Original Article

Efficacy of nepafenac in maintaining mydriasis during phacoemulsification surgery

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Objective: To evaluate the efficacy of nepafenac 0.1% in maintaining mydriasis during phacoemulsification surgery.

Methodology: This randomised control RCT is of six-month duration was performed on 120 patients who were randomized in 2 groups. The study group was given 3 drops of nepafenac 1 day prior to surgery and 4 drops on the day of surgery in addition to the preoperative dilating drops (tropicamide 1% and epinephrine 0.5%) one hour before surgery, repeated after 30 minutes. Control group received only pre-operative dilating drops. Calipers were used to measure pupil size immediately before and at end of surgery. The difference in size was noted and the decrease in pupil size was calculated using SPSS 21.0. $p<0.05$ was considered significant.

Results: Out of 120 patients, 42(35%) were male and 78(65%) female. The mean age was 52.13±7.34 years in control group and 52.93±7.09 years in nepafenac group. At baseline in nepafenac group, pupil size was 7.74±0.92 mm and 6.3±0.99 mm at the end of surgery. Mean decrease was 0.9±0.89 mm. In the control group, pupil size was 7.6±0.61mm before surgery and 5.84±0.56 mm at end of surgery. Mean decrease in pupil size was 1.76±0.81mm. The difference in the two groups was significant ($p<0.001$).

Conclusion: The use of nepafenac 0.1% during phacoemulsification surgery can be beneficial in maintaining mydriasis. (Rawal Med J 202;45:810-812).

Keywords: Nepafenac, phacoemulsification, cataract.

INTRODUCTION

Currently, surgical treatment of choice for cataract extraction is phacoemulsification with intraocular lens (IOL) implantation, for which, stable and adequate mydriasis is essential to prevent nucleus loss and posterior capsule rupture resulting from constriction of the pupil.[1,2] During cataract extraction, the increased prostaglandin quantities in aqueous humor also lead to blood-aqueous barrier breakdown, hyperemia and miosis.[3] It is well-known that the chances of posterior capsule rupture decrease to about half with greater than 6mm mydriasis.[4] The significance of sustained mydriasis during cataract surgery can also be anticipated with the increased use of toric and multifocal IOLs.[5] Also it is essential for ease of anterior capsule incision, safe cataract elimination, and IOL implantation.[6]

To ease cataract extraction and to avoid intraoperative miosis; mydriatics and anti-prostaglandins are routinely administered preoperatively. The non-steroidal anti inflammatory drugs (NSAIDs) inhibit the cyclo-oxygenase enzyme leading to inhibition in prostaglandins production.[7,8] Topical NSAIDs, including indomethacin, ibuprofen, and flurbiprofen are effective in preventing miosis.[9] A study including bromfenac and ketorolac also showed the same results.[10] However, NSAIDs usage has resulted in side effects and complications like corneal ulceration, irritations, corneal melting, and globe perforation.[11] Therefore, recent evidence suggests that the previously suggested NSAIDs have to be replaced by a new topical NSAID.[12]

In 2005, topical nepafenac suspension was approved for the management of cataract surgery associated pain and inflammation.[13] Following topical administration, nepafenac penetration in eye is rapid and its active metabolite amfenac is formed by enzymatic activity in the retina, iris, ciliary body, and choroid.[14,15] Amfenac is a non-selective cyclo-oxygenase enzyme inhibitor that inhibits prostaglandins synthesis.[16] These prostaglandins are responsible for intraoperative narrowing of

pupil.[17,18] Thus this study was done to evaluate the effect of nepafenac 0.1% in maintaining effective mydriasis, which has only been done once in Hyderabad and has not been performed in our setup in Punjab.

METHODOLOGY

This study was conducted from August 2016 to February 2017. Ethical Approval was taken from Institutional Review Board of Services Institute of Medical Sciences. To avoid selection bias, all consecutive patients, both males and females, between 40 and 65 years of age with moderate cataract were included. Patients were divided into two groups, Nepafenac group and the control group. Patients with the following conditions were excluded: pseudoexfoliation, pupil abnormalities such as posterior synechiae, previous intraocular surgery, history of ocular trauma, diabetic retinopathy confirmed with slit-lamp biomicroscopy.

Nepafenac group was administered nepafenac 0.1% eye drops (3 drops per day) 1 day prior to surgery. In addition, on the day of surgery also they had 4 drops of nepafenac at 15 minutes interval for 1 hour before surgery. Control group did not receive nepafenac drops. Preoperatively, all patients of both groups received tropicamide 1% eye drops and epinephrine 0.5% eye drops 1 hour before surgery repeated after 30 minutes for dilation. The pupil size was measured and recorded in mm using calliper at the following stages: immediately before the phacoemulsification cataract surgery and at end of phacoemulsification. The difference in pupillary diameters at two stages was noted and decrease in pupil size was calculated.

Statistical Analysis: SPSS version 21 was used for analysis. Independent t-test was used to compare pre-operative and post-operative results. $p<0.05$ was considered significant.

RESULTS

The mean patient age was 52.13±7.34 years in control group and 52.93±7.09 years in nepafenac group. Overall, the study included 42 (35%) males and 78 (65%) females. At baseline in nepafenac group pupil size was 7.74±0.92 mm and 6.3±0.99 mm at the end of surgery (Table 1).

Table 1. Pupil size in Nepafenac group (n=60).

Pupil Size (mm)	Mean±SD
Before Surgery	7.74±0.92
After Surgery	6.3±0.99

Table 2. Pupil size in control group (n=60).

Pupil Size (mm)	Mean±SD
Before Surgery	7.6±0.61
After Surgery	5.84±0.56

Table 3. Decrease in pupil size/loss of mydriasis (mm) (n= 60).

	Mean±SD
Nepafenac group	0.9±0.89
Control group	1.76±0.81

In the control group, pupil size was 7.6±0.61mm before surgery and 5.84±0.56 mm at end of surgery (Table 2). Mean decrease was calculated to be 0.9±0.89 mm. (Table 3). Mean decrease in pupil size was calculated to be 1.76±0.81mm. (Table 3) The difference in the two groups was significant ($p<0.001$).

DISCUSSION

Sustained mydriasis is necessary not only to support anterior capsule proper incision, uncomplicated cortex removal, harmless emulsified nucleus delivery but also for intraocular lens implantation.[19] The posterior capsule rupture, a well-known trans-operative complication is reduced to half if pupillary diameter >6mm is maintained during surgery.[4] In most surgeries subsequent miosis commences soon after entry to the anterior chamber is made.

In our study, the mean decrease in pupil size was 0.9±0.89mm, which is in concurrence with a previously conducted study of 60 cases in Hyderabad in which the mean decrease of pupil size with nepafenac was 0.55±0.51mm.[1] Another study reported a mean decrease of 0.78±0.56mm in pupil size.[20] These results suggest that if nepafenac is used prophylactically, it not only effectively sustains trans-operative mydriasis but also decreases the development of macular edema after cataract surgery.[20] However, one study mean decrease in pupil size was 1.46±1.03mm.[6]

Moreover, it was concluded that during

phacoemulsification, compared to topical ketorolac or any other NSAIDs, the topical nepafenac is more effective in preventing miosis and sustaining constant mydriatic effect throughout the surgical procedure.[6] Another study reported a significant decrease in pupil size to 3.4±1.05 mm with nepafenac.[20]

CONCLUSION

Nepafenac was effective in maintaining mydriasis during cataract surgeries.

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