Original Article

Comparative Study of Topical Steroids Vs Non-steroidal Anti-Inflammatory Drugs to Control Post-Cataract Surgery Macular Edema

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ABSTRACT

Purpose: To compare the efficacy of topical steroids with non-steroidal anti-inflammatory drugs in controlling post-cataract surgery macular edema.
Study Design: Quasi experimental study.
Place and Duration of Study:"Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan" from 1st July 2022 to 31st December 2022.
Methods: Forty patients who had undergone cataract surgery were selected for this study by convenient sampling. After informed consent, patients were divided into two groups: Group S (n = 20) was given 1% prednisone eye drops for 14 days while group N (n = 20) was given 0.1% nepafenac acid eye drops for 14 days. 30 days after surgery, central macular thickness (CMT), using Optical Coherence Tomography (OCT), was assessed and documented in both groups. Data was analyzed by SPSS 21.
Results: Mean age of patients was 44.02 ± 6.08 years. There were 60% (24) males and 40% females. Mean pre-operative CMT difference between two groups was statistically insignificant. Post-operative CMT was significantly lower in group N as compared to group S [243.00 ± 21.71µm vs 223.90 ± 17.52µm; p = 0.004]. Frequency of post-operative ME was lower in group N as compared to group S [35% (7) vs 15% (3); p = 0.144].
Conclusion: Topical eye drops containing NSAIDs and steroids are useful to control post-cataract surgery macular edema but NSAIDs drops have better efficacy in controlling post-cataract surgery macular edema.
Key Words: Cataract, Macular Edema, NSAIDs, Steroids.

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INTRODUCTION

Cataract is a widely recognized disorder characterized by opacification of lens. It is one of the leading causes of blindness worldwide.[1,2] Both developing and industrialized nations face a significant challenge when it comes to ophthalmological morbidity due to cataracts, which imposes a disease burden as well as a financial cost on the public health system.[3,4]There are different grading systems for cataract, including "Lens Opacities Classification System II (LOCS II) system", "Lens Opacities Classification System III (LOCS III) system"[7] and "Simple Pre-Operative Nuclear Classification Score (SPONCS)".[5-8]

Macular edema is one of the complications of cataract surgery.[9] It has an incidence as high as 10.6%.[10]

Medications to control post-surgery macular edema include steroids (like prednisolone, florometholone and dexamethasone) and non-steroidal anti-inflammatory drugs (NSAIDs) like nepafenac acid, ketorolac, etc.[11,12] However, which of these

medications is superior to other is still a topic of debate. This comparative study is, therefore, aimed at comparing topical steroids versus non-steroidal anti-inflammatory drugs to control post-cataract surgery macular edema.

METHODS

This study was conducted at the ophthalmology unit of Pakistan Institute of Medical Sciences (PIMS), Islamabad, Pakistan, from July 2022 to December 2022.We obtained approval from ethical review board (ERB) and sample size of 40 (20 each in group S and N) was calculated using WHO sample size calculator by assuming level of significance 5%, power80%, anticipated mean CMT in NSAIDs group of 205.713 ± 17.14, anticipated mean CMT in steroids group of 220.984 ± 32.83 and[13] using following formula:

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Patients with age 18-70 years, either male or female and scheduled to undergo elective procedure of cataract surgery by phacoemulsification were included by non-probability consecutive sampling technique. Patients who had history of proliferative diabetic retinopathy, diabetic macular edema, hypertensive retinopathy, traumatic cataract, glaucoma and those who developed complication during surgery were excluded. Informed consent was taken from all patients.

Baseline demographic information, such as age, gender, duration of cataract, type of cataract (nuclear/cortical/posterior sub-capsular) and CMT by OCT was documented. Patients underwent phacoemulsification by the same surgical team to prevent operator bias. The patients were assigned either to group S or group N using the medical record number, writing it on a paper and then applying lottery method. Patients in group S were treated with 1% prednisone eye drops while patients in group N were treated with 0.1% nepafenac acid eye drops. Patients in both groups were treated for 14 days. They were called for follow up OCT at day 30 after surgery to assess CMT and presence of macular edema (defined as CMT $\geq$ 250 µm).

SPSS 26 was used to analyze the data. The mean with standard deviation and the median (IQR) were used for quantitative data. Percentage and frequency were used for qualitative data. Shapiro-Wilk test was used to check data normality. The Chi square test (for qualitative variables) and the unpaired t-test (for quantitative variables) were used, with $p \leq 0.05$ being significant.

RESULTS

Out of 40 patients, 60% (24) were males and 40(16) were females. Composite baseline parameters are demonstrated below in the following table 1.

Table 1: *Baseline Parameters.*

Sr. No.	Characteristics	Value %(n)
1.	**Age**	44.02 ± 6.08 years
2.	**Duration of Cataract**	12.65 ± 1.85months
3.	**Type of Cataract**	
	a) Nuclear	60.00% (24)
	b) Cortical	30.00% (12)
	c) Posterior Sub-capsular	10.00% (4)
4.	**CMT**	204.05 ± 6.49 µm

Comparison of all these baseline parameters between group S and N are tabulated below in table 2.

Table 2: *Comparison of Baseline Parameters.*

Parameter	Group S (n = 20)	Group N (n = 20)	p-value
Age (years)	44.25 ± 6.29	43.80 ± 6.02	0.819
Gender			
Male	60.00% (12)	60.00% (12)	1.000
Female	40.00% (8)	40.00% (8)	
Duration of Cataract (months)	12.50 ± 1.93	12.80 ± 1.79	0.614
Type of Cataract			
a) Nuclear	55.00% (11)	65.00% (13)	0.287
b) Cortical	40.00% (8)	20.00% (4)	
c) Posterior sub-capsular	5.00% (1)	15.00% (3)	
CMT (µm)	205.50 ± 6.55	202.60 ± 6.25	0.160

Comparison of post-treatment parameters (day 30 after surgery) are tabulated below in table 3.

Table 3: *Comparison of Post-treatment Parameters.*

Parameter	Group S (n=20)	Group N (n=20)	p-value
CMT	243.00 ± 21.71	223.90 ± 17.52	0.004
Macular Edema present	35.00% (7)	15.00% (3)	0.144

DISCUSSION

Macular edema is one of the common complications of phacoemulsification.[14] In this study the most common type of cataract was nuclear cataract. In terms of baseline parameters, there was no statistically significant difference between both groups; age (p = 0.819), duration of cataract (p = 0.614), type of cataract (p = 0.287) and pre-operative CMT (0.160). However, at the end of study period we found that CMT after surgery was comparatively lesser in patients treated with NSAID eye drops with statistically significant value (p = 0.004). Concomitantly, frequency of post-cataract surgery macular edema was lower in NSAID group as compared to steroid group but the difference was statistically insignificant (p = 0.144).Sarkar et al[13] and El Gharbawy et al,[15] also reported that the difference in post-cataract surgery CMT in patients, treated with NSAIDs eye drops versus those treated with steroid eye drops, was statistically significant and the CMT was much lower in NSAID group. Miyake et al,[16] reported that frequency of post-cataract surgery macular edema was lower in NSAID group as compared to steroid group. However, contrary to our results, difference between the two groups was statistically significant. Similar findings were observed in another study where this difference in frequency of post-cataract surgery macular edema between the two groups was statistically significant in favor of NSAIDs eye drops.[17]

Literature shows that pseudophakic macular edema occurs commonly after phacoemulsification cataract surgery, even in the absence of complications and risk factors.[18]

Another study shows that small increase in macular thickness after routine cataract surgery is very common and not clinically significant. In such cases with low risk for CME, the routine use of preoperative NSAID may be sufficient.[19] However, there are certain group like patients with diabetes are more prone to get post-operative macular edema.[20] Such patients should be especially put on NSAID before surgery.

Limitations of this study were single center study, short follow-up period and a small sample size.

CONCLUSION

Following phacoemulsification both NSAIDs eye drops and steroids eye drops are useful to control post-surgery macular edema but NSAIDs drops have better efficacy in controlling post-cataract surgery CMT and prevent macular edema.

Conflict of Interest: Authors declared no conflict of interest.

Ethical Approval: The study was approved by the Institutional review board/Ethical review board **(F.1-1/2015/ERB/SZABMU/1062).**

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Authors' Designation and Contribution

Hafiz Muhammad Jahanzaib; Medical Officer: *Concepts, Design, Literature Search, Data Analysis, Statistical Analysis.*

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