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A PROSPECTIVE COMPARATIVE STUDY TO ASSESS THE EFFICACY OF TOPICAL NEPAFENAC IN PREVENTION OF POST-OPERATIVE CYSTOID MACULAR EDEMA AFTER CATARACT SURGERY

Ophthalomology

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ABSTRACT

Objective: To measure the efficacy of topical Nepafenac 0.1% in the prevention of cystoid macular edema (CME) following cataract surgery. **Method:** A comparative study took place at Department of ophthalmology in tertiary care. The study included two groups of patients (64 each) undergoing uneventful phacoemulsification/ SICS was carried out prospectively. Group A received a topical Nepafenac of 0.1% along with the routine regimen postoperative treatment. Group B only received the standard regimen. Subsequently, patients were advised for follow up at 7, 14, and 28 days after surgery and were reviewed accordingly. The principal outcome measures were the incidence of CME cases and the modification in central macular thickness (CMT), assessed using Spectral domain optical coherence tomography (SD-OCT). Additionally performed adequate comparative tests for statistical analysis with p value < 0.05 defined as significant.**Result :** We included all patients who completed the follow-up. Both groups showed comparable baseline characteristics and improvement postoperatively, the nepafenac group A had fewer CME events than the control group. The mean CMT showed a much smaller rise in Group A Nepafenac group at all postoperative visits at 7, 14, and 28 days, patients who took Nepafenac had better BCVA scores. The drug was well tolerated, and there were no serious side effects in the eyes or body. **Conclusion** Post study and experimentation, it was observed that ,Topical Nepafenac significantly reduces the risk of CME and prevents the macula from thickening post cataract surgery. Further, it also improves BCVA when used with regular treatment.

KEYWORDS

INTRODUCTION

Cataract remains the leading cause of reversible blindness worldwide, particularly in low- and middle-income countries. It is characterized by loss of lens transparency due to structural or biochemical changes, resulting in progressive visual impairment. In India, cataract contributes to nearly 80% of blindness cases, creating a substantial healthcare burden [1][2][3]. Although surgical techniques such as phacoemulsification and manual small-incision cataract surgery (MSICS) have significantly improved outcomes, postoperative complications still affect visual recovery.

One important complication is pseudophakic cystoid macular edema (PCME), also known as Irvine-Gass syndrome [4][5]. It results from accumulation of fluid in the macula following surgery, primarily due to inflammation triggered by surgical trauma. Release of prostaglandins and other mediators disrupts the blood-retinal barrier, increasing vascular permeability and leading to cystic changes in the retina. While modern surgical techniques have reduced the incidence of clinical PCME to 0.1–2.35%, subclinical macular thickening remains common and clinically relevant[6].

Various risk factors influence PCME development, including diabetes mellitus, prior history of PCME, systemic vascular disorders, and surgical variables such as prolonged operating time and intra ocular manipulation. Early detection is crucial, and Optical Coherence Tomography (OCT) has become the preferred diagnostic tool due to its non-invasive nature and ability to detect subtle retinal changes [7][8].

Topical non steroidal anti-inflammatory drugs (NSAIDs) play a key role in prevention by inhibiting prostaglandin synthesis. Among them, nepafenac is particularly effective due to its prodrug nature, allowing better corneal penetration and conversion to its active form, amfenac, within ocular tissues [9].

Given the differences in surgical techniques and inflammatory responses, this study aims to evaluate postoperative macular thickness changes and assess the efficacy of nepafenac in preventing PCME following uneventful cataract surgery[10][11]. The goal is to improve postoperative outcomes and promote faster visual recovery.

MATERIAL AND METHOD

Study Design and Setting

This study was done in the Department of Ophthalmology, conducted over 18 months at the Amaltas Institute of Medical Sciences in Dewas. Which is a tertiary care teaching hospital. It was an observational, randomised, comparative, clinical study that was conducted to test and determine the effectiveness of topical nepafenac in preventing cataract surgery- related postoperative cystoid macular edema.

Study Population

The study included patients diagnosed with immature senile cataract attending the Ophthalmology OPD. There were 128 patients in the study. Screening was performed through detailed ophthalmic examination and then split into two groups . The patients in Group A received nepafenac in their eyes along with the standard treatment after surgery. The patients in Group B received only standard treatment, after surgery.

Inclusion and Exclusion Criteria

People who are 44 years old or more and have immature cataracts in this study. They were also able to undergo reliable preoperative OCT imaging and surgery. People with conditions like diabetes and high blood pressure were included in the study if these conditions are under control. We did not include people who have cataracts from an injury or Mature or hypermature cataract (NS grade IV–V) preventing OCT imaging. We also did not include people who have pre-existing **cystoid macular edema** or any retinal and cornea pathology. Not consented to participate in the study.

Study Methods

People taking part in the study were put into two groups. The people in Group A got nepafenac eye drops, which they started using the day before their surgery and kept using after the surgery along with antibiotics and steroids. The people in Group B only got antibiotics and steroids. Optical coherence tomography was taken preoperatively and then again on the 1, 7 and 28 days after the surgery to see central macular thickness and to check for cystoid edema. We wanted to see in each group macular thickness and visual acuity and they compared the two groups, Group A and Group B to see changes between them the people who got nepafenac and the people who did not.

Clinical Examination

All patients had an eye exam at three phases: preoperative, intra operative, and postoperative. The eye examination included, Visual acuity was measured using a standard Snellen's visual acuity chart. Each eye was tested separately and A detailed examination of the cornea, anterior chamber depth, iris, pupil, and lens was conducted using a slit-lamp bio microscope. This assessment allowed evaluation

of cataract morphology (nuclear sclerosis, cortical changes, posterior subcapsular opacity) and ensured the absence of any active anterior segment pathology such as keratitis, uveitis, or corneal scars that could interfere with surgery or postoperative recovery. The OCT data served as the baseline macular profile, ensuring that no patient with pre-existing CME or maculopathy was included.

Preoperative Assessment

Before surgery, every patient was subjected to a thorough ophthalmic evaluation to establish baseline ocular status and ensure surgical suitability. They used an OCT **as the macular status**, ensuring that no patient with pre-existing CME or maculopathy was included. They also checked for other health problems, like high blood pressure and diabetes, fit for surgery.

Preoperative Care

The patients who were going to have surgery were given nepafenac twenty-four hours before the surgery and dilated with eye drops tropicamide and phenylephrine to dilate, the pupil evaluated with the OCT. All sterile precautions should be taken before surgery.

Surgical Procedure

All surgeries were done under anesthesia. The doctors followed sterile precautions. Each patient **underwent either** phacoemulsification or Manual Small Incision Cataract Surgery (SICS), depending on suitability. The chosen surgical technique was noted in the patient record. With phacoemulsification clean corneal incision was made and foldable lens was implanted.

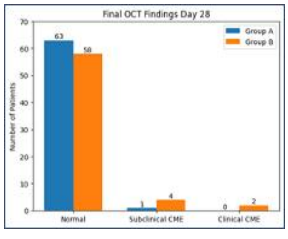
Postoperative Care

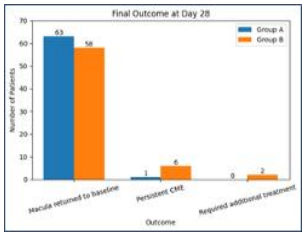
Postoperative follow-up was conducted on days 1, 7, and 28. All patients established standard postoperative treatment with topical antibiotics and corticosteroids, while the intervention group A additionally continued nepafenac. At each follow up, patients underwent visual acuity assessment, slit-lamp examination, fundus evaluation, and OCT imaging to monitor macular thickness and detect early or subclinical cystoid macular edema.

RESULT SUMMARY

The following table summarizes the study findings in a clearer group-wise format for better understanding and comparison between Group A (Nepafenac) and Group B (Control).

Parameter	Group A	Group B	Overall Result	Interpretation
Study Population	64 patients (50%)	64 patients (50%)	128 patients included	Equal distribution ensured comparability
Age Distribution	56–75 yrs: 59.4%	56–75 yrs: 65.6%	Most patients belonged to 56–75 yrs age group	Age distribution comparable in both groups
Gender Distribution	Male: 56.3% Female: 43.7%	Male: 59.4% Female: 40.6%	Males predominated overall (57.8%)	No significant gender difference
Diabetes Mellitus	Diabetic: 34.4%	Diabetic: 37.5%	35.9% patients diabetic	Groups similar regarding diabetes status
Hypertension	Hypertensive: 40.6%	Hypertensive: 43.8%	42.2% hypertensive overall	No major baseline difference
Surgical Technique	Phaco: 53.1% SICS: 46.9%	Phaco: 56.3% SICS: 43.7%	Phaco more common overall	Technique distribution balanced
Preoperative Foveal Thickness	248.6 ± 18.2 µm	249.3 ± 17.9 µm	No significant baseline difference	Groups were comparable before surgery
Post-op Day 1 Foveal Thickness	252.1 ± 19.4 µm	259.6 ± 21.3 µm	Higher thickness in Group B	Nepafenac reduced early inflammation
Post-op Day 7 Foveal Thickness	250.4 ± 18.6 µm	257.8 ± 20.7 µm	Group B remained thicker	Reduced postoperative edema with Nepafenac
Post-op Day 28 Foveal Thickness	249.2 ± 18.0 µm	254.9 ± 19.8 µm	Persistent thickening in Group B	Better macular recovery in Group A
Change in Macular Thickness Day 28	+0.6 µm	+5.6 µm	Greater increase in Group B	Nepafenac limited macular thickening
CME Incidence Day 1	6.3%	18.8%	Significant difference (p=0.03)	Lower CME in Nepafenac group
CME Incidence Day 7	3.1%	14.1%	Significant difference (p=0.04)	Sustained protective effect
CME Incidence Day 28	1.6%	9.4%	Borderline significance (p=0.05)	Reduced long-term CME incidence
Final OCT Findings	Normal: 98.4% Clinical CME: 0%	Normal: 90.6% Clinical CME: 3.1%	Better OCT outcomes in Group A	Nepafenac improved retinal outcomes
Diabetic Patients (Day 28 Thickness)	251.1 ± 18.0 µm	259.3 ± 20.4 µm	Higher edema in diabetic Group B	Nepafenac beneficial in diabetics
Hypertensive Patients (Day 28 Thickness)	250.6 ± 18.3 µm	257.9 ± 19.6 µm	Higher edema in hypertensive Group B	Reduced inflammation with Nepafenac
CME and Gender	Male: 60% Female: 40%	Male: 60% Female: 40%	No gender association	Gender did not affect CME occurrence
CME and Age	Most cases: ≥56 yrs	Most cases: ≥56 yrs	Older age groups more affected	No statistically significant association
CME and Diabetes	60% diabetic cases	60% diabetic cases	Diabetes associated with higher CME	Diabetes identified as risk factor
CME and Hypertension	80% hypertensive cases	46.7% hypertensive cases	Hypertension associated with CME	Requires closer postoperative monitoring
Final Outcome at Day 28	98.4% returned to baseline	90.6% returned to baseline	Persistent CME more common in Group B	Nepafenac improved recovery outcomes





DISCUSSION

Study Overview

This study was about Nepafenac. How it helps prevent swelling in the eye after someone has cataract surgery. The study had 128 patients, in it. These patients were divided into two groups that were the size. Nepafenac was used to see how well it works at preventing swelling in the eye after this kind of surgery. The patients were split into two groups to compare the results of using Nepafenac. The people in the two groups were similar at the start. The group that got Nepafenac had swelling in the back of the eye on the first day after surgery and also on the seventh day and the twenty eighth day. This shows that Nepafenac is good at preventing this kind of swelling. The people who got Nepafenac had eyes that were not as swollen. On the day their eyes were 7.5 micrometers less swollen. By the day their eyes were 7.4 micrometers less swollen. On the twenty eighth day their eyes were 5.7 micrometers less swollen. So Nepafenac really helps prevent swelling after cataract surgery. The doctors were trying to find out if Nepafenac works. Now we know that Nepafenac does help with the swelling. This is what the doctors wanted to know about Nepafenac.

Intra operative Complications

The doctors did not see any problems during the operations, in either the group or the second group. The surgical procedures were very similar which is good because it means the results are fair and not influenced by the way the operations were done. This helps to make sure that the results are accurate and can be trusted.

Postoperative Complications

The Nepafenac group had a lot cases of Cystoid Macular Edema or CME on Day 1. This is because 6.3 percent of the people in the Nepafenac group got CME but 18.8 percent of the other people got it. The Nepafenac group also had cases of CME on Day 7 and Day 28. Macular thickening was a problem for the people who were not in the Nepafenac group. We found out that people with diabetes and high blood pressure were more likely to get CME. Diabetes was a factor and so was high blood pressure. The Nepafenac group had problems, with CME especially when you compare them to the other people on Day 1 Day 7 and Day 28.

Visual Outcomes

The people who got Nepafenac had good results from their OCT tests. In fact 98.4 percent of them had macular architecture, which is a lot better than the 90.6 percent of people who did not get Nepafenac. This is a thing because Nepafenac helps people get better from their eye problems. Nepafenac also helps people see better after some time. The people who used Nepafenac had results. This is important for people who really care about their eyes and want to have vision. Nepafenac is helpful, for people who want to see.

CONCLUSION

This study evaluated the efficacy of topical Nepafenac in reducing postoperative macular swelling and cystoid macular edema (CME) following cataract surgery. Although some degree of postoperative macular thickening was observed in both groups, the increase was significantly lower in patients who received Nepafenac therapy.

The final outcomes of the study demonstrated a clear benefit in the Nepafenac-treated group. Restoration of normal macular architecture was achieved in 98.4% of patients receiving Nepafenac, compared with 90.6% in the control group. Persistent cystoid macular edema was observed in only 1.6% of patients treated with Nepafenac, whereas 9.4% of patients in the non-Nepafenac group developed persistent CME. Furthermore, none of the patients in the Nepafenac group required additional treatment, while 3.1% of patients in the control group required further therapeutic intervention.

The study also identified diabetes mellitus and hypertension as significant risk factors associated with the development of cystoid macular edema. In contrast, patient age, sex, and intraoperative surgical parameters did not show a significant association with the occurrence of CME.

Limitations

Single-center study, modest sample size (n=128), and short follow-up (4 weeks) limit generalizability and long-term outcome assessment.

Clinical Implications

Topical Nepafenac helps control inflammation after surgery. It also helps the macula heal faster and reduces the risk of cystoid edema (CME). This is especially good for patients who're, at high risk. Routine OCT monitoring is important. It helps doctors find and manage problems early.

Future Scope

We need to do studies with people and follow them for a longer time. This will help us figure out the way to treat people after surgery. We should also compare Nepafenac to medicines like Bromfenac and Ketorolac to see which medicine works best for people. We need to compare Nepafenac to these medicines like Bromfenac and Ketorolac so we can find out which one is the treatment for people, after surgery.

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