Section: Opthalmology

Original Research Article

IMPACT OF TOPICAL POSTOPERATIVE NEPAFENAC 0.1% EYE DROPS ON RETINAL THICKNESS AFTER CATARACT SURGERY IN PATIENTS WITHOUT RISK FACTORS FOR CME

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ABSTRACT

Background: Cataract is one of the most commonly performed surgery. Cystoid macular edema (CME) is a common postoperative complication following uncomplicated cataract surgery, significantly impacting visual outcomes. Topical nonsteroidal anti-inflammatory drugs (NSAIDs) like nepafenac have shown promise in mitigating this condition. This study assesses the effect of topical nepafenac 0.1% eye drops compared to a placebo in preventing macular edema post-cataract surgery. The primary objective is to assess the effect of topical administration of nepafenac 0.1% eye drops in patients undergoing uncomplicated cataract surgery to prevent the occurrence of macular oedema. **Materials and Methods:** A randomized, triple-blind, placebo-controlled study was conducted with 200 patients under-going uncomplicated cataract surgery. Patients were divided into two groups: Group A re-ceived nepafenac 0.1%, and Group B received a placebo. Preoperative, intraoperative, and postoperative data, including CMT and best-corrected visual acuity (BCVA), were collected and analyzed at 1st, 3rd, and 6th weeks. The collected details were entered in MS excel and analysis was done in SPSS 23. **Result:** In Group A the mean CMT was found to be significantly reduced. Group A exhibited significantly lower mean CMT and improved BCVA at 6 weeks postoperatively compared to Group V. The nepafenac-treated group showed an earlier resolution of CMT by the sixth week compared to the placebo group. **Conclusion:** Topical postoperative administration of nepafenac 0.1% effectively reduces the incidence of CME and improves visual recovery in patients undergoing uncomplicated cataract surgery. Initiating nepafenac treatment postoperatively and continuing for 6 week postoperatively is recommended for optimal management of postoperative inflammation and CMT. This study supports the use of nepafenac as a preventive measure against CME, ensuring better postop-erative visual outcomes.

INTRODUCTION

Globally the most leading cause for blindness and visual impairment is Cataract.[1] Cataract is one of the most commonly performed surgery .This may be due to effects of aging,for other age group it may be due to environmental and genetic factors.[2-4] Opacification of the crystalline lens due to any reason ,which is then removed and it is substituted by the intraocular lens.[5] Despite the advancements in the cataract surgery techniques, cystoid macular oedema (CME) occurs as the uneventful complication postoperatively.[6,7] It occurs in complicated surgical procedure or in healthy eyes even after uncomplicated cataract surgery or in patients with retinal vein occlusion, diabetic retinopathy and uveitis.[8,9]

Macular oedema (MO), is the accumulation of the extracellular fluid in the central ret-inal region that might present following the cataract surgery after IOL implantation known as pseudophakic MO which results in poor visual outcome with distorted central vision and reduced visual acuity.[10,11] Cystoid macular oedema (CME) occurs due to in-flammation and subsequent breakdown of the blood-aqueous barrier postoperatively and the pseudophakic CME (PCME) characterized by the cystic spaces and symptomatic vi-sion loss (6/12 or worse).

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In 10-20% of patients CME manifest only as a perifo-veal capillary leakage without clinically significant MO12. Using the slit-lamp biomicroscopic examination of the macula we diagnose CME.[13] In most of the patients, it resolves spontaneously and it can be controlled by use of the anti-inflammatory agents.[14,15] Among patients with uncontrolled inflammation it results in complication such as secondary glaucoma and uveitis, which ultimately leads to vision loss. Steroids and non-steroidal anti-inflammatory agents (NSAID's) are used for the treatment of PCME to control the inflammation. The treatment for PCME at present was the use of.[16]

Nepafenac, is an amide analog of Non –steroidal anti-inflammatory drug and a potent inhibitor of COX1 and COX2 enzymes, have high corneal permeability rate which is metabolized and hydrolyzed as amfenac, an active metabolite, rapidly penetrates intraocularly to exert an anti-inflammatory effect. Nepafenac also had a better absorption, tissue-specific activation, and longer half-life when compared to other NSAIDs make it as the superior in controlling inflammation following micro-incisional cataract surgery (MICS).[17-19]

Additionally nepafenac can be used in patients with compromised corneas such as patients with severe dry eyes. The strength is 0.1% suspen-sion. A new non invasive tool used for diagnosing and moitoring the macular thickness and retinal pathologies is Optical Coherence tomorgraphy. The CME incidence ranges from 1% to 30%.[20,21] Many studies assessed the effect of nepafenac, a NSAIDs with other steroids and moreover done in patients who developed CME.[22,23] Also, other studies in comparing the topical Nepafenac with another NSAID or steroid in patients with occurrence or non-occurrence of CME to assess its superiority and its effects. With this background, the aim of the study is to compare the effect of post-operative use along with a group with no nepafenac to understand the improvement in the surgery related inflammation and prevent-ing the CME.

Aim: To assess the effect of topical administration of nepafenac 0.1% eye drops in patients undergoing uncomplicated cataract surgery to prevent the occurrence of macular oedema.

MATERIALS AND METHODS

Study Setting: The present study was carried out in the Department of Ophthalmology, Sri Manakula Vina-yagar Medical College and Hospital (SMVMCH), Madagadipet, which is a tertiary care hospital in Pondicherry, India.

Study Design: The design employed in our study was a hospital-based triple-blinded randomized control tri-al.

Study Participants: Patients with senile cataract attending the Ophthalmology department with age more than 50 yearsof both sexes included.

Inclusion Criteria

Patients eligible for recruitment to the study should fulfil the following crite-ria given below,

- Age >50 years,
- Both genders,
- Diagnosed as senile cataract clinically.

Exclusion Criteria

Patients were excluded for any of the following conditions mentioned below,

- Patients presented with anterior segment pathology including corneal opacity, pseudoexfoliation syndrome and dense cataract interfering with OCT imaging,
- Patient with traumatic or complicated cataract
- History of topical or systemic NSAID use prior to surgery, allergy or hypersensitiv-ity to NSAIDs,
- Previous ocular surgery,
- Other conditions such as amblyopia, retinal abnormalities, connective tissue disease,T2DM, on steroids, or immunosuppressive treatment,
- Patients with any intraoperative or postoperative complications.

Study Duration: The duration of the study was 18 months from the date of approval by IEC committee (No-vember 2022 to May 2024).

Sample Size: Based on inclusion and exclusion criteria the study participants recruited were 200 during the study period (100 in each group).

Through computer generated random numbers placed in sealed envelopes the study participants were divided into two groups. These envelopes, kept in the order of the block randomization list and opened at the time of selection of participants by the duty doctor or the staff nurse other than the principal investigator. Further, the patients were also blinded for treatment A and B as patients with list A were assigned in intervention group and patients with list B were as-signed in control group.

Two groups were assigned based on the sealed envelope using allocation concealment method,

Group A: For patients with group A sealed envelope – topical Nepafenac 0.1% eye drops as an add-on (three times a day for six weeks) with gatifloxacin 0.3% and Prednisolone 1% eye drops.

Group B: For patients with group B sealed envelope – Carboxymethyl cellulose 0.5% eye drops as placebo (three times a day for six weeks) with gatifloxacin 0.3% and Predni-solone 1% eye drops.

Data Collection: After obtaining consent from IEC and written informed consent from all patients included in the study, the study was preceded. Followed by that, cataract surgery was done for the patients. The principal investigator the ophthalmologist and the were blinded.

The patients were asked about their socio-demographic details including age, gender, education, and occupations using a pre-tested and pre-structured questionnaire case proforma sheet for both groups. Other history such as his-tory of trauma, night blindness, and any VR surgery were also

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assessed. Then the patients were taken for the detailed ocular examination including BCVA, dilated fundus examina-tion, IOP measurement and biometry using low-coherence optical biometer. BCVA wasassessed using the Snellen chart and converted to Logmar,60 and the targeted postopera-tive refractive error was 0.0 diopter. As for the IOP measurement applanation tonometry was used to assess the pressure. On slit-lamp examination patient's cornea, anterior chamber, pupillary reaction, grading of cataract and any other ocular status were assessed. Axial length, AC depth, lens thickness were assessed using biometry, for all patients.

After completing the above mentioned examination patient was taken for baseline spectral-domain OCT (SD-OCT) scan before surgery and images with a quality of 20 or above were considered for evaluation. Every OCT data included a fast macular thickness map scan, and the retinal thickness imaging was performed using SD-OCT via a 30-degree linear enhanced depth imaging mode, which was passed from the fovea. The central retinal thickness (CRT) was determined in fovea using the values by the device soft-ware automatically.

The macular volume, the measurement results of the central 1mm diameter of the macular segment and the central 3 mm diameter of the macular surrounding area were obtained in rapid macular thickness measurement mode. The CRT and macular volume (3mm) of each patient were recorded.

In cataract, the hardness of the nucleus was graded depending on the color on slit-lamp exam-ination. It is utmost important for setting the cataract extraction technique. .Surgical procedure for Cataract - Manual small incision cataract surgery (SICS):

All patients underwent manual small incision cataract surgery by a single operating surgeon following standard technique and the patient who had any complication during the surgery were excluded.

Postoperative procedure: After surgery patients were transferred to the ward and treated with allotted agents for both groups. Again SD-OCT was performed during post-operative visits, 1st week, 3rd week, and 6th week with the image quality of 20 or above for evaluation. Every SD-OCT included a fast macular thickness map scan. Retinal thickness imaging was performed using SD-OCT, via 30 degree linear enhanced depth imaging mode, which was passed from the fovea. CRT also determined in fovea using the values given automatically by the software in the device. As for the macular volume, the measurement results of the central 1mm diameter of the macular segment obtained in the rapid macular thickness measurement mode in the SD-OCT and recorded. Also, BCVA was measured by Snellen chart for distant vision converted to logmar on postoperative visit including 1st week, 3rd week, and 6th week.

Statistical analysis of data: The quantitative data was entered in MS EXCEL. The analysis was done using SPSS 23. Descriptive statistics were calculated for all categorical variables and expressed in terms of frequencies and percentages, while the continuous variables were presented as mean ± SD. As for the inferen-tial statistics, for normal distribution, the student-t test was used to compare, while for non-normally distributed variables Pearson's chi-square test was performed. If p value <0.05, then it was statistically significant.

RESULTS

The mean age of the study participants was found to be 63.83 in Group A and 62.22 in Group B. Majority of the study participants were in 61-70 years of age in Group A and in 51-60 years age in group B.Females were predominant in both the groups (Group A (61%),Group B 51%)

Table 1: Demographic details of the study participants

Variables	Group A (N = 100)	Group B (N = 100)	p value
Age			
51-60	36	44	0.134
61-70	9	42	
>70	25	14	
Gender			
Male	39	49	0.07
Female	61	51	

Table 2: Visual acuity (LogMar) among the study participants

Variables	Group A (N = 36) Mean ± SD	Group B (N = 36) Mean ± SD	Mean difference	p value
Pre-operative				
Operated eye	0.763 ± 0.175	0.761 ± 0.147	-0.002	0.93
Post-operative				
1st week	0.463 ± 0.109	0.161±0.107	-0.301	<0.00001
3rd week	0.294 ± 0.082	0.163 ± 0.109	-0.131	<0.00001
6th week	0.097 ± 0.065	0.275 ± 0.281	0.178	<0.00001

Preoperatively there is no significant difference in the mean value between the two groups.But postoperatively Group B showed a stronger response, Group A exhibited more consistent outcomes over time, which could indicate a steadier progression or less fluctuation in response to the intervention.

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Table 3: Central macular thickness (CMT) among the study participants (N = 200)

Variables	Group A (N = 36)	Group B (N = 36)	Mean difference	p value
Preoperatively	211.25 ± 7.92	210.97 ± 7.02	-0.28	0.791
1st week	237.89 ± 9.02	228.56 ± 7.00	-9.33	<0.0001
3rd week	235.89 ± 6.21	244.89 ± 15.12	9.0	<0.0001
6th week	222.28 ± 3.36	269.11 ± 27.02	46.83	<0.0001

Both the groups have similar Central macular thickness in both the groups (Group A: 211.25 ± 7.92, Group B: 210.97 ± 7.02), with no significant difference. At first week postoperatively the mean value was higher in Group A compared to Group B and it is significant. The mean has increased significantly in Group B from third week compared to Group A. It indicates that Group A experienced a more significant and consistent reduction in CMT over the postoperative period compared to Group B. The progressively higher CMT in Group B suggests that the agent used in Group A was more effective in reducing CMT, leading to potentially better visual outcomes for these participants. Thus, the agent administered to Group A is likely more beneficial for post-surgical reduction of CMT.

Table 4: Association of CMT) with gender among the study participants (N = 200)

Variables	Male	Female	p value
CMT at 6th week			
Group A	221.50 ± 3.25	276.47 ± 30.96	<0.0001*
Group B	222.77 ± 3.40	260.88 ± 19.67	<0.0001

We observe that in Group A, males have a mean CMT of 221.50 ± 3.25, while females have a higher mean of 276.47 ± 30.96 and the difference is significant. Similarly in Group B females have higher mean value 260.88 ± 19.67 compared to males and it is also significant.

DISCUSSION

The mean age of the study participants was found to be 63.83 in Group A and 62.22 in Group B. In Ullah W et al study the mean age was found to be 58.73 in Group A and 58.64 in Group B.Majority of the study participants were in 61-70 years of age in Group A and in 51-60 years age in group B. In Ullah W et alstudy majority of the study participants were in 56-70 years of age (Group A-33(78.57%), Group B-30(71.42%).

Females were predominant in both the groups .(Group A (61%),Group B 51%).This was contrast to the results of Ullah W et al study where the male's were more (Group A-54.76%,Group B-52.38%).In Arooj Ajmad et al study the male and females were more or less equal .

Preoperatively there is no significant difference in the mean value of visual between the two groups. But postoperatively Group B showed a stronger response, Group A exhibited more consistent outcomes over time, which could indicate a steadier progression or less fluctuation in response to the intervention. In Arooj Ajmad et al study there was lower visual acquity decrease of more than five letters than the other group and it is statistically significant.

Both the groups have similar Central macular thickness in both the groups (Group A: 211.25 ± 7.92, Group B: 210.97 ± 7.02), with no significant difference. At first week postoperatively the mean value was higher in Group A compared to Group B and it is significant. The mean has increased significantly in Group B from third week compared to Group A. It indicates that Group A experienced a more significant and consistent reduction in CMT over the postoperative period compared to Group B. The progressively higher CMT in Group B suggests that the agent used in Group A was more effective in reducing CMT, leading to potentially better visual outcomes for these participants. Thus, the agent administered to Group A is likely more beneficial for post-surgical reduction of CMT. In Aroochangj Ajmad et al study there is a statistically significant

We observe that in Group A, males have a mean CMT of 221.50 ± 3.25, while females have a higher mean of 276.47 ± 30.96 and the difference is significant. Similarly in Group B females have higher mean value 260.88 ± 19.67 compared to males and it is also significant.

As for the BCVA, in our study we found it was statistically significant in 1st, 3rd and 6th week after cataract surgery (p <0.001, respectively) in both groups, Cagini C et al,[26] demonstrated a significantly lower anterior chamber flare and in-flammatory response in the nepafenac-treated group compared to controls. Similarly, Şa-hin S et al,19 reported significantly lower macular volume increase in patients adminis-tered with nepafenac. Abu Hussein NB et al,[27] highlighted the effectiveness of nepafenac in reducing macular edema post pan-retinal photocoagulation with notable improvements. Various literatures supports the findings, such as a study by Cagini et al,[26] supports the notion that nepafenac substantially reduces inflammation and consequently CMT, highlighting its effectiveness in patients undergoing straightforward cataract surgeries. In the case of NS2 with PSCC, the increased inflammatory load might con-tribute to a more pronounced peak CMT. Understanding this peak timeframe and its correlation with specific cataract types provides insights into strategizing the treatment window for better postoperative outcomes. Our results regarding the correlation of gender with CMT present intriguing insights when viewed in light

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of existing literature. In our study gender significantly impact the CMT outcomes between Group A (nepafenac) and Group B (placebo). InSingh RP et al,28 which demonstrated that administration of nepafenac significantly reduces macular edema, irrespective of patient demographics, given its potent anti-inflammatory properties but not significant.

Our study found that CMT in patients treated with nepafenac started to resolve nota-bly by the sixth week post-cataract surgery. Thereby, the inflammation-induced macular thickening receded effectively following this timeframe. This observation is in line with the findings of Şahin S et al,[19] who reported that the group treated with nepafenac exhibited sig-nificantly smaller increases in macular volume at both the three and six-week checkpoints. Similarly, Miyake K et al.30 stated that patients in the nepafenac group had a thinner fovea and substantially decreased CME incidence at five weeks compared to other treatments.

Based on our study findings, the initiation of nepafenac treatment postoperatively from day 1 appears crucial for optimal outcomes in preventing postoperative CME. Studies by Miyake K et al,[29] and Cagini C et al,[26] suggest that preoperative administation of topical nepafenac significantly lower the peaks of inflammatory markers post-surgerically and re-duces the postoperative flare and CME incidence substantially.

Limitations: First limitations is our study is relatively short follow-up period, which might not capture long-term outcomes or late-onset complications of cataract surgery. In addition, our study does not include patients with high-risk factors for CME, such as diabetic retinopathy, limiting its generalizability to a broader patient population. The reliance on self-reported adherence to eye drop regimen could introduce variability in treatment efficacy. Finally, the study did not explore the potential side effects or tolerability of nepafenac, which is essential for a comprehensive understanding of its safety profile.

CONCLUSION

Our study found that the efficacy of postoperative administration of nepafenac 0.1% eye drops significantly reduces the incidence of CME and improves postoperative visu-al outcomes in patients undergoing uncomplicated cataract surgery and showed a substantial reduction in the occurrence of ME and enhanced BCVA in patients treated with nepafenac over placebo. The peak CMT was observed in postoperative patient, particularly affecting patients with NS2 and PSCC. By the end of six week the resolution of CMT is observed, highlighting the anti-inflammatory action of nepafenac. Postoperatively initiating the nepafenac will helps in better management of postoperative inflammation and will be a quicker resolution for macular thickening. Thus by starting on the day 1 of postoperative period after cataract surgery we can see the maximum benefit in the patients as the inflammatory response and associated CMT resolves around six weeks postoperatively. Our study concludes that that nepafenac 0.1% is a crucial therapeutic agent in reducing postoperative CME and im-proving visual outcomes in cataract surgery patients.Its postoperative use are recommended to optimize patient recovery and VA.

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