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A PROSPECTIVE STUDY ON THE COMPARISON OF MACULAR THICKNESS BETWEEN DIABETICS AND NON-DIABETICS FOLLOWING A SUCCESSFUL CATARACT OPERATION.

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Abstract

Objectives

The study aims to note optical tomographic features in the macula post-cataract surgery among diabetic patients, with or without pre-existing macular edema. Additionally, it seeks to assess the incidence of macular edema and changes in macular thickness in diabetic and non-diabetic (control) patients after cataract surgery.

Methods

This prospective study, spanning May 2022 to August 2023, investigated 139 individuals (Group-A: diabetics with pre-existing macular edema, Group-B: diabetics without macular edema, Group-C: non-diabetic controls) undergoing cataract surgery. Standardized surgical procedures, postoperative care, and Spectral domain- optical coherence tomography (SD-OCT) scans were utilized. Repeated Measures ANOVA assessed macular edema progression and visual outcomes.

Results

The study included 139 individuals (101 diabetic, 38 non-diabetic) undergoing cataract surgery. Diabetic patients with macular edema (ME) had higher baseline BCVA, and ME severity varied. Repeated Measures ANOVA revealed a significant BCVA change over four weeks (p=0.001). CSMT increased significantly post-surgery (p=0.001). Diabetic ME patients exhibited higher BCVA and CSMT than controls. Postoperative changes included foveal dip elevation, cystoid changes, and increased hyperreflective foci, more pronounced in diabetics. ME development post-surgery was significantly higher in diabetics without ME (21.5%) compared to controls (5.26%).

Conclusion

The study underscores the heightened susceptibility of diabetic individuals to post-cataract macular edema and worsening of pre-existing macular edema, suggesting SD-OCT as a suitable non-invasive tool to differentiate ME attributed to diabetes and PCME.

Recommendation

The study recommends meticulous pre-operative glycemic control for diabetic patients and routine screening for macular edema. Implementing timely interventions and considering surgery delays in cases of detected macular edema are crucial to optimize post-operative visual outcomes.

Keywords: *Cataract surgery, Diabetic macular edema, Optical Coherence Tomography, Post-operative complications*
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Introduction

Globally, around 425 million individuals grapple with diabetes mellitus (DM), a prevalent non-communicable ailment recognized as a key contributor to compromised vision, often accompanied by cataracts and diabetic retinopathy [1]. Diabetic patients face an earlier onset and faster progression of cataracts compared to non-diabetic counterparts. Cataract surgery, a common outpatient procedure, not only improves visual acuity but also aids in early diabetic retinopathy identification [2].

Complications from cataract surgery significantly impact vision, particularly affecting diabetics more frequently than the general population. Clinically significant cystoid macular edema (CSCME) affects around 1% to 2% of cases after surgery, leading to substantial visual loss, with diabetic patients facing a higher risk [3].

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Approximately 9% of diabetic patients experience macular edema near the fovea, with 40% involving central macular impairment [4].

Pseudophakic cystoid macular edema (PCME), known as "Irvine-Gass syndrome," increases macular thickness post-cataract surgery due to cystic gaps in the macular layers. While this syndrome often self-resolves, chronic cases may result in permanent loss of vision [5]. Optical coherence tomography (OCT) is crucial for assessing postoperative CME, offering high-resolution imaging of retinal layers and thickness changes [6].

The study employs Spectralis HRA+OCT to assess macular edema, which is the increase in macular thickness post-surgery by 30%. It aims to scrutinize macular thickness changes in individuals with and without diabetes, highlighting the persistence of diabetic macular edema compared to post-cataract surgery macular edema [8]. Both healthy and diabetic individuals experience a breach of the blood-retinal barrier after cataract surgery, especially in patients with elevated levels of inflammatory cytokines and vascular endothelial growth factor (VEGF). This inflammation poses a risk to retinal vasculature healing, potentially contributing to the formation or persistence of macular edema [9-13].

Despite apparently successful cataract surgeries, OCT reveals subtle subclinical alterations in macular thickness and retinal leakage that could escape the notice of ophthalmologists. The primary purpose of this investigation is to delve into and comprehensively understand these observed changes in macular thickness among patients, both with and without diabetes, who have undergone routine cataract surgery. By doing so, this study intends to shed light on the intricacies of postoperative outcomes and potentially contribute valuable insights to enhance clinical practices in managing patients undergoing cataract surgery. The current study aims to observe optical tomographic characteristics in the macula after cataract surgery in diabetic patients, both with and without pre-existing macular edema, and to examine the occurrence of macular edema and changes in macular thickness in diabetic and non-diabetic (control) patient's post-cataract surgery.

Materials and Methods

Study design

A single-center prospective study was carried out at Department of Ophthalmology, Pradyumna BAL Memorial Hospital, Kalinga Institute of Medical Sciences (PBMH-KIMS), KIIT University, Bhubaneswar between May 2022 to August 2023. The study involved 139 patients with and without diabetes.

Inclusion and exclusion criteria

The inclusion criteria for this study encompassed individuals aged 50 to 70 years, of both genders, presenting with operable senile cataracts, and willing to participate. The patient pool included those with and without diabetes mellitus, with diabetes diagnosis based on American Diabetes Association (2007) criteria. Diabetic patients were categorized into Group-A (diagnosed with diabetes and macular edema by OCT), Group-B (diagnosed with diabetes but without macular edema), and Group-C (randomly selected non-diabetic patients undergoing cataract surgery). Exclusion criteria comprised non-compliant individuals, and those with hazy media preventing OCT, a history of ocular surgery, trauma, recent infections or inflammation, congenital cataracts, non-diabetes-related ocular lesions, surgical complications during cataract surgery, high refractive error, elevated intraocular pressure, history of laser photocoagulation or intravitreal interventions, type 1 diabetes mellitus, essential hypertension, and dyslipidemia.

Study size

The study employed a total of 139 individuals, who were diagnosed with operable senile cataracts and attended the Outpatient Department (OPD) of Ophthalmology at PBM Hospital, were included in the study. Among them, 101 participants had diabetes, while 38 did not. The gender distribution comprised 68 males and 71 females within the study cohort.

Study setting

The study, originally scheduled from 2020 to 2022, experienced delays and a reduced timeframe due to the COVID-19 outbreak and was carried out between May 2022 to August 2023. The participants were sourced from individuals presenting at the ophthalmology outpatient department with operable cataracts undergoing uncomplicated cataract surgery at the Department of Ophthalmology, Pradyumna Bal Memorial Hospital, Kalinga Institute of Medical Sciences (PBMH-KIMS), KIIT University, Bhubaneswar. All participants' demographic details were meticulously documented on a Proforma, ensuring that individuals were adequately briefed and furnished formal written consent. In the initial assessments, the determination of participants' diabetic status involved fasting and post-meal blood glucose examinations, complemented by blood pressure evaluations aimed at excluding hypertensive conditions.

Pre-surgery Eye Examination

Every individual underwent an extensive pre-surgery eye examination, encompassing assessments such as testing visual acuity, utilizing slit lamp biomicroscopy, conducting biometric evaluations for intraocular lens (IOL) power calculation, measuring intraocular pressure, irrigating lacrimal passages, and examining the fundus

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with a +90 D lens. The grading of diabetic retinopathy was determined using the ETDRS classification.

Analysis with Optical Coherence Tomography (OCT)

OCT scans were employed to analyze retinal thickness and create a macular map, verifying the presence or absence of macular edema.

Pre-surgery Medication

Prior to the operation, patients were administered Moxifloxacin/Gatifloxacin-Ketorolac eye drops to mitigate the risk of infection.

Data Collection During Surgery

Throughout the surgical procedures, information regarding the surgery type (manual SICS or Phacoemulsification), total surgical duration, actual phaco-time, and any intraoperative complications were documented.

Surgical Techniques

Phacoemulsification was conducted on 85 patients, featuring a 2.8 mm clear cornea incision, employing techniques like stop-chop fragmentation or divide and conquer, and inserting a foldable intraocular lens (IOL) into the capsular bag. Subsequently, the wound underwent hydro-sealing or closure following anterior chamber reformation. In contrast, the remaining 54 individuals were treated using manual small incision cataract surgery (SICS), which involved a self-sealing sclero-corneal tunnel and a 5.5-7mm scleral incision. This was followed by anterior capsulotomy/capsulorrhexis, lens nucleus delivery, prolapse, and separation. A rigid/foldable IOL was kept in the capsular bag, and the wound closed spontaneously.

Postoperative Medication and Follow-up

Following surgery, patients were administered antibiotic-steroid eye drops and a short course of oral antibiotics and analgesics. Follow-up appointments were scheduled for postoperative day 1, one week, and four weeks.

Postoperative Examinations

Postoperative assessments included determining Best Corrected Visual Acuity (BCVA), conducting anterior segment examinations, fundus examinations, and indirect ophthalmoscopy after pupil dilatation to assess diabetic retinopathy status, and performing OCT macular scans by SD-OCT.

OCT Examination Procedure

During OCT examination, both eyes were dilated, and patients focused on an internal fixation target while comfortably seated in front of the OCT device. Image analysis involved calculating retinal thickness for each quadrant in the ETDRS grid surrounding the fovea. Additional aspects, such as foveal contour, retinal architecture, cystoid spaces, edema, sub-retinal fluid, and hard exudates, were meticulously scrutinized.

Analysis of OCT Scans

Reflectivity patterns in the OCT scans were scrutinized, with hyperreflectivity with backshadowing indicating conditions like hard exudates, neovascular membranes, and scar tissue, while hyporeflective patterns suggested the presence of serous fluid, optically vacant areas, and cystoid spaces in the retina.

Bias

The study may be susceptible to selection bias as participants were sourced from individuals presenting at the ophthalmology outpatient department, which might not be representative of the general population. Additionally, the delayed timeframe due to the COVID-19 outbreak could introduce temporal bias, potentially affecting the study's outcomes.

Ethical consideration

This observational case-control investigation received Institutional ethical clearance (KIIT/KIMS/IEC/110/2019) and adhered to the principles of the Declaration of Helsinki.

Statistical Analysis

Repeated Measures ANOVA was utilized to analyze variations in Best Corrected Visual Acuity (BCVA) at different time points among diabetic individuals with macular edema. Pairwise comparisons were conducted, and statistical significance was set at p=0.05.

Results/Outcomes

Participants

The study enrolled 139 individuals diagnosed with operable senile cataract, consisting of 101 diabetic patients and 38 non-diabetics, with a gender distribution of 68 males and 71 females. The mean ages for diabetic patients with and without macular edema were 57.78±5.4 years and 57.43±5.4 years, respectively, while the control group had a mean age of 58.53±5.33 years, showing no significant variations among the three cohorts. In the diabetic with ME cohort, there were 20 (55.6%) men and 16 (45.4%) women. In the diabetic without ME group, there were 24 (36.9%) men and 41 (63.1%) women, and in the control group, there were 24 (63.2%) men and 14 (36.8%) women (Table 1).

Analysis of cataract surgery types revealed that manual SICS was performed on 26 (40.0%) diabetic patients with ME, 12 (33.3%) without ME, and 16 (42.1%) in the control group. Similarly, Phacoemulsification was conducted on 39 (60.0%) diabetic patients with ME, 24

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(66.7%) without ME, and 26 (57.9%) in the control group. Regarding diabetes duration, less than five years accounted for 66.7% in the ME cohort and 66.2% in the without ME cohort, while the 5-10 years duration was consistent at 22% for both groups. Over 10 years duration represented 11% in the ME cohort and 12% in the cohort comprising without ME patients with no significant association found (p = 0.983).

In the diabetic group with macular edema, NPDR + focal DME was the most prevalent severity (55.6%), followed by PDR + cystoid DME (11%), NPDR + diffuse DME (22.2%), and 11.1% of patients had PDR with focal DME. In the Diabetics without ME group, 60% of patients exhibited no diabetic retinopathy, while 40% had NPDR. The control group showed no retinopathy changes.

Repeated Measures of ANOVA assessed BCVA variations over four weeks among diabetic patients with macular edema, revealing a significant change (p=0.001). Pair-wise comparisons indicated significant changes from baseline to one week (p=0.001), baseline to one day (p=0.001), baseline to one week (p=0.001), and baseline to the fourth week (p=0.001). The mean BCVA values for group A, B, and C from baseline to one day was 0.29, 0.24, and 0.24 respectively. In group 1, BCVA gradually decreased from POD-1 to final mean BCVA of 0.55 ± 0.08 at 4 weeks post-operatively. A similar trend was witnessed in group B as well, but in group C a linear improvement in BCVA from POD-1 to POD-4week with the best mean BCVA (0.12) identified at POD-4 week (Table 2).

Table 1: Clinical features of the participants

Group	DM with ME (group A)	DM without ME (group B)	Control (group C)
Mean age (in years)	57.78±5.4	57.43±5.4	58.53±5.33
Male	20 (55.6%)	24 (36.9%)	24 (63.2%)
Female	16 (45.4%)	41 (63.1%)	14 (36.8%)
Type of cataract surgery			
Manual SICS	26(40.0%)	12(33.3%)	16(42.1%)
Phacoemulsification	39(60.0%)	24(66.7%)	22(57.9%)
Duration of diabetes			
< 5 years	24 (66.7%)	43 (66.2%)	67 (66.3%)
5-10 years	8 (22.2%)	14 (21.5%)	22 (21.8%)
>10 years	4 (11.1%)	8 (12.3%)	12 (11.9%)
Severity of DR and ME			
No diabetic retinopathy	0(0.0%)	39 (60.0%)	38(100.0%)
NPDR without CSME	0(0.0%)	26 (40.0%)	0(0.0%)
NPDR + focal DME	20 (55.6%)	0(0.0%)	0(0.0%)
NPDR + cystoid DME	4(11.1%)	0(0.0%)	0(0.0%)
NPDR + Diffuse DME	8(22.2%)	0(0.0%)	0(0.0%)
PDR	0(0.0%)	0(0.0%)	0(0.0%)
PDR + Focal DME	4(11.1%)	0(0.0%)	0(0.0%)

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Table 2: Comparison of Mean BCVA (in logMAR)

	Group A	Group B	Group C	p value
POD-1	0.29 ± 0.07	0.24 ± 0.03	0.24 ± 0.02	
POD 4week	0.55 ± 0.08	0.43 ± 0.08	0.12 ± 0.03	0.001
p value	0.001	0.001	0.084	

Table 3: Comparison of mean CMT (in µm)

	Group A	Group B	Group C	p value
Pre-op	271.1 ± 10.1	230.5 ± 3.9	218.6 ± 6.7	
POD 4week	296.5 ± 22.0	236.1 ± 3.5	224.4 ± 4.7	0.001
p value	0.001	0.001	0.072	

Additionally, the same statistical analysis for Central Subfield Macular Thickness (CSMT) displayed a significant increase from baseline to one day (p=0.001), baseline to one week (p=0.001), and baseline to the fourth week (p=0.001). The CSMT increased progressively from pre-operative to POD-1. This progression of CSMT continued linearly to POD-4week (baseline- 271.1 ± 10.1 µ to 296.5 ± 11.0 µ in POD-4 week). The same mode of CSMT from pre-op to POD-4 week was also found in patients of group B. Comparing both the groups, the CSMT of group A was more than that of group B in pre-operative and all the post-operative period. Concurrently, a similar trend was formed in the controls (group C) also. This was of statistical significance (p = 0.001) (Table 3).

Comparing BCVA post-cataract surgery in the control, diabetic macular edema, and diabetic without macular edema groups using ANOVA showed a significant difference (p=0.001). Post-hoc analysis revealed higher mean BCVA in diabetic macular edema patients compared to controls and those without macular edema. Similarly, CSMT analysis at four weeks post-op revealed a prominent difference (p=0.001), with diabetic macular edema patients having a higher mean CSMT than controls and those without macular edema.

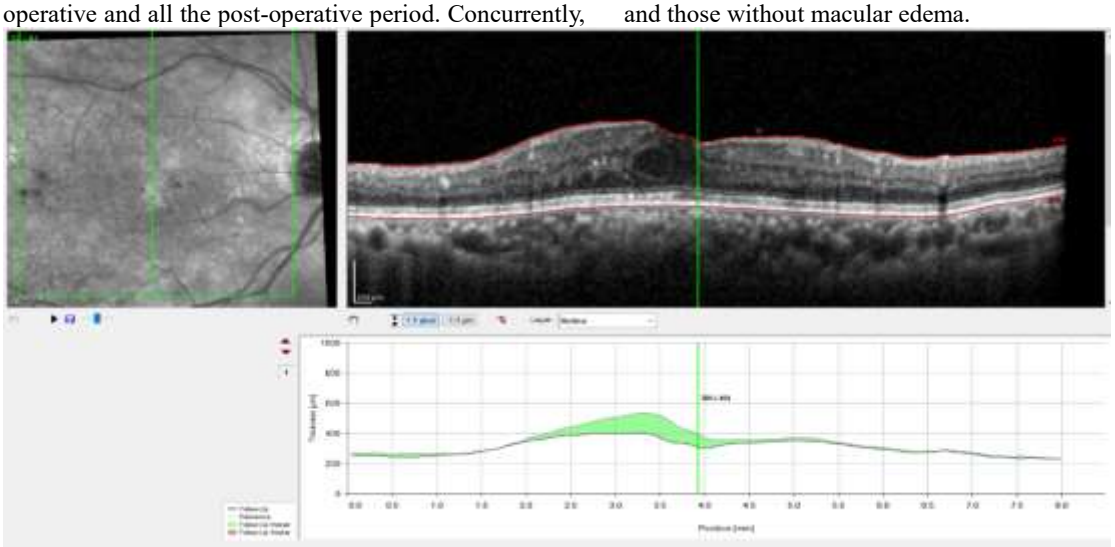

Figure-1: OCT Macula showing almost flattened fovea (CSMT= 306µ) with sub-foveal macular edema with diffuse macular thickening in a patient at 4weeks post-operatively

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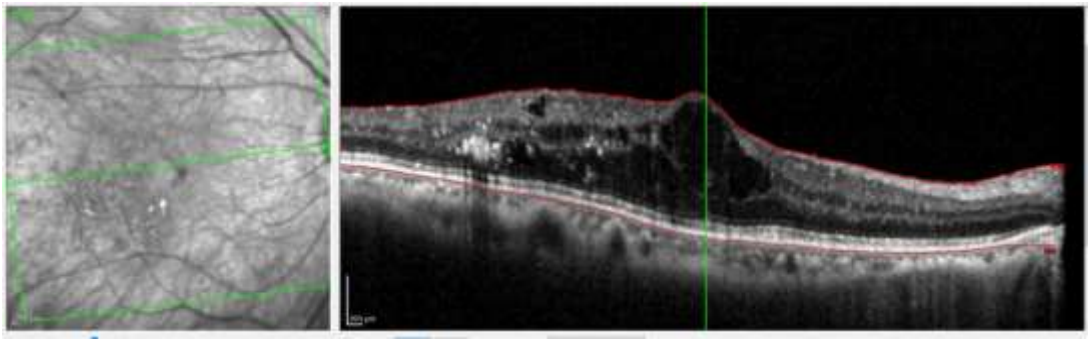

Figure-2: OCT Macula showing elevated foveal contour (CSMT ~ 316µ) due to multiple sub-foveal cystic spaces in outer and inner retinal layers

Table 4: Structural features of macula in OCT

OCT features		Group A		Group B		p value
		PRE-OP (%)	POD 4 WKS (%)	PRE-OP (%)	POD 4 WKS	
Foveal dip	Normal	66.7	11.1	100	80	0.001
	Elevated	11.1	55.6	0	12	
	Flattened	22.2	33.3	0	8	
Cystoid changes	Absent	11.1	0	100	80	NA
	In inner retinal layers	22.2	22.2	0	17	
	In outer retinal layers	66.7	77.8	0	3	
RPE complex	HRF absent	55.6	22.2	0	6.2	0.04
	HRF present	44.4	77.8	100	93.8	

In both Group A and Group B, substantial changes in various ocular parameters were noted both pre-operatively and at the 4th week post-op. Among individuals in Group A at baseline, 24 individuals (66.7%) exhibited a normal foveal dip, but this proportion significantly decreased to 11.1% (4 patients) after the 4th week. Conversely, elevated foveal dip was observed in 11.1% at baseline, rising to 55.6% (20 patients) post-operatively. In contrast, all 65 patients in Group B had a normal foveal dip before the operation, and at the 4th week post-op, this percentage increased notably to 80% (52 patients). The alterations in foveal dip in both groups reached statistical significance (p=0.001). Cystoid changes in the macula were present in 66.7% (24 patients) at baseline in Group A, while such morphological changes were absent in Group B (Table 4).

Discussion

The investigation involved a cohort of 139 individuals categorized into three groups: diabetics with macular edema (Group A), diabetics without macular edema (Group B), and a non-diabetic control group (Group C). Group B emerged as the largest subset, and a distinctive gender predilection was observed, with male dominance in Groups A and C, while Group B exhibited a female bias. The study, distinct in its inclusion of both manual SICS and Phacoemulsification, expands upon previous research conducted by Spoorthy et al. and Jamaiyar et al. [14, 15].

The preference for phacoemulsification across all groups, coupled with uneventful surgeries, underscores the safety and efficacy of these procedures. Of particular note is the higher prevalence of diabetic individuals with a diabetes duration of less than 5 years, setting the current study apart from existing literature.

Examining the severity of diabetic retinopathy, the results deviate from patterns observed in studies by Sethia et al. [16]. By encompassing diverse diabetic retinopathy presentations and durations, the present study unveils a cohort devoid of prior laser or intravitreal therapy.

The pre-operative mean BCVA of 1.24 ± 0.16 in Group A significantly improved to 0.29 ± 0.07 in POD-1, showcasing the immediate positive impact of cataract removal and IOL implantation. However, by 4 weeks post-operatively, the BCVA gradually decreased to 0.55 ± 0.08, possibly influenced by corneal remodeling and pseudophakic macular edema. Group B mirrored this trend, while Group C, with superior pre-op BCVA, demonstrated linear improvement, peaking at POD-4week. Notably, Group A exhibited a progressive increase in central subfield macular thickness (CSMT) from pre-op to POD-4week, surpassing Group B and C, indicating a significant impact ($p = 0.001$).

Comparing CSMT among diabetic groups and controls at 4 weeks post-op revealed significant differences ($p = 0.001$), with Group A displaying the highest increase (25-60µ). Moreover, 15.5% of patients without pre-existing diabetic macular edema developed macular edema by 4 weeks, significantly higher than controls (5.26%) ($p = 0.02$). This aligns with Pollack et al.'s findings and emphasizes the risk in diabetics without pre-op macular edema [9].

Several studies, including those by Jamaiyar et al. and Gharbiya et al., validate the post-cataract surgery increase in macular thickness [15, 17]. The current study, encompassing various surgical techniques, emphasizes the pronounced effect on diabetics, contributing to persistent visual dissatisfaction. The development and progression of cystoid changes post-surgery, particularly in diabetics with pre-existing DR and DME, suggest a nuanced prognosis.

While Sethia et al. reported insignificant changes in macular thickness post-surgery, the findings of this study, consistent with Wang and Cheng's study, highlight substantial increases in diabetics, underscoring the need for nuanced monitoring and management strategies in this population [16, 18].

The present study introduces novel insights into post-cataract surgery macular edema (ME) features. Controls showed minimal changes (5.3%), while diabetics without ME exhibited diverse foveal contours (12.3%). Diabetics with pre-existing ME displayed a significant foveal dip alteration (55.6%) and various cystoid changes. Group B demonstrated a 20% incidence of cystoid changes, predominantly in outer layers. Hyper-reflective foci (HRF) significantly increased in Group A (33.5%), indicating heightened capillary permeability. Limited research explores these ME features post-surgery, underscoring the need for comprehensive investigations [19-21].

Moreover, this study highlights that diabetics face a higher risk of post-operative complications, such as pseudophakic cystoid macular edema (PCME) or worsening pre-existing DME due to increased inflammation. Emphasizing the importance of strict blood sugar control, pre-operative macular edema screening, and timely intervention aligns with literature recommendations. A surgery delay of 3-6 months upon ME detection and vigilant post-operative monitoring of diabetic retinopathy status are crucial for preventing irreversible vision decline.

Conclusion

The study observed a positive relation between post-operative macular thickness and diabetes, inverse relation with visual outcome by underscoring the increased susceptibility of diabetics to post-operative complications, particularly pseudophakic cystoid macular edema and exacerbated diabetic macular edema (DME). Pre-operative macular edema screening, and timely intervention are crucial measures, for which OCT is a suitable non-invasive tool for detection and multiple follow up scans to assess morphological features of macula in patients with diabetic retinopathy/ maculopathy and to differentiate PCME from DME, so that appropriate treatment measures can be taken before permanent damage to the macular morphology.

Limitations

The study is limited by its short duration, hindering the assessment of macular edema progression beyond 6 months post-operatively. Additionally, exclusion of hypertension and local ocular co-morbidities as risk factors, along with challenges related to long-term follow-up and financial constraints, poses limitations. The study also omits the evaluation of macular edema in patients with a history of laser therapy or intravitreal injections and does not explore the impact of diabetes duration and blood glucose levels on post-operative macular edema.

Recommendations

This study recommends extending the duration of follow-up for observing macular edema progression, considering hypertension as a potential risk factor, and investigating the impact of diabetes duration and blood glucose levels on post-operative outcomes. A recommended surgery delay of 3-6 months upon ME detection, coupled with vigilant post-operative monitoring, is essential to prevent irreversible vision deterioration.

Generalizability

The generalizability of the study findings may be limited as the sample was drawn from individuals presenting at a specific ophthalmology outpatient department, potentially affecting the representation of broader populations. Additionally, the study's timeframe, impacted by the COVID-19 outbreak, may influence the applicability of the results to different time periods or settings.

Acknowledgement

To all the participants for their cooperation and patience.

List of Abbreviations

DM - Diabetes Mellitus
CSCME - Clinically Significant Cystoid Macular Edema
PCME - Pseudophakic Cystoid Macular Edema
OCT - Optical Coherence Tomography
VEGF - Vascular Endothelial Growth Factor
OPD - Outpatient Department
BCVA - Best Corrected Visual Acuity
CSMT - Central Subfield Macular Thickness
HRF - Hyperreflective Foci
RPE - Retinal Pigment Epithelium
ME - Macular Edema
DME - Diabetic Macular Edema

Source of funding

None.

Conflict of interest

None.

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