ORIGINAL RESEARCH PAPER

Ophthalomology

STUDY OF TOPICAL NEPAFENAC (0.1%) EYE DROPS VERSUS FLURBIPROFEN (0.03%) EYE DROPS IN MAINTAINING INTRAOPERATIVE MYDRIASIS IN PHACOEMULSIFICATION

KEY WORDS: Cataract; Phacoemulsification; NSAIDs; Mydriasis.

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ABSTRACT

Background: Cataracts remain the principal cause of blindness where over 17.7 million individuals worldwide suffer from cataracts, which account for 47.8% of preventable blindness. Phacoemulsification is the preferred surgical technique with in-the-bag intraocular lens insertion since it provides the greatest visual outcomes and quicker recovery. Topical ophthalmic NSAIDS suppress the cyclooxygenase enzyme, which significantly reduces prostaglandin release. **Objectives:** This study was conducted to compare the effectiveness of Nepafenac and Flurbiprofen in maintaining intraoperative mydriasis in phacoemulsification. **Methods:** A prospective, randomized, double-blinded, parallel group, comparative study was conducted from April 2023 to August 2023 among patients undergoing phacoemulsification surgery at a tertiary care hospital, South India. Approval of the ethics committee of the institution was taken. The sample size was 100 patients who met the inclusion and exclusion criteria. The study participants were randomly allotted into two groups A and B with 50 patients in group A and 50 patients in group B respectively, where group A received 0.1% Nepafenac eye drops, and group B received 0.03% Flurbiprofen eye drops. Descriptive statistics of the explanatory and outcome variables were calculated, and the level of significance was set at 5%. **Results:** A total of 100 patients participated in this study, where 58% were females and 42 % patients were males. 25 patients belonged to the age group of 50 to 59 years, 44 patients belonged to the age group of 60 to 69 years, 31 patients belonged to the age group of 70 to 79 years. We found a statistical significance (*p=0.001*) for vertical and horizontal pupillary diameters when compared at different stages of the surgery for both the groups. **Conclusion:** In our study, both the drugs were equally effective at different time intervals of the surgery. However, Nepafenac (0.1%) was found to be slightly better than flurbiprofen (0.03%) in maintaining intraoperative mydriasis.

INTRODUCTION

According to the World Health Organisation (WHO), cataract is the leading cause of blindness globally. Over 17.7 million individuals worldwide suffer from cataracts, which account for 47.8% of preventable blindness[1]. In India, between 50 and 80 percent of bilateral blindness is caused by cataracts[2]. The preferred surgical technique is now Phacoemulsification with in-the-bag intraocular lens insertion since it provides the greatest visual outcomes and quicker recovery[3].

Intraocular tissue damage after cataract surgery activates phospholipase A2, which in turn releases pro-inflammatory mediators such prostaglandins and leukotrienes. During surgery, these endogenous prostaglandins cause miosis, increased blood-aqueous barrier permeability, conjunctival hyperemia, postoperative inflammation, and alterations in intraocular pressure[4].

A smaller pupil width increases the risk of surgical trauma, posterior capsule tears, and postoperative inflammation. It can also make surgery more challenging[5].

Topical ophthalmic NSAIDS suppress the cyclooxygenase enzyme, which significantly reduces prostaglandin release[6]. The FDA approved Flurbiprofen in 1988 has been the first medication for the maintenance of intraoperative mydriasis[7]. Nepafenac, a more recent topical NSAIDS, also had encouraging results. It is a prodrug that stops the cyclooxygenase enzyme from working. Because of its increased ocular bioavailability and improved corneal penetration, it produces target-specific NSAIDs that block prostaglandins[8].

This study was undertaken to study Nepafenac in comparison with Flurbiprofen in maintaining intraoperative mydriasis in phacoemulsification.

Objective Of The Study

This study was conducted to compare the effectiveness of topical Nepafenac (0.1%) eye drops and Flurbiprofen (0.03%) eye drops in maintaining intraoperative mydriasis in phacoemulsification.

METHODOLOGY

We conducted a prospective, randomized, double-blinded, parallel group, comparative study conducted in patients undergoing phacoemulsification surgery at a tertiary care hospital, South India. Approval of the ethics committee of the institution was taken. The study was conducted from April 2023 to August 2023. 100 patients who met the inclusion and exclusion criteria were taken as the sample size.

Inclusion Criteria:

1) Patients age > 50 years.
2) Diagnosed with cataract grade nuclear opalescence (NO) and/or nuclear color (NC) 2–3 {according to Lens Opacities Classification System (LOCS) III}.

Exclusion Criteria:

1) Age <50 years.
2) History of trauma or any previous ocular surgeries in the operating eye.
3) Glaucoma or active ocular inflammation.
4) Ocular surface disease and viral keratoconjunctivitis.
5) History of diabetes mellitus and hypertension.

6) Use of topical or systemic steroids within 30 days prior to surgery.
7) Use of any other topical medications within 30 days prior to surgery (except lubricants).
8) Allergy or hypersensitivity to topical NSAIDS and its preservatives.
9) Intraoperative complications like iridodialysis, PCR, vitreous loss, premature entry or hyphema.
10) Pseudo-exfoliation, uveitis, local pupillary abnormalities, less than 6.00 mm pupil size.

MATERIALS AND METHODS

We performed a thorough ophthalmic evaluation prior to the surgery in all the study participants and a proper history was taken especially medications regarding Benign prostrate hypertrophy as they cause floppy iris. Best corrected visual acuity using Snellen's chart, slit lamp bio microscopy, IOP by Goldmann applanation tonometry, and dilated fundus examination by indirect ophthalmoscopy and grading of cataract according to LOCS III was done.

Informed consent for Cataract surgery was obtained from all the patients. All the patients who met the inclusion criteria were randomly allotted in the two groups A and B with 50 patients in group A and 50 patients in group B.

Group A received 0.1% Nepafenac eye drops and group B received 0.03% Flurbiprofen eye drops. Patients in each group received drops 1 hour prior to surgery with one drop every 15 mins interval and the last drop being administered 5 mins before peribulbar block. Mydriatic combination of tropicamide 0.8% and phenylephrine 5% was administered 1 hour prior to surgery with 15 mins interval, last drop was installed 10 mins before giving block in all the patients. There was a 5 mins gap during installation of two drops.

Clear corneal phacoemulsification was done in all cases by a single surgeon, under peribulbar anaesthesia with lignocaine (2%), sodium hyaluronidase (1500 IU) and bupivacaine (0.5%).

Both vertical and horizontal pupillary diameters were measured by placing Castroviejo's caliper in front of the cornea at three steps; immediately before the surgical incision (baseline), at the end of emulsification of nucleus (before irrigation and aspiration) and at the end of surgery (after stromal hydration). Intracameral use of adrenaline or pilocarpine was not done in any of the cases.

Statistical Analysis

Data was entered in the excel spread sheet. SPSS (Statistical Package for Social Sciences) version 20 was used to perform the statistical analysis. Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation for quantitative variables, frequency, and proportions for qualitative variables. Unpaired t test was applied to test the mean difference between the groups in respect to pupillary diameters. Repeated measures of ANOVA were applied to test the statistical significance between papillary diameters at different intervals. The level of significance was set at 5%.

RESULTS

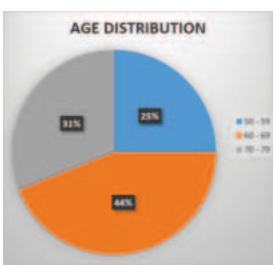

Figure 1: Age Distribution Of The Patients (n=100)

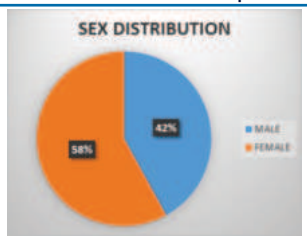

Figure 2: Gender Distribution Of The Patients (n=100)

Table 1: Vertical and Horizontal Pupillary Diameters (mm) Of Patients At Different Stages Of Surgery

Vertical Pupil Diameter (mm) Mean± SD	Nepafenac (n = 100)	Flurbiprofen (n = 100)
At start of surgery	7.82	7.58
After phacoemulsification of nucleus	7.34	6.92
At end of surgery	6.88	6.4
Horizontal Pupil Diameter (mm) Mean± SD	**Nepafenac (n = 100)**	**Flurbiprofen (n = 100)**
At the start of surgery	7.66	7.1
After phacoemulsification of nucleus	6.94	6.78
At end of surgery	6.76	6.18

Table 2: Comparison of Vertical and Horizontal Pupillary Diameters (mm) Of Patients

Nepafenac(0.1%)	Time	Mean	Std. Dev	F value	p value*
Vertical pupillary diameter	At the start of surgery	7.82	.482	102.387	0.001
	After phacoemulsification of nucleus	7.34	.519		
	At the end of the surgery	6.88	.480		
Horizontal pupillary diameter	At the start of surgery	7.66	.479	104.317	0.001
	After phacoemulsification of nucleus	6.94	.424		
	At the end of the surgery	6.76	.431		
Flurbiprofen(0.03%)	**Time**	**Mean**	**Std. Dev**	**F value**	**p value***
Vertical pupillary diameter	At the start of surgery	7.58	.538	114.043	0.001
	After phacoemulsification of nucleus	6.92	.396		
	At the end of the surgery	6.40	.495		
Horizontal pupillary diameter	At the start of surgery	7.10	.364	83.158	0.001
	After phacoemulsification of nucleus	6.78	.418		
	At the end of the surgery	6.18	.388		

This study included 100 patients who were aged more than 50 years and were diagnosed with cataract grade nuclear opalescence (NO) and/or nuclear color (NC) 2–3 {according to Lens Opacities Classification System (LOCS) III}. The study participants were randomly allotted into two groups A and B with 50 patients in group A and 50 patients in group B respectively. Group A received 0.1% Nepafenac eye drops and group B received 0.03% Flurbiprofen eye drops.

The patients were distributed between 50 and 59 years of age, 60 and 69 years of age and 70 and 79 years of age [*Figure 1*]. 25 patients (25%) belonged to the age group of 50 to 59 years, 44 patients (44%) belonged to the age group of 60 to 69 years, 31 patients (31%) belonged to the age group of 70 to 79 years. As depicted in *Figure 2,* 58 patients were females (58%) and 42 patients were males (42%).

Both vertical and horizontal pupillary diameters (in mm) were measured among patients in both the groups at different stages of the surgery.

The vertical pupillary diameter in group A and group B at the start of surgery was 7.82mm and 7.58mm respectively. The vertical pupillary diameter in group A and group B after phacoemulsification of nucleus was 7.34mm and 6.92mm respectively, whereas at the end of the surgery was 6.88mm and 6.4mm for group A and group B respectively. The horizontal pupil diameter in group A and group B at the start of surgery was 7.66mm and 7.1mm respectively. The horizontal pupillary diameter in group A and group B after phacoemulsification of nucleus was 6.94mm and 6.78mm respectively, whereas at the end of the surgery was 6.76mm and 6.18mm for group A and group B respectively [*Table 1*].

As shown in *Table 2*, the vertical and horizontal pupillary diameters were compared at different stages of the surgery for group A and group B separately. We found a statistical significance (*p=0.001*) for vertical and horizontal pupillary diameters when compared at different stages of the surgery (at the start of surgery, after phacoemulsification of nucleus and at the end of surgery) for group A who received 0.1% Nepafenac eye drops.

Similarly, the vertical and horizontal pupillary diameters when compared at different stages of the surgery (at the start of surgery, after phacoemulsification of nucleus and at the end of surgery) for group B who received 0.03% Flurbiprofen eye drops was also statistically significant (*p=0.001*).

DISCUSSION

In the present study, topical Nepafenac (0.1%) proved to be more efficacious in maintaining intra-operative mydriasis during phacoemulsification surgery as compared to topical Flurbiprofen (0.03%).

Nepafenac is a neutral medication that diffuses easily into the anterior chamber. The hydrolases that are more concentrated in the intraocular vascular tissues, specifically the retina and choroid, subsequently hydrolyze it into its active metabolite, amfenac[3].

Few randomized control trials from the Indian subcontinent have previously been published. They compared the effectiveness of topical Nepafenac (0.1%) with Flurbiprofen (0.03%) in preserving intraoperative mydriasis. Sarkar et al. and Pradeep et al. compared the effectiveness of these two medications in small incision cataract surgery (SICS) while Prakash et al. investigated their effectiveness in extra capsular cataract excision. Compared to phacoemulsification, both of these surgical techniques handle iris tissue more, which increases the risk of intraoperative miosis[4,9,10]. This study compared the effectiveness of topical Nepafenac (0.1%) with Flurbiprofen (0.03%) in sustaining intra-operative mydriasis during phacoemulsification, the favored surgical technique at the moment.

According to a study report by Guzek JP, mydriasis greater than 6 mm during surgery has reduced posterior capsule tear incidence by 50%[11]. Both the vertical and horizontal pupillary diameters in the present study was above 6mm, however it was more than 7mm at the start of the surgery in both the groups.

In our study, we found a statistical significance (*p=0.001*) for vertical and horizontal pupillary diameters when compared at different stages of the surgery (at the start of surgery, after phacoemulsification of nucleus and at the end of surgery) for both the groups. However, in a study by Sarkar et al.[9] measured the vertical and horizontal pupillary diameters and applied topical NSAIDs one day prior to surgery and they concluded that there was no discernible difference in the vertical and horizontal pupil diameter at the beginning of surgery, suggesting that starting NSAIDs the day before surgery has no additional benefits over commencing them the day of the procedure which was similar to the study by Shrivastava AK et al.[3] Unlike Prakash et al[4], the findings of Pradeep et al[10], Shrivastava AK et al.[3] and Sarkar et al[9] indicated that Nepafenac was more effective near the end of surgery.

CONCLUSION

In our study, both the drugs were equally effective at different time intervals of the surgery. However, topical Nepafenac (0.1%) eye drops were found to be slightly better than Flurbiprofen (0.03%) eye drops in maintaining intraoperative mydriasis.

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