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ORIGINAL ARTICLE

Changes in Macular Thickness after Phacoemulsification with Foldable Intraocular Lens with and without Post-Operative topical Non-Steroidal Anti-Inflammatory Drugs in Diabetes Mellitus

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ABSTRACT

Background: Diabetic patients undergoing phacoemulsification are at an increased risk of postoperative complications such as cystoid macular edema (CME). Postoperative inflammation contributes significantly to changes in central macular thickness (CMT). Topical non-steroidal anti-inflammatory drugs (NSAIDs) such as nepafenac have been proposed to reduce this risk, but evidence from the Pakistani population is limited.

Objective: To compare changes in central macular thickness after phacoemulsification with foldable intraocular lens implantation in diabetic patients, with and without postoperative topical NSAIDs.

Methods: This randomized controlled trial was conducted at the department of Ophthalmology, Sir Ganga Ram Hospital, Lahore, from January 2023 to June 2023. A total of 60 diabetic patients aged 40-80 years undergoing phacoemulsification were randomized equally into two groups: control (artificial tears) and NSAID (Nepafenac 0.1%). All patients received a standard steroid-antibiotic regimen. Central macular thickness (CMT) was measured using spectral-domain optical coherence tomography preoperatively and at 3 months postoperatively. Data were analyzed using SPSS version 26, with independent sample t-tests applied; $p \leq 0.05$ was considered statistically significant.

Results: Baseline demographic and clinical characteristics were comparable between the two groups (mean age 59.3 ± 8.1 years; male-to-female ratio 1.2:1). At 3 months, mean postoperative CMT was significantly higher in the control group (267.5 ± 61.2 µm) compared to the NSAID group (231.7 ± 21.5 µm; $p = 0.011$). Stratified analyses confirmed that the protective effect of nepafenac was consistent across age, gender, and diabetes duration subgroups.

Conclusion: Topical nepafenac significantly reduced postoperative increases in macular thickness compared to control treatment in diabetic patients undergoing phacoemulsification. Incorporating NSAIDs into postoperative regimens may reduce the risk of CME and improve visual outcomes in this high-risk population.

Keywords: Diabetes mellitus, Phacoemulsification, Nepafenac, Central macular thickness, Cataract surgery, Non-steroidal anti-inflammatory drugs.

INTRODUCTION

Cataract surgery, specifically phacoemulsification, is one of the most commonly performed procedures worldwide, particularly in patients with diabetes mellitus (DM), who are at a higher risk of postoperative complications such as cystoid macular edema (CME). Diabetic patients often experience distinct responses to surgical interventions due to underlying vascular abnormalities associated with their condition, particularly diabetic retinopathy (DR)[1]. The postoperative consequences in diabetic individuals can significantly differ from those in non-diabetic patients, necessitating specific considerations regarding the management of outcomes, including changes in macular thickness[2].

The primary concern following phacoemulsification in diabetic patients is the development of postoperative CME, a condition where fluid accumulates in the macula, leading to vision impairment[3]. The mechanisms underlying CME in diabetic individuals are multifactorial, involving inflammatory mediators and changes in vascular permeability that can exacerbate pre-existing diabetic retinopathy post-surgery. Recent findings indicate that preoperative factors, such as the presence and severity of diabetic retinopathy, significantly influence postoperative outcomes[4]. For example, Khodabande et al. demonstrated a clear correlation between the severity of diabetic retinopathy and the incidence of persistent macular edema post-phacoemulsification, emphasizing the importance of tailored postoperative management strategies for this population[1].

To mitigate complications such as CME, various prophylactic strategies have been explored. The use of topical non-steroidal anti-inflammatory drugs (NSAIDs), such as Nepafenac and Diclofenac, has been proposed as a preventative measure. Studies indicate that the administration of topical NSAIDs during the postoperative period can effectively reduce the incidence of macular edema in diabetic patients undergoing phacoemulsification[2,5]. Howaidy et al. reported that topical Nepafenac was significantly effective in preventing macular edema compared to intravitreal treatments, highlighting the role of NSAIDs as a first-line pharmacological intervention post-surgery[2].

Recent research has focused on the comparative efficacy of different anti-inflammatory modalities. For instance, studies comparing the effectiveness of NSAIDs with that of corticosteroids have provided insights into their safety and efficacy profiles. Kamal et al. noted that NSAIDs could be more favorable in preventing CME without the risk of complications inherent to steroid use, which can exacerbate diabetes-related issues such as glucose dysregulation[3]. By reducing inflammatory responses through the use of such agents, it is hoped to limit the thickness of the macula and preserve visual acuity. This finding underscores the necessity for continued research into the optimal perioperative management of diabetic patients undergoing cataract surgery.

In the context of the Pakistani population, a thorough understanding of these dynamics is crucial. Diabetes is a significant public health concern in Pakistan, where its prevalence continues to rise alongside increasing cataract surgery rates. According to recent epidemiological data, complications related to diabetes and cataracts are prevalent, posing significant challenges to healthcare[1,6]. There is a need for localized research that examines the responses of Pakistani patients with diabetes to phacoemulsification and the role of postoperative NSAIDs in effectively managing macular thickness. Exploring these relationships will contribute not only to improved clinical outcomes but also to the optimization of healthcare strategies tailored to the unique needs of the diabetic population in Pakistan.

Understanding cultural factors that influence patients' access to postoperative medications and follow-up care is paramount. Tailoring treatment regimens to align with the healthcare system's resources in Pakistan, balancing effective care with available

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resources, can ultimately improve patient outcomes. Given that ocular healthcare resources may be limited, identifying effective treatment protocols that utilize existing resources is vital for enhancing the management of diabetic patients undergoing cataract surgery in Pakistan.

Thus, the potential changes in macular thickness following phacoemulsification in diabetic patients raise essential questions about postoperative management, particularly concerning the administration of topical NSAIDs. With the increasing burden of diabetes in the Pakistani context, focused research on this topic has the potential to enhance clinical practices and outcomes for diabetic patients undergoing cataract surgery, ensuring their specific needs and challenges are met with appropriate, evidence-based strategies.

METHODOLOGY

The present study was designed as a randomized controlled trial conducted at the department of Ophthalmology, Sir Ganga Ram Hospital, Lahore, Pakistan. The study was conducted over a six-month period, from January 2023 to June 2023, following approval of the synopsis and ethical clearance from the institutional review board. A total of 60 patients were recruited using a non-probability consecutive sampling technique. All enrolled participants were adults between the ages of 40 and 80 years who had been diagnosed with diabetes mellitus for at least one year and presented with a visually significant cataract requiring phacoemulsification with foldable intraocular lens implantation. Both male and female patients were included, ensuring a representative sample of the Pakistani diabetic population undergoing cataract surgery.

Patients with anterior segment pathologies such as corneal opacities, pseudoexfoliation syndrome, or dense cataracts interfering with OCT imaging were excluded. Exclusion criteria also comprised posterior segment diseases, including diabetic retinopathy, prior diabetic macular edema, age-related macular degeneration, retinal vascular disorders, or history of uveitis and retinitis pigmentosa. Furthermore, patients with intraoperative complications such as posterior capsular rupture, vitreous loss, or IOL placement outside the capsular bag were excluded. Those using systemic or topical corticosteroids, non-steroidal anti-inflammatory drugs, prostaglandin analogues, or having hypersensitivity to NSAIDs were also not considered eligible. Patients with a history of ocular trauma, previous intraocular surgery, or high myopia were excluded to avoid confounding factors affecting macular thickness.

All patients underwent a standardized preoperative assessment, including a detailed medical and ophthalmic history, with an emphasis on the duration and treatment of diabetes. Ophthalmic evaluation consisted of best corrected visual acuity (BCVA) measurement, anterior segment examination with slit lamp biomicroscopy, intraocular pressure assessment using Goldmann applanation tonometry, and dilated fundus examination with a +90 D non-contact lens. Baseline central macular thickness (CMT) was measured using spectral-domain optical coherence tomography (OCT) with the Topcon 3D-1000 system, ensuring reproducibility and high-resolution imaging of the macula.

Following informed written consent, patients were randomly allocated into two groups using a lottery method. The control group received artificial tear substitutes three times daily postoperatively, while the intervention group was prescribed nepafenac 0.1% ophthalmic suspension thrice daily. Both groups were additionally treated with a standard postoperative regimen of combined steroid-antibiotic eye drops, administered six times daily for the first week and tapered gradually over the subsequent six weeks. All surgeries were performed by experienced ophthalmic surgeons using a uniform technique that involved a precise corneal incision, divide-and-conquer phacoemulsification, and posterior chamber foldable intraocular lens implantation within the capsular bag.

Postoperative follow-up was scheduled on the first day to rule out early complications such as corneal edema, anterior chamber reaction, malposition of IOL, or abnormal intraocular pressure. The final evaluation was conducted three months postoperatively, at which point CMT was re-assessed by OCT to determine changes from baseline. Patients were monitored for the development of cystoid macular edema or other macular changes.

Data were entered and analyzed using SPSS version 26. Quantitative variables, including age and central macular thickness, were expressed as mean and standard deviation, while categorical variables, such as gender, were described as frequencies and percentages. An independent sample t-test was applied to compare the mean postoperative CMT between the two groups. Stratification by age, gender, and duration of diabetes was performed to control for potential confounders, with a apost-stratification t-test applied. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 60 diabetic patients undergoing phacoemulsification with foldable intraocular lens implantation were enrolled at the department of Ophthalmology, Sir Ganga Ram Hospital, Lahore. Patients were randomized equally into two groups: the control group (placebo drops) and the NSAID group (Nepafenac 0.1%). The mean age of participants was 59.3 ± 8.1 years (range: 42-78 years). The male- to-female ratio was approximately 1.2:1, reflecting the higher prevalence of cataracts among elderly males in the Pakistani population. (Table 1)

Table 1. Demographic and Clinical Characteristics of Study Participants (n = 60)

Variable	Control Group (n = 30)	NSAID Group (n = 30)	Total (n = 60)
Age, years (mean ± SD)	59.6 ± 7.9	59.0 ± 8.3	59.3 ± 8.1
Gender, n (%)			
• Male	17 (56.7)	16 (53.3)	33 (55.0)
• Female	13 (43.3)	14 (46.7)	27 (45.0)
Duration of DM (years, mean ± SD)	9.2 ± 3.1	9.5 ± 3.5	9.4 ± 3.3
Laterality (Right eye), n (%)	15 (50.0)	14 (46.7)	29 (48.3)
Laterality (Left eye), n (%)	15 (50.0)	16 (53.3)	31 (51.7)

Table 2. Comparison of Central Macular Thickness between Groups

Time Point	Control Group (n = 30) (Mean ± SD, µm)	NSAID Group (n = 30) (Mean ± SD, µm)	p-value
Pre-operative	225.9 ± 15.2	229.5 ± 19.6	0.421
3rd Month Post-operative	267.5 ± 61.2	231.7 ± 21.5	0.011*

*Statistically significant (p ≤ 0.05)

Table 3: Stratification of Postoperative Central Macular Thickness (CMT) by Demographic Variables

Variable	Control Group (Mean ± SD, µm)	NSAID Group (Mean ± SD, µm)	p-value
Age ≤ 60 years	263.2 ± 59.8	230.4 ± 20.7	0.018*
Age > 60 years	271.6 ± 62.3	233.0 ± 22.1	0.024*
Male	268.9 ± 60.4	232.2 ± 21.3	0.013*
Female	265.8 ± 62.7	231.0 ± 22.0	0.020*
DM Duration ≤ 10 years	264.5 ± 58.1	229.8 ± 21.1	0.015*
DM Duration > 10 years	270.1 ± 63.2	233.2 ± 22.4	0.019*

*Statistically significant (p ≤ 0.05)

Preoperative baseline CMT values were comparable between the two groups. At 3 months postoperatively, there was a significant increase in mean CMT in the control group compared to the NSAID group, indicating the protective effect of topical nepafenac. (Figure 1, Table 2)

When stratified by age, gender, and duration of diabetes, the difference in postoperative CMT remained significant in favor of the NSAID group. This finding suggests that the prophylactic use of topical NSAIDs is effective across different demographic strata. (Table 3)

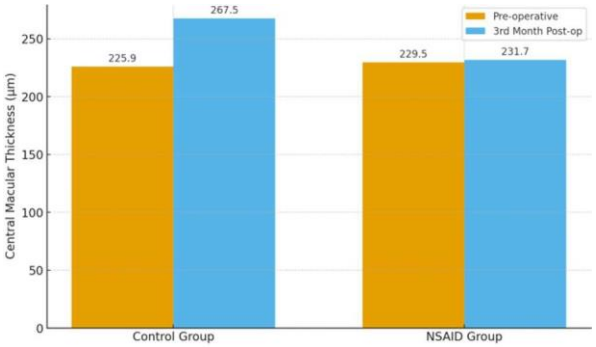

Figure 1: Comparison of central macular thickness

DISCUSSION

The management of cataracts in patients with diabetes mellitus (DM) poses considerable challenges in ophthalmology due to the increased risk of postoperative complications such as cystoid macular edema (CME). Phacoemulsification, combined with the implantation of a foldable intraocular lens (IOL), is a common surgical technique used to effectively treat cataracts and restore vision. However, its relationship with changes in macular thickness is a significant area of investigation, particularly given the specific pathophysiological conditions present in diabetic patients. The present study examines these changes in central macular thickness (CMT) in a cohort of diabetic patients undergoing phacoemulsification, with a focus on the role of topical NSAIDs, specifically Nepafenac 0.1%.

Our findings suggest a notable increase in CMT in the control group (mean increase from 225.9 to 267.5 µm) compared to the NSAID group, which experienced a minimal change (from 229.5 to 231.7 µm), indicating the effective prophylactic action of Nepafenac against postoperative macular thickening. This result is consistent with the literature demonstrating the role of topical NSAIDs in reducing CME after cataract surgery. For example, Howaidy et al. found that topical Nepafenac significantly decreased macular edema in diabetic patients without preexisting diabetic macular edema[7]. Our study further emphasizes the practical applicability of this treatment in the Pakistani context, where healthcare challenges are prevalent.

Additionally, stratifying postoperative CMT by demographic factors like age, gender, and duration of diabetes revealed consistent significant benefits for the NSAID group across all strata. These results align with findings by Torabi et al., indicating that surgical trauma from phacoemulsification may provoke inflammatory responses that result in varying CMT, which can be more pronounced in diabetic patients without proper anti-inflammatory management[8].

The mean CMT observed at three months postoperatively demonstrates significant variations in macular thickness among diabetic patients after surgery, a pattern consistent with the literature. Feng et al. reported that diabetic patients showed a higher prevalence of changes in macular vascular density and thickness after surgery, underscoring the link between surgical intervention and retinal alterations[9]. The dynamics of such changes are particularly relevant for diabetic patients, where underlying retinal conditions may increase the risk of adverse outcomes like CME.

Our findings also indicate that the duration of diabetes significantly impacts postoperative CMT changes. We observed substantial increases in CMT in both groups correlated with the duration of diabetes, supporting studies that suggest a more extended history of diabetes is associated with a higher severity of complications, including postoperative macular edema[10,11]. This highlights the need for proactive management strategies for diabetic patients undergoing surgery.

The gender distribution in our study reflects broader epidemiological trends, indicating a higher prevalence of cataracts among males. 12, 13 However, the balanced representation in our study underscores the necessity for gender-specific evaluations in diabetes management and cataract interventions, informed by emerging evidence of varying treatment responses based on gender[14].

The correlation between inflammation and macular thickness remains a critical focus. Inflammation from cataract extraction can exacerbate existing diabetic conditions, contributing to elevated macular thickness and potential vision impairment[15]. Our results indicate that using NSAIDs can significantly improve CMT outcomes in diabetic patients, corroborating previous research that demonstrated a reduction in CME with effective anti-inflammatory intervention[16,17].

Our findings offer implications for clinical practices not just in Pakistan but also in comparable healthcare settings grappling with the dual burden of diabetes and cataracts. Given the rising prevalence of diabetes in Pakistan, characterized by prolonged durations and exacerbated complications, strategies such as implementing prophylactic NSAIDs in routine cataract surgical protocols may significantly enhance patient outcomes.

In conclusion, this study highlights the critical interaction between the use of topical NSAIDs and the postoperative management of macular thickness in diabetic patients undergoing cataract surgery. The evidence suggests that integrating prophylactic measures, such as Nepafenac, can be beneficial across diverse demographic profiles, providing a practical intervention in contemporary clinical practice. Our findings advocate for tailored approaches that consider the unique circumstances of diabetic patients, fostering a more responsive healthcare strategy to address the complexities faced by this population.

CONCLUSION

This study shows that prophylactic use of topical nepafenac after phacoemulsification effectively prevents postoperative macular thickening in diabetic patients. By minimizing inflammatory changes, NSAIDs can reduce the risk of cystoid macular edema and improve visual outcomes. These findings support the inclusion of topical NSAIDs as part of routine postoperative care in diabetic patients undergoing cataract surgery, particularly in resource-limited settings like Pakistan.

REFERENCES

1 Khodabande A., Fadaifard S., Abdollahi A., Karkhaneh R., Roohipoor R., Abdi F.et al.. Role of combined phacoemulsification and intravitreal injection of bevacizumab in prevention of postoperative macular edema in non-proliferative diabetic retinopathy. Journal of Current Ophthalmology 2018;30(3):245-249. https://doi.org/10.1016/j.joco.2018.04.004

2 Howaidy A., Eldaly Z., Anis M., & Othman T. Prophylaxis of macular edema after cataract surgery in diabetic patients, topical nepafenac versus intravitreal ranibizumab. European Journal of Ophthalmology 2021;32(1):205-212. https://doi.org/10.1177/11206721211001275

3 Kamal M., Habib A., & EL-HENNAWI M. Comparing the effect of different anti-inflammatory treatment regimens on the incidence of pseudophakic cystoid macular edema after uneventful phacoemulsification surgery. The Egyptian Journal of Cataract and Refractive Surgery 2020;26(1):1-10. https://doi.org/10.21608/ejcrs.2021.188583

4 Anastasopoulos E., Koronis S., Matsou A., Dermenoudi M., Ziakas N., &TzamalisA. Safety and efficacy of prostaglandin analogues in the immediate postoperative period after uneventful phacoemulsification. Vision 2023;7(2):45. https://doi.org/10.3390/vision7020045

5 Delfi D., Virgayanti V., &AlandyJ. Macular alteration of topical diclofenac sodium after phacoemulsification surgery in diabetic patients. Open Access Macedonian Journal of Medical Sciences 2021;9(T3):156-159. https://doi.org/10.3889/oamjms.2021.6287

6 Shafi M., Khan M., Lodhi Y., Aftab A., & Sarfraz M. Central macular thickness after cataract surgery in non-diabetics and diabetics without retinopathy. Pakistan Armed Forces Medical Journal 2021;71(6):1993-96. https://doi.org/10.51253/pafmj.v6i6.6840

7 Howaidy A., Eldaly Z., Anis M., & Othman T. Prophylaxis of macular edema after cataract surgery in diabetic patients, topical nepafenac versus intravitreal ranibizumab. European Journal of Ophthalmology 2021;32(1):205-212. https://doi.org/10.1177/11206721211001275

8 Torabi H., Sadraei M., Jadidi K., &AlishiriA. Choroidal thickness changes following cataract surgery in patients with type 2 diabetes mellitus. Journal of Current Ophthalmology 2019;31(1):49-54. https://doi.org/10.1016/j.joco.2018.07.004

9 Feng L., Azhati G., Li T., & Liu F. Macular vascular density changes following cataract surgery in diabetic patients: an optical coherence tomography angiography study. Journal of Ophthalmology 2021;2021:1-7. https://doi.org/10.1155/2021/6641944

10 Kavşut B., Özcan S., Tunçbilek Z., Solmaz N., & Önder F. Cataract surgery outcomes: comparison of 2.4 mm and 2.8 mm clear corneal incisions. Van Medical Journal 2018;25(3):349-354. https://doi.org/10.5505/vtd.2018.70894

11 Bassi S., Salim S., & Rishi E. Phacoemulsification in patients with diabetic macular edema – a real-world data of 75 eyes. Oman Journal of Ophthalmology 2023;17(1):53-58. https://doi.org/10.4103/ojo.ojo_75_23

12 Shafi M., Khan M., Lodhi Y., Aftab A., & Sarfraz M. Central macular thickness after cataract surgery in non-diabetics and diabetics without retinopathy. Pakistan Armed Forces Medical Journal 2021;71(6):1993-96. https://doi.org/10.51253/pafmj.v6i6.6840

13 Lashari M., Memon S., Maree G., Channa S., Das N., & Hussain A. Incidence and risk factors of macular edema after phacoemulsification in southern Pakistan. Annals of Pims-Shaheed Zulfiqar Ali Bhutto Medical University 2023;20(1):40-44. https://doi.org/10.48036/apims.v20i1.661

14 Kulkarni A. and ThoolA. A comparative study of central macular thickness and endothelial cell changes in patients with diabetes mellitus undergoing phacoemulsification.. F1000research 2023;12:1446. https://doi.org/10.12688/f1000research.140576.1

15 BamahfouzA. Correlation of central macular thickness and the best-corrected visual acuity in three months after cataract surgery by phacoemulsification and with intraocular lens implantation. Cureus 2021. https://doi.org/10.7759/cureus.13856

16 Khodabande A., Fadaifard S., Abdollahi A., Karkhaneh R., Roohipoor R., Abdi F.et al.. Role of combined phacoemulsification and intravitreal injection of bevacizumab in prevention of postoperative macular edema in non-proliferative diabetic retinopathy. Journal of Current Ophthalmology 2018;30(3):245-249. https://doi.org/10.1016/j.joco.2018.04.004

17 Ahmed A., El-Latif I., Abozaid M., & Hafez M. Macular OCT outcomes of phacoemulsification cataract surgery in diabetic versus non diabetic patients. Egyptian Journal of Clinical Ophthalmology 2021;4(1):1-13. https://doi.org/10.21608/ejco.2021.189053

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