ORIGINAL RESEARCH

Efficacy of 0.07% bromfenac ophthalmic solution in patients with cataract surgery

Dr. Kamlesh Kumar Sharma

Associate Professor, Department of Ophthalmology, Venkateshwara Institute of Medical Sciences, Amroha, India

Corresponding author
Dr. Kamlesh Kumar Sharma
Associate Professor, Department of Ophthalmology, Venkateshwara Institute of Medical Sciences, Amroha, India

Received: 17 September, 2019 Accepted: 23 October, 2019

ABSTRACT

Background: In the US and around the world, cataracts are the primary cause of blindness. The present study assessed efficacy of 0.07% bromfenac ophthalmic solution in patients with cataract surgery. **Materials & Methods:** 120 patients scheduled for cataract surgery of both genders were divided into 2 groups. In group I patients, Bromfenac 0.07% and in group II, placebo was administered once daily starting one day prior to cataract surgery, on the day of the procedure, and for 14 days following the procedure. **Results:** The percentage of subjects with summed ocular inflammation score (SOIS) of grade 0 at day 1 was 2.6% and 1.6%, at day 3 was 10.4% and 3.4%, at day 8 was 35.7% and 16.8% and at day 15 was 49.5% and 25.6% in group I and II respectively. The difference was significant (P< 0.05). The percentage of subjects with summed ocular pain score of grade 0 at day 1 was 70.2% and 51.6%, at day 3 was 81.5% and 53.4%, at day 8 was 90.2% and 61.8% and at day 15 was 92.5% and 63.2% in group I and II respectively. The difference was significant (P< 0.05). **Conclusion:** In participants who had undergone cataract surgery, bromfenac ophthalmic solution 0.07% dosed once day was clinically safe and effective in treating ocular inflammation and pain when compared to a placebo.

Keywords: Bromfenac, Cataract, Ocular inflammation score

INTRODUCTION

In the US and around the world, cataracts are the primary cause of blindness.[1] Despite the fact that about 10 million cataract surgeries are carried out globally each year, the number of people who suffer from untreated cataract-associated blindness is rising by about 1 million each year, and the number of people whose cataracts result in visual acuity worse than 6/60 is rising by 4 to 5 million each year. Over 30 million Americans are expected to suffer from cataracts by 2020.[2]

Age and female gender are the primary risk factors for cataract onset, according to numerous population-based studies; the incidence of a nuclear cataract is thought to affect 40% of US individuals over 75.[3] After cataract surgery, ophthalmic NSAIDs are used to help patients with ocular pain and inflammation.[4] In the US, starting NSAID dosage one to two days before to surgery is becoming more common. The cyclooxygenase enzymes that produce prostaglandins through the arachidonic acid pathway are inhibited by nonsteroidal anti-inflammatory medications.[5] Prostaglandins are essential forrole in the onset of postoperative pain and inflammation. Bromfenac, a well-studied NSAID, has been shown to be a potent inhibitor of cyclooxygenase. The United States Food and Drug Administration (FDA) has approved several NSAIDs for the reduction of postoperative inflammation after cataract surgery.[6]The present study assessed efficacy of 0.07% bromfenac ophthalmic solution in patients with cataract surgery.

MATERIALS & METHODS

The study was carried out on 120 patients scheduled for cataract surgeryof both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. In group I patients, Bromfenac 0.07% and in group II, placebo was administered once daily starting one day prior to cataract surgery, on the day of the procedure, and for 14 days following the procedure (for a total of 16 days). Following surgery, the subjects were assessed on days 1, 3, 8, 15. By day 15, the total ocular inflammation score (anterior chamber cell count ¼ 0 and lack of flare) was zero, indicating that the primary efficacy end point had been eliminated. The number of participants who were pain-free on day 1 and the amount of cleared ocular inflammation at

day 15 were secondary endpoints. Both groups comprised 60 patients. Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I The percentage of subjects with summed ocular inflammation score (SOIS) of grade 0

SOIS	Group I	Group II	P value
Day 1	2.6%	1.6%	0.05
Day 3	10.4%	3.4%	0.01
Day 8	35.7%	16.8%	0.01
Day 15	49.5%	25.6%	0.01

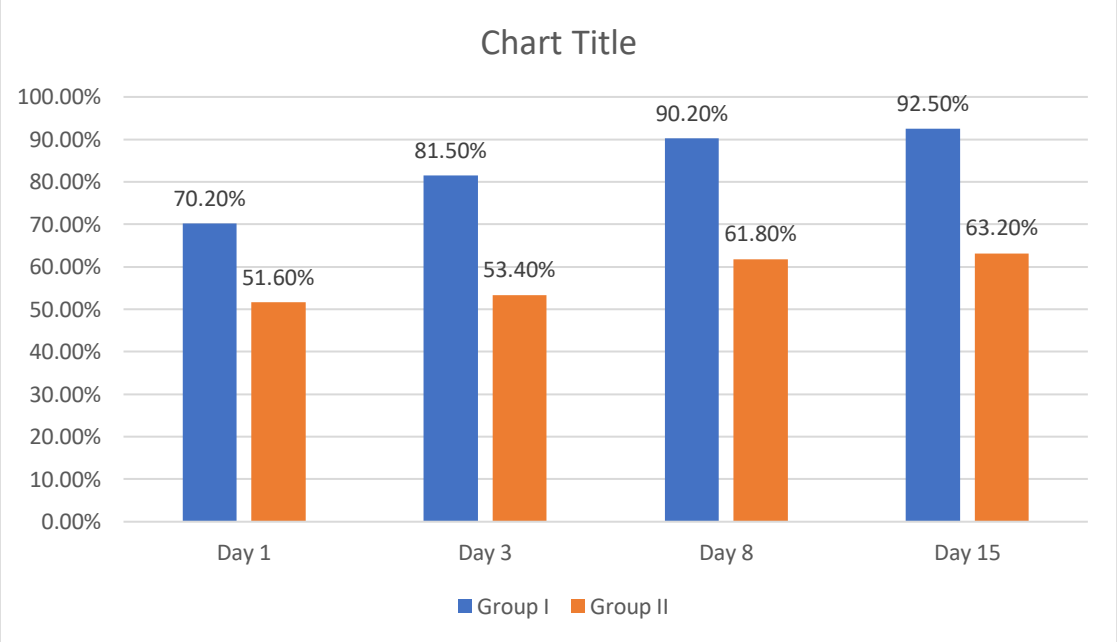
Table I shows that the percentage of subjects with summed ocular inflammation score (SOIS) of grade 0 at day 1 was 2.6% and 1.6%, at day 3 was 10.4% and 3.4%, at day 8 was 35.7% and 16.8% and at day 15 was 49.5% and 25.6% in group I and II respectively. The difference was significant (P< 0.05).

Table II The percentage of subjects with ocular pain score of 0

Ocular pain score	Group I	Group II	P value
Day 1	70.2%	51.6%	0.04
Day 3	81.5%	53.4%	0.02
Day 8	90.2%	61.8%	0.01
Day 15	92.5%	63.2%	0.01

Table II, graph I shows that the percentage of subjects with summed ocular pain score of grade 0 at day 1 was 70.2% and 51.6%, at day 3 was 81.5% and 53.4%, at day 8 was 90.2% and 61.8% and at day 15 was 92.5% and 63.2% in group I and II respectively. The difference was significant (P< 0.05).

Graph I The percentage of subjects with ocular pain score of 0



DISCUSSION

Ocular inflammation is a common result of cataract surgery, producing pain and photophobia in many patients and potentially leading to serious complications including increased intraocular pressure (IOP), posterior capsule opacification, cystoid macular edema (CME), and decreased visual acuity.[7,8] The goals of topical prophylactic nonsteroidal anti-inflammatory drug (NSAID) treatment include the prevention of intraoperative miosis, management of postoperative inflammation, prevention or treatment of CME, and reduction of ocular pain.[9] Steroidal agents have been the standard treatment for ocular inflammation in the past, while the use of topical NSAIDs has increased over the past 2 decades. Bromfenac sodium is designated chemically as sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate.[10] The additional bromine atom increases the absorption into ocular tissue and increases the duration of effect.Once-daily dosing has the potential benefits of both improved patient compliance and limited ocular exposure to the active ingredient.[11,12]The present study assessed efficacy of 0.07% bromfenac ophthalmic solution in patients with cataract surgery.

We found that the percentage of subjects with summed ocular inflammation score (SOIS) of grade 0 at day 1 was 2.6% and 1.6%, at day 3 was 10.4% and 3.4%, at day 8 was 35.7% and 16.8% and at day 15 was 49.5% and 25.6% in group I and II respectively. Walters et al[13]evaluated the efficacy and ocular safety of bromfenac ophthalmic solution 0.07% (Prolensa) dosed once daily for the treatment of ocular inflammation and pain in subjects who underwent cataract surgery with posterior chamber intraocular lens implantation. A significantly higher proportion of subjects treated with bromfenac 0.07% achieved complete clearance of ocular inflammation by day 15 and at day 15 compared with placebo ($P < 0.0001$). A statistically significantly higher proportion of subjects in the bromfenac 0.07% group were pain free at all study visits compared with those in the placebo group ($P < 0.0001$). Fewer subjects in the bromfenac group (3.2%) discontinued investigational product early because of a lack of efficacy than in the placebo group (23.9%; $P < 0.0001$). The incidence of adverse events was significantly lower in the bromfenac 0.07% group compared with the placebo group (P ¼ 0.0041)

We found that the percentage of subjects with summed ocular pain score of grade 0 at day 1 was 70.2% and 51.6%, at day 3 was 81.5% and 53.4%, at day 8 was 90.2% and 61.8% and at day 15 was 92.5% and 63.2% in group I and II respectively. Walters et al[14]evaluated the aqueous humor concentrations and cyclooxygenase (COX) inhibitory activities of nepafenac, amfenac, ketorolac, and bromfenac after topical ocular administration of Nevanac (nepafenac 0.1%), Acular LS (ketorolac 0.4%), or Xibrom (bromfenac 0.09%).Patients requiring cataract extraction were randomized to 1 of 3 treatment groups: Nevanac, Acular LS, or Xibrom. Patients were administered 1 drop of the test drug 30, 60, 120, 180, or 240 minutes before cataract surgery. At the time of paracentesis, an aqueous humor sample was collected and later analyzed for drug concentration. In addition, COX-1 (homeostatic) and COX-2 (inducible) inhibitory activities of nepafenac, amfenac, ketorolac, and bromfenac were determined via the in vitro measurement of prostaglandin E(2) (PGE(2)) inhibition.Seventy-five patients participated in the study. The prodrug nepafenac had the shortest time to peak concentration and the greatest peak aqueous humor concentration (C(max)). The C(max) of nepafenac was significantly higher than that of the other drugs ($P<.05$), including the higher-concentration ketorolac (0.4%). The area under the curve (AUC) of nepafenac was significantly higher ($P<.05$) than the AUCs of amfenac, ketorolac, and bromfenac. The combined AUCs of nepafenac and amfenac were the highest of all drugs tested ($P<.05$). Ketorolac showed the most potent COX-1 inhibition, whereas amfenac was the most potent COX-2 inhibitor. The PGE(2) aqueous humor levels of each study medication were highly variable; as a result, meaningful interpretation of the data was not possible.

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that in participants who had undergone cataract surgery, bromfenac ophthalmic solution 0.07% dosed once day was clinically safe and effective in treating ocular inflammation and pain when compared to a placebo.

REFERENCES

1. Robin AL, Novack GD, Covert DW, et al. Adherence in glaucoma: objective measurements of once-daily and adjunctive medication use. Am J Ophthalmol2007;144:533–40.
2. Asai T, Nakagami T, Mochizuki M, et al. Three cases of corneal melting after instillation of a new nonsteroidal anti-inflammatory drug. Cornea 2006;25:224–7.
3. Gaynes BI, Fiscella R. Topical nonsteroidal anti-inflammatory drugs for ophthalmic use: a safety review. Drug Saf 2002;25: 233–50.
4. Isawi H, Dhaliwal DK. Corneal melting and perforation in Stevens Johnson syndrome following topical bromfenac use. J Cataract Refract Surg2007;33:1644–6.
5. Wolf EJ, Kleiman LZ, Schrier A. Nepafenac-associated corneal melt. J Cataract Refract Surg2007;33:1974–5.
6. Jones J, Francis P. Ophthalmic utility of topical bromfenac, a twice-daily nonsteroidal anti-inflammatory agent. Expert OpinPharmacother2009;10:2379–85.
7. Stewart RH, Grillone LR, Shiffman ML, et al; Bromfenac Ophthalmic Solution 0.09% Study Group. The systemic safety of bromfenac ophthalmic solution 0.09%. J OculPharmacol Ther 2007;23:601–12.
8. Donnenfeld ED, Donnenfeld A. Global experience with Xibrom (bromfenac ophthalmic solution) 0.09%: the first twice-daily ophthalmic nonsteroidal anti-inflammatory drug. Int Ophthalmol Clin 2006;46:21–40.
9. Abelson MB, Gomes PJ. Olopatadine 0.2% ophthalmic solution: the first ophthalmic antiallergy agent with once-daily dosing. Expert Opin Drug MetabToxicol2008;4:453–61.
10. Cho H, Mozayan A. New look at ocular inflammation controldpowerful and fast-acting twice-daily bromfenac for a novel standard in the treatment of inflammation. Eur Ophthalmic Rev 2011;5:20–6.
11. Xiong C, Chen D, Liu J, et al. A rabbit dry eye model induced by topical medication of a preservative benzalkonium chloride. Invest Ophthalmol Vis Sci 2008;49:1850–6.
12. . Nichols J, Snyder RW. Topical nonsteroidal anti-inflammatory agents in ophthalmology. Curr OpinOphthalmol1998;9:40–4.
13. Walters TR, Goldberg DF, Peace JH, Gow JA, 0.07% Once Daily Study Group. Bromfenac ophthalmic solution 0.07% dosed once daily for cataract surgery: Results of 2 randomized controlled trials. Ophthalmology. 2014 Jan 1;121(1):25-33.
14. Walters T, Raizman M, Ernest P, et al. In vivo pharmacokinetics and in vitro pharmacodynamics of nepafenac, amfenac, ketorolac, and bromfenac. J Cataract Refract Surg2007;33:1539–45.