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ROLE OF NEPAFENAC 0.1%IN MAINTAINING MYDRIASIS DURING PHACOEMULSIFICATION SURGERY

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ABSTRACT

Background: *Maintenance of adequate pupil size during phacoemulsification surgery is crucial for optimal surgical outcomes. Pharmacologic agents like nepafenac are commonly used to minimize pupil constriction during surgery.*

Objective: *To compare the efficacy of 0.1% nepafenac eye drops with placebo (natural tears) in maintaining intraoperative pupil size during phacoemulsification surgery.*

Material and methods: *This randomized controlled trial was carried out at Department of Ophthalmology, Hayatabad Medical Complex, from June 2022 to June 2023. In total, 60 patients who were planned to undergo phacoemulsification surgery were selected and included into the study. Patients were then randomly divided into two groups; each group having a subject population of 30 patients. Group A was given 0.1% nepafenac eye drops while the control group, Group B, was given placebo which is the natural tears. Recruitment was done through a nonprobability consecutive sampling technique.*

Results: *Mean diameter at the end of emulsification in group A was noted as 8.21±0.525mmcompare to group B 8.06±0.718mm. Mean diameter at theend of surgery in nepafenac group versus placebo group was7.89±0.350vs 7.05±0.621mmrespectively. The right eye was involved in 50% of cases in group A and 60% in group B, while the left eye was involved in 50% cases in group A and 40% cases of group B. Regarding the diameter difference, 83.3% of patients in group A experienced a pupil size reduction of ≤0.7mm compared to 23.3% in group B. Conversely, only 16.7% of cases in group A had a reduction >0.7mm, in contrast to 76.7% patients in group B.*

Conclusion: *Nepafenac 0.1% significantly reduced pupil size constriction during phacoemulsification surgery compared to placebo, demonstrating its effectiveness in maintaining adequate pupil size and improving surgical outcomes. These findings highlight the utility of nepafenac in enhancing the efficiency and safety of cataract surgeries.*

Keywords: *Nepafenac, Phacoemulsification, Pupil size, Cataract surgery, emulsification.*

INTRODUCTION

Phacoemulsification is the most common surgical procedure in cataract extraction that has been highly encouraged because of its effectiveness and minimal risks involved. An important precondition for this surgery's success is the proper mydriasis during it that provides a good visualization of the intraocular structures and proper shading of the instruments being used in the eye (1). However, the management of miosis intraoperatively is a complex issue; the presence of miosis makes it difficult to perform maneuvers and potentially increases the risk of capsular rupture and prolong the surgery duration (2,3).

The aetiology of intraoperative miosis is, therefore, complex and includes prostaglandins which are liberated from the injured iris and ciliary body. These mediators stimulate the sphincter pupillae muscle dilating the effect of preoperative mydriatic agents resulting into gradual constriction of the pupil (4). Some of the most frequently used drugs in ophthalmology to prevent this inflammatory response have been NSAIDs. Among them topical nepafenac 0.1 %, being a prodrug, converted to its active metabolite, amfenac, in ocular tissues has been reported to have promising anti-inflammatory and analgesic effectivity (5,6).

Nepafenac 0.1% eye drops demonstrate good penetration through the corneal epithelium and exerts a potent and selective action on cyclooxygenase enzymes, which is an essential prerequisite for preventing intraoperative inflammation occurring due to prostaglandin synthesis inhibition. Specifically, its pharmacokinetics of fast absorption and a protracted effect and, thus, it is appropriate for preoperative and intraoperative treatment of patients of cataract surgery (7). Literature reviews have shown that nepafenac helps to not only sustain mydriasis but also pain and inflammation that are present after surgery as a result promoting improved outcome and patient satisfaction (8,9).

Although several studies have shown the efficacy of nepafenac (10), the particular use of nepafenac in maintaining mydriasis during phacoemulsification surgery is still not fully investigated. In the current study, the use of nepafenac 0.1% topical preparation is sought to assess whether it will maintain sufficient mydriasis during the procedure and the effects on contextual surgical factors and patients' results. In doing so, this research aims to make a contribution towards enhancing applicative knowledge of cataract surgery, particularly for high volume surgical centers.

MATERIAL AND METHODS

This randomized controlled trial was carried out at Department of Ophthalmology, Hayatabad Medical Complex, from June 2022 to June 2023. In total, 60 patients who were planned to undergo phacoemulsification surgery were selected and included into the study. Patients were then randomly divided into two groups; each group having a subject population of 30 patients. Group A was given 0.1% nepafenac eye drops while the control group, Group B, was given placebo which is the natural tears. Recruitment was done through a nonprobability consecutive sampling technique.

The inclusion criteria defined patients between 45 and 65 years old, both sexes, who are to undergo phacoemulsification outcome. Patients with local pupil abnormalities, pseudoexfoliation syndrome, diabetes mellitus, history of ocular trauma, or prior ocular surgery were excluded.

Following approval from the hospital's research review board, participants were enrolled from the ophthalmology indoor unit. Signed written informed consent before enrollment to the study was obtain. Participant's age, gender and BMI were collected as part of demographic data in the beginning of the study. Block randomization was used, ensuring equal allocation to the two study groups.

Group A used 0.1% nepafenac eye drops; for this group, there were four drops in total, at intervals of 15 minutes before surgery. Group B was given natural tears as a control, administered according to this dosage regimen. All other participants were also administered topical tropicamide and phenlyephrine for mydriasis. Intraoperatively, epinephrine was applied as an irrigating solution. The primary outcome, pupil size, was measured at three key time points: postoperatively prior to initial phacoemulsification, upon completion of the phacoemulsification portion of the surgery and at the conclusion of the surgery.

The data was analyzed descriptively using the statistical tool-IBM SPSS version 23. Categorical data including gender and laterality of the affected eye were described using frequencies and percentages. Age, BMI, and pupil size at the three time points were categorized as continuous variables and are presented as mean ± SD. To control for potential confounding factors such as age and gender, data were stratified, and

post-stratification analysis was performed using the Student's t-test. A p value of ≤ 0.05 was used to determine statistically significance of the study.

RESULTS

Age of the patients ranged from 45 to 65 years with a mean age of 51.04±4.014 in group A and 52.04±5.323years in group B. There were 46.7% male and 53.3% females in group A, this ratio was 56.7% & 43.3% respectively in group B. In group A, 17 (56.7%) patients belonged to the age group 45-55 years compared to 19 patients (63.3%) in placebo group. Mean BMI of the patients in group A was 22.137±1.8570as compare to group B 22.111±1.7124 kg/m^2. Mean baseline diameter in both groups were comparable 8.43±0.739versus8.37±0.699mm. Mean diameter at the end of emulsification in group A was noted as 8.21±0.525mmcompare to group B 8.06±0.718mm. Mean diameter at theend of surgery in nepafenac group versus placebo group was7.89±0.350vs 7.05±0.621mmrespectively**.** The right eye was involved in 50% of cases in group A and 60% in group B, while the left eye was involved in 50% cases in group A and 40% cases of group B. Regarding the diameter difference, 83.3% of patients in group A experienced a pupil size reduction of ≤0.7mm compared to 23.3% in group B. Conversely, only 16.7% of cases in group A had a reduction >0.7mm, in contrast to 76.7% patients in group B. Table-1

Stratification of pupil diameter difference with respect to age, gender and laterality in both groups is shown in table 2, 3 and 4 respectively.

Table-1. Demographic and other clinical characteristics

Characteristics	Group A	Group B
Age groups		
45-55 years	17 (56.7%)	19 (63.3%)
56-65 years	13 (43.3%)	11 (36.7%)
Mean age(yrs)	51.04 ± 4.014	52.04 ± 5.323
Gender		
Male	14 (46.7%)	17 (56.7%)
Female	16 (53.3%)	13 (43.3%)
Laterality		
Right	15 (50%)	18 (60%)
Left	15 (50%)	12 (40%)
Diameter difference ≤0.7mm		
Yes	25 (83.3%)	7 (23.3%)
No	5 (116.7%)	23 (26.7%)
Mean pupildiameter(mm) beforesurgery	8.43±0.739	8.37±0.699
Mean pupildiameter(mm) attheendof phaco	8.21±0.525	8.06±0.718
Mean pupildiameter(mm) attheendof surgery	7.89±0.350	7.05±0.621
Mean difference in diameter	0.54±0.389	1.32±0.078
Mean BMI (kg/m^2)	22.137±1.8570	22.111±1.7124

Table 2: Stratification by Age with Respect to Diameter Difference ≤0.7mm

Age (years)	Group	≤0.7mm (Yes)	>0.7mm (No)	P-value
45-55	A	14 (82.4%)	3 (17.6%)	0.007
	B	5 (26.3%)	14 (73.7%)	
56-65	A	11 (84.6%)	2 (15.4%)	
	B	2 (18.2%)	9 (81.8%)	

Table 3: Stratification by Gender with Respect to Diameter Difference ≤0.7mm

Gender	Group	≤0.7mm (Yes)	>0.7mm (No)	P-value
Male	A	12 (85.7%)	2 (14.3%)	0.007
	B	4 (23.5%)	13 (76.5%)	
Female	A	13 (81.2%)	3 (18.8%)	
	B	3 (23.1%)	10 (76.9%)	

Table 4: Stratification by Laterality with Respect to Diameter Difference ≤0.7mm

Laterality	Group	≤0.7mm (Yes)	>0.7mm (No)	P-value
Right	A	12 (80.0%)	3 (20.0%)	0.006
	B	5 (27.8%)	13 (72.2%)	
Left	A	13 (86.7%)	2 (13.3%)	
	B	2 (16.7%)	10 (83.3%)	

DISCUSSION

When comparing both groups the demographic features of patients revealed that there was no statistical difference in age, gender distribution as well as mean BMI. Age distribution of the participants was similar between group A, mean age was 51.04 ± 4.014 years and group B, mean age was 52.04 ± 5.323 years. The mean age of patients in both groups was also reasonably similar, and this excluded the possibility that initial physical features would shape results from the study. Additionally, laterality of the eye was nearly uniform in Group A, whereas Group B had 60% right eye and 50% left eye involvement.

The first outcome measure in this trial, pupil size at three predefined time-points, thus supports nepafenac's greater effectiveness in reducing intraoperative miosis. The mean baseline pupil diameter was also similar in the two groups for baseline measurements (8.43 ± 0.739mm in Group A vs 8.37 ± 0.699mm in Group B). But at the end of phacoemulsification, in the Group A the mean pupil diameter was slightly higher as compared to the Group B (8.21 ± 0.525 mm Vs. 8.06 ± 0.718 mm) and the same was obtained at the end of surgery (7.89 ± 0.350 mm Vs. 7.05 ± 0.621 mm). These results are consistent with previous literature suggesting that NSAIDs are responsible for the management of pupil size during cataract surgery due to the inhibition of prostaglandin induced miosis (Yanni SE et al, Chaistain JE et al)[11,12].

This makes the analysis of the difference in pupil diameter even more supportive of the effectiveness of nepafenac. The proportion of patients with ≤ 0.7 mm of pupils size reduction was significantly higher in Group A (83.3%) compared to the patients in Group B (23.3%). On the other hand, 76.7% of the patients in Group B had a reduction of > 0.7 mm while only 16.7% of patients in Group A had a reduction of > 0.7mm. These results stress the benefits of nepafenac in preventing pupil constriction, a result consistent with published studies that have shown that NSAIDs reduce intraoperative miosis (Mirshahi A et al, Kim BZ et al) [13,14].

A further analysis of the results in this study by age, gender, and laterality improved our understanding. In age group of 45-55 years, we observed a statistically significant difference, 82.4% of patients from Group A achieved a diameter difference ≤ 0.7 mm, compared to 26.3% of patients in Group B (p = 0.007). Likewise in the age group 56-65 years, out of the 50 patients in Group A, 42 maintained the smaller diameter difference as against three patients in Group B.

A prospective gender analysis of this study show that individuals of Group A, both male and female respondents maintain a pupil size reduction ≤ 0.7 mm more than those in Group B, 85.7% of males and 81.2% of females contrasted to 23.5% of males and 23.1% of females respectively (p = 0.007). Regarding the laterality of the eyes, 26 cases were in the right eye and 29 in the left eye, all from Group A, which retained a smaller diameter difference of 80.0% in the right eye and 86.7% in the left eye compared with 27.8% in the right eye and 16.7% in the left eye in Group B (p = 0.006).

The ability of nepafenac to maintain pupil size during phacoemulsification is clinically significant (15). Intraoperatively miosis causes increased operative time, more difficulty and high risk of complications. By selectively suppressing prostaglandin synthesis, nepafenac minimizes intra-operative miosis thus making the surgery safer and more efficient (Danni R et al, Riley AF et al)[16,17]. Therefore, the findings of this study contribute to the accumulating body of literature indicating the topical NSAIDs as an important component of the preoperative management of patients undergoing cataract surgery.

In spite of its significant findings, this study has limitations. The study was conducted over a six-month period with a relatively small sample size. Larger sample sizes and longer follow-up periods could provide more robust evidence in future research. The optimization of preoperative regimens could also be improved by testing other NSAIDs or combining them.

CONCLUSION

In this study, 0.1% nepafenac eye drops decreased intraoperative pupil constriction during phacoemulsification surgery. The ability of nepafenac to maintain larger pupil diameters and limit miosis makes it an effective preoperative agent, improving surgical conditions and results. The results of this study support the routine use of nepafenac in cataract surgery for enhanced safety and efficiency.

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