



Original Research Article

Nepafenac vs bromfenac: A comparative study to determine their role in maintaining mydriasis during cataract surgery

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ABSTRACT

Aim: To assess and compare the role of topical nepafenac (0.1%) v/s bromfenac (0.09%) in sustaining intra-operative mydriasis while doing cataract extraction.

Study Design: Prospective, randomized study.

Place and Duration of Study: Regional Institute of Ophthalmology, Rajendra Institute of Medical Sciences (RIMS), Ranchi (Jharkhand). The duration of study was from June 2019 to February 2020.

Materials and Methods: Topical NSAIDs (nepafenac and bromfenac) and carboxymethylcellulose (control) were administered to the cataract patients before Phaco surgery. Pupillary diameters were assessed first at starting of surgery and then after completing the surgery; average values were calculated for the three groups. Study was done on 90 patients having age 40-80 years, planned for cataract surgery with PCIOL implantation.

Results: in group A (i.e. control) reduction in pupillary diameter came out to be more statistically significant unlike in group B (nepafenac) and in group C (bromfenac) ($p < 0.003$). But on comparing group B and group C ($p < 0.80$) reduction in pupillary diameter was not that much statistically different. Mydriasis sustaining effect was more pronounced in groups B and C than in group A.

Conclusion: Both nepafenac (0.1%) and bromfenac (0.09%) administered a day before operation are helpful in sustaining pupil size intra-operatively but bromfenac comparatively seemed to be better than nepafenac in sustaining mydriasis during SICS/Phaco.

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1. Introduction

In spite of all the recent advances in the field of ophthalmology cataract still remains one of the leading causative factors responsible for preventable blindness. The management of choice is extraction of the cataractous lens and placing artificial posterior chamber intraocular lens (PCIOL).¹ Tremendous improvement has been observed in various techniques used for extracapsular extraction (ECCE) in last several years, with SICS and nowadays Phacoemulsification technique being most widely used procedure. However, while performing surgery, some amount of injury to the ocular tissue does occur which leads to productions of prostaglandin and leukotriens. Ocular

effects like constriction of pupil (miosis) while performing surgery, ocular inflammation after surgery, congestion in conjunctiva, variations in intraocular pressure^{2,3} can result due to the action of inflammatory mediators.

Reduced pupillary diameter can hinder various steps in cataract extraction, thereby increasing the chances of causing injury to ocular tissues during the surgery and leading to postoperative ocular inflammation,⁴ PCT (posterior capsular tear).⁵ Thus, sustainance of proper mydriasis is an important part of ensuring a good and successful cataract surgery. According to reports, mydriasis more than 6mm, decreases chances of posterior capsular tear by half.

Nepafenac, bromfenac, ketoralac and diclofenac are topical NSAIDs which act on the enzyme cyclo-oxygenase,

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causing its inhibition thus decreasing PG formation⁶ and hence can be used for treating conditions like surgically induced miosis, post operative ocular inflammation, management of cystoid macular edema (CME).^{7–9}

Studies have been done in India on Nepafenac & Bromfenac, for assessing its role in sustaining mydriasis during cataract surgery but more emphasis has been given on its purpose of managing post-operative inflammation.^{10–14}

Therefore, this study has been performed to compare and assess the role of Nepafenac and Bromfenac (both in topical formulations) in sustaining mydriasis while carrying out the procedure of cataract extraction.

2. Materials and Methods

A prospective, randomised study was conducted at Regional Institute of Ophthalmology (RIO), Rajendra Institute of Medical Sciences (RIMS), Ranchi (Jharkhand) on 90 patients of age group 40-80 years, planned for cataract surgery with PCIOL implantation. The duration of study was from June 2019 to February 2020. After taking approval from the Institution Ethics Committee, study was done following the GCP guidelines. Patients who were reported to be having some systemic disease were chosen for study, provided there were no ocular involvement of that specific disease. All the participating patients were asked to give written informed consent.

Those patients who were excluded from study included those having contraindications to the study drugs, systemic disease refractory to any treatment (uncontrolled), posterior synechiae, any history of previous intraocular surgery, nuclear sclerosis of more than grade 3, need of any topical ophthalmic drugs except the study drugs, diabetes mellitus patients having diabetic macular edema (DME) or diabetic retinopathy, CRVO/BRVO, patients with uveitis.

After having selected the patients, they were randomly categorised into each one of the three groups.

Carboxymethyl cellulose sodium 0.5% TDS was administered to Group A patients (30): one day pre-operatively.

Group B (30 patients) got topical nepafenac 0.1% TDS from one day before doing surgery.

Topical bromfenac 0.09% BD was administered to group C patients (30); one day before (pre-operatively).

Standard rule of treatment was followed in all groups i.e.

1. Tab. Ciprofloxacin 500 mg BD- 5 days starting from a day prior to surgery.
2. Moxifloxacin (0.5%) 1 drop 4 times in a day, from the preoperative day upto 1 week postoperatively.

Before performing the operation, (one hour preoperatively) Tropicamide (0.8%) and Phenylephrine (5%) eye drops were administered at an interval of every 10 minutes, 3-4 times or until and unless the pupil diameter was measured

to be of 8-9mm. In all the groups, surgery was done in same way by one ophthalmic surgeon. Squint calliper was used to measure pupillary diameter first before starting surgery and then after completing the surgery. Data was analysed with the help of MS- Excel worksheet and SPSS 21.0 software. Chi square test helped to analyse the demographic factors.

Results were evaluated and analysis was done via unpaired t- test, comparing the baseline and end of treatment readings in each of the groups. For comparing the significant difference between the groups, ANOVA was done; p- value <0.05 was taken to be significant.

3. Results

In the study, 90 patients were selected, 30 patients to be chosen randomly for each group. No statistically significant differences were present between the three groups.

The mean age of patients was 60.2 ± 10.7 years; 75.5% being females.

3.1. Comparison between the groups

3.1.1. Group A v/s Group B (control v/s nepafenac)

Mean preoperative pupillary diameter as assessed in the two groups were 8.25 mm and 8.65 mm of control and nepafenac groups, respectively.

Post-operative pupillary size in the control and the nepafenac groups, were 6.60 ± 0.68 mm and 8.20 ± 0.75 mm respectively ($p < 0.003$). Total reduction in the size of pupil upto the end of surgery was statistically significantly ($p < 0.003$) different on comparing the placebo group (1.65 ± 0.54 mm) and group B (0.45 ± 0.48 mm).

Thus, as observed in the control group loss of mydriasis was about 20% in contrast to approx. 5% loss in group B i.e nepafenac group ($p < 0.003$).

Therefore nepafenac used prophylactically helps in sustaining mydriasis during cataract surgery.

3.1.2. Group B v/s Group C

Mean preoperative pupillary diameter were measured to be same in the two groups i.e 8.65 mm and 8.65 mm in the nepafenac (group B) and the bromfenac (group C), respectively.

Pupillary diameter difference measured after completion of surgery was statistically not significant (8.20 ± 0.84 mm & 8.32 ± 0.77 mm in the groups B and C, respectively). Decrease in pupillary size till completion of cataract surgery also came out to be statistically not significantly different ($p = 0.80$) between the group B (0.45 ± 0.48 mm) and the group C (0.33 ± 0.44 mm).

However, in the nepafenac group about 5% loss of mydriasis was seen on contrary to about 4% loss observed in bromfenac group. Thus, prophylactic administration of bromfenac appears to be slightly more effective than in sustaining mydriasis during surgery.

Table 1: Demographic profile of patients in all groups

Parameter	Groups		
	A (total=30)	B (total=30)	C (total=30)
Age (in years) (Mean ± SD)	62.5 ± 10.5	58±10.9	60±10.6
Gender			
Male	6	8	8
Female	24	22	22
Eye			
Right eye	20	18	13
Left eye	10	12	17

Table 2: Mean pupillary diameter (Group A, B & C)

Groups	Preoperative pupillary diameter Mean (mm)	Postoperative pupillary diameter Mean (mm)	PreOp pupillary diameter minus post-OP pupillary diameter
A (30)	8.25	6.60	1.65
B (30)	8.65	8.20	0.45
C (30)	8.65	8.32	0.33

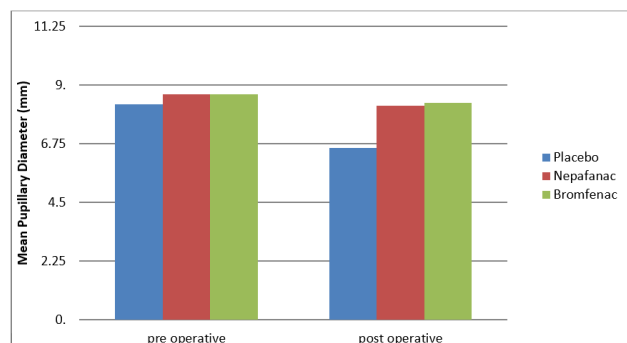
3.1.3. Group A v/s Group C (control v/s bromfenac)

Mean preoperative pupil diameters as measured in groups A and C were 8.25 mm and 8.65 mm, respectively.

On completion of surgery, postoperative pupil size, as per the calculations, came out to be statistically significantly different between both the groups A and C i.e 6.60 ± 0.68 mm and 8.32 ± 0.74 mm, respectively (p<0.003).

Decrease in pupillary diameter hence, as calculated, appeared to be statistically significantly different (p < 0.003) between control group A (1.65 ± 0.54 mm) and the bromfenac group C (0.33 ± 0.44 mm).

At the end/completion of cataract surgery, about 20% loss in mydriasis was seen in the group A i.e control group in contrast to about 4% loss as observed in the bromfenac group (p<0.003). Thus bromfenac given preoperatively is helpful in sustaining mydriasis during cataract surgery.

**Fig. 1:**

4. Discussion

In the study performed, preoperative use of bromfenac and nepafenac showed statistical significant difference in sustaining intraoperative pupillary dilatation (mydriasis)

unlike the placebo.

A significant reduction (20%) was observed in pupillary diameter on completing cataract surgery in group A where no NSAID was given before the surgery.

Very minor reduction in pupillary diameter was seen in Groups B (5%) and C (4%) who were given nepafenac and bromfenac respectively. From the study performed the p-value in case of groups A v/s B, and groups A v/s C, was significant (p<0.003).

Many other studies have previously used other NSAIDs such as ketorolac and diclofenac to demonstrate their effect on pupillary size while performing the surgery of cataract extraction.

As demonstrated in a study done by Roberts, diclofenac (0.1%) as well as flurbiprofen (0.03%) both drugs appeared to be equally helpful in sustaining mydriasis while doing cataract surgery.¹⁵

Comparison of effects of flurbiprofen v/s indomethacin as done in a study done by Gimbel et al¹⁶ showed that both the drugs are equally efficient in sustaining intra-operative mydriasis.

Atanis R,¹⁷ similarly carried out a study, demonstrating topical formulation of nepafenac to be comparatively more effective mydriasis sustaining drug while performing cataract surgery by phacoemulsification technique hence, showing relatively better mydriasis sustaining action during the entire surgery in contrast to topical ketorolac or any control.¹⁷

Here the purpose of our study was to show that both Nepafenac (0.1%) given thrice daily and bromfenac (0.09%) twice a day before cataract extraction procedures are helpful in sustaining mydriasis intra-operatively.

Bromfenac, on comparison with Nepafenac, was shown to be having relatively greater effectiveness, clinically, in sustaining mydriasis, although we couldn't find that much statistically significant difference.

In other words, it can thus be said that both the topical drugs are effective and can surely help in performing more safe and better surgery.

5. Source of Funding

None.

6. Conflict of Interest

None.

References

- Güell JL, Morral M, Kook D, Kohner T. Phakic intraocular lenses. *J Cataract Refract Surg.* 2010;36(11):1976–93. doi:10.1016/j.jcrs.2010.08.014.
- Colin J. The Role of NSAIDs in the Management of postoperative ophthalmic Inflammation. *Drugs.* 2007;67:1291–308.
- Koay P. The emerging roles of topical non-steroidal anti-inflammatory agents in ophthalmology. *Br J Ophthalmol.* 1996;80(5):480–5. doi:10.1136/bjo.80.5.480.
- Drolsum L, Davanger M, Haaskjold E. Risk factors for an inflammatory response after extracapsular cataract extraction and posterior chamber IOL. *Acta Ophthalmol (Copenh).* 1994;72:21–6.
- Podos SM. Prostaglandins, nonsteroidal anti-inflammatory agents and eye disease. *Trans Am.* 1976;74:637–60.
- Guzek JP, Holm M, Cotter JB, Cameron JA, Rademaker WJ, Wissinger DH, et al. Risk Factors for Intraoperative Complications in 1000 Extracapsular Cataract Cases. *Ophthalmology.* 1987;94:461–6. doi:10.1016/s0161-6420(87)33424-4.
- Nichols J, Snyder RW. Topical nonsteroidal anti-inflammatory agents in ophthalmology. *Curr Opin Ophthalmol.* 1998;9(4):40–4. doi:10.1097/00055735-199808000-00007.
- Schalnus R, Schalnus R. Topical Nonsteroidal Anti-Inflammatory Therapy in Ophthalmology. *Ophthalmologica.* 2003;217:89–98. doi:10.1159/000068563.
- Kim A, Stark WJ. Are Topical NSAIDs Needed for Routine Cataract Surgery? *Am J Ophthalmol.* 2008;146(4):483–5. doi:10.1016/j.ajo.2008.07.027.
- Heinrichs DA, Leith AB. Effect of flurbiprofen on the maintenance of pupillary dilation during cataract surgery. *Can J Ophthalmol.* 1990;25:239–42.
- Keates RH, McGowan KA. Clinical trial of flurbiprofen to maintain pupillary dilation during cataract surgery. *Ann Ophthalmol.* 1984;16:919–21.
- Sachdev MS, Singh K, Talwar D, Gupta SK, Given VK. Comparative efficacy of diclofenac and flurbiprofen for maintenance of pupillary dilatation during cataract surgery. *Ophthalmic Surg.* 1994;25:92–4.
- Gupta VP, Dhaliwal U, Prasad N. Ketorolac tromethamine in the maintenance of intraoperative mydriasis. *Ophthalmic Surg Lasers.* 1997;28:731–8.
- Sachdev MS, Mehta MR, Dada VK, Jain AK, Garg SP, Gupta SK. Pupillary dilatation during cataract surgery - relative efficacy of indomethacin and flurbiprofen. *Ophthalmic Surg.* 1990;21:557–9.
- Roberts CW. Comparison of Diclofenac Sodium and Flurbiprofen for Inhibition of Surgically Induced Miosis. *J Cataract Refract Surg.* 1996;22(1):780–7.
- Gimbel H, Westenbrugge JV, Cheetham JK, DeGryse R, Garcia CG. Intraocular availability and pupillary effect of flurbiprofen and indomethacin during cataract surgery. *J Cataract Refract Surg.* 1996;22(4):474–9. doi:10.1016/s0886-3350(96)80045-9.
- Atanls R, Tuano P, Vlcenclo J. Effect of topical ketorolac tromethamine and topical nepafenac on maintaining pupillary dilation during phacoemulsification. *Philipp J Ophthalmol.* 2011;36:23–7.

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