroid vs. steroid alone in low risk cataract surgery patients, Am J Ophthalmol,2008;146:554-60.
8. McColgin AZ, Raizman MB, Efficacy of topical Voltaren in reducing the incidence of post-operative cystoid macular edema, Invest Ophthalmol Vis Sci, 1999;40:s289.
9. Juthani VV, Clearfield E, Chuck RS. Non-steroidal anti- inflammatory drugs versus corticosteroids for controlling inflammation after uncomplicated cataract surgery. Cochrane Database Syst Rev 2017;7:CD010516.
10. Sheppard JD. Topical bromfenac for prevention and treatment of cystoid macular edema following cataract surgery: A review. Clin Ophthalmol Auckl NZ 2016; 10:2099–111.
11. Duong HQ, Westfield KC, Singleton IC, Comparing Three Post-Op Regiments for Management of Inflammation Post Uncomplicated Cataract Surgery. 'Are Steroids Really Necessary?'. J Clin Exp Ophthalmol, 2011;2:163.
12. Flach AJ. Topical nonsteroidal anti-inflammatory drugs in ophthalmology. IntOphthalmolClin. 2002; 42:1-11.
13. Schalnus R. Topical nonsteroidal anti-inflammatory therapy in ophthalmology. Ophthalmologica. 2003; 217:89-98.
14. Cho H, Wolf KJ, Wolf EJ, Management of ocular inflammation and pain following cataract surgery: focus on bromfenac ophthalmic solution. Clin Ophthal. 2009; 3:199-210.
15. Keith AW, Amy JE. Management of ocular inflammation following routine cataract surgery-Topical corticosteroid (Prednisolone) Vs Topical Non-steroidal (Bromfenac). US Ophthalmic Review. 2011;4(2):97-100.
16. Misra S, Gaydhankar S, Mehta R. Comparative evaluation of the anti-inflammatory effect of topical 0.1% dexamethasone sodium and topical 1% prednisolone acetate eye drops after small incision cataract surgery in Indian eyes. DJO. 2012; 22:263-6.
17. Schoenwald RD, Boltralik JJ. A bioavailability of comparison in rabbits of two steroids formulated as high viscosity gels and reference aqueous preparation. Invest Ophthalmol Vis Sci. 1979; 18:61-6.
18. Ophthalmology by the American Academy of Ophthalmology. 2014; 121:1915-24.
19. Donnenfeld ED, Holland EJ, Stewart RH, Gow JA, Grillone LR. Bromfenac Ophthalmic Solution 0.09% (Xibrom) Study Group. Bromfenac ophthalmic solution 0.09% (Xibrom) for postoperative ocular pain and inflammation. Ophthalmology. 2007; 114:1653-62.
20. Berthelot, M., Rieker, A., & Correia, J. C. The difficulties experienced by patients with low back pain in France: a mixed methods study. Journal of Medical Research and Health Sciences, 2022:5(6), 2039–2048.
21. Clark AF. Basic sciences in clinical glaucoma: steroids, ocular hypertension and glaucoma. J Glaucoma 1995; 4:354-369.

22. Roberts CW, Brennan KM. A comparison of topical dicolfenac with prednisolone for post-cataract inflammation. Arch Ophthal. 1995; 113:725–727.
23. El-Harazi SM, Ruiz RS, Feldman RM, et al. A randomized double-masked trial comparing ketorolac tromethamine 0.5%, diclofenac sodium 0.1%, and prednisolone acetate 1% in reducing post phacoemulsification flare and cells. Ophthalmic Surg Lasers. 1998; 29:539–544.
24. Wolf EJ, Braunstein A, Shih C, Braunstein RE. Incidence of visually significant pseudophakic macular edema after uneventful phacoemulsification in patients treated with nepafenac. J Cataract Refract Surg. 2007 Sep; 33(9):1546–1549.
25. Hsu JK, Johnston WT, Read RW, et al. Histopathology of corneal melting associated with diclofenac use after refractive surgery. J Cataract Refract Surg. 2003; 29:250– 256.