

Clinical Profile of Cystoid Macular Edema Following Small Incision Cataract Surgery

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Abstract:

Background: The study aimed to analyze the occurrence of Cystoid Macular Edema (CME) after small incision cataract surgery in the context of age-related ocular conditions, focusing on postoperative outcomes and associations with diabetic status.

Objective: To investigate CME incidence, particularly in the postoperative phase, and evaluate its association with diabetic status.

Methods: Inclusion and exclusion criteria were set to maintain a uniform patient population. A sample size of 325 was determined based on calculated CME incidence. Pre-operative evaluations were conducted, followed by small incision cataract surgeries. Postoperative follow-ups occurred at specific intervals (1st week, 6th week, 12 weeks, and 6 months). Diagnosis of CME was established through OCT assessments. Statistical analyses were performed using SPSS software.

Results: None of the patients developed CME in the first postoperative week. Incidence increased by the 6th week, notably higher in diabetic individuals. The association between diabetes and increased CME risk was statistically significant.

Conclusion: The study identified a distinct escalation of CME post-surgery, particularly in diabetic patients. Tailored postoperative care and vigilant monitoring for diabetic individuals are crucial in mitigating the impact of CME on visual outcomes.

Keywords: Cystoid Macular Edema, Small Incision Cataract Surgery, Postoperative Outcomes, Diabetic Status, OCT Assessment, Statistical Analysis.

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Introduction

Cataract has been documented to be the most significant cause of bilateral blindness both in India as well as on the global scale. It has been estimated that there are about 12.5 million blind people in India, with 50-80% of this group due to cataract [1]. The techniques for cataract extraction have progressed over the years from intracapsular cataract extraction to micro incision cataract surgery. The final visual outcome of cataract surgery has also improved over the years. Although cataract surgery is a common outpatient procedure, numerous vision-threatening complications can occur postoperatively. [2,3]

Cystoid macular edema (CME) represents one of the common causes of unexpected poor visual acuity after cataract surgery. It has been described with greater frequency after complicated surgery or in patients with eye disease, but also in normal eyes

after uncomplicated cataract surgery. [4] Modern cataract surgery with phacoemulsification, self-sealed corneal incision and the implant of foldable intra ocular lens (IOL) in the capsular bag seems to have reduced considerably the prevalence of angiographic as well as clinical CME. Cystoid macular edema develops following uneventful cataract surgery in about 60% of patients with intracapsular and 20 -30 % of patients with extracapsular surgery. [2,3,5]

Generally vision loss tends to be self-limiting; however, chronic CME with permanent visual loss occurs in approximately 1% of patients undergoing extracapsular cataract extraction. The precise pathogenesis of CME continues to perplex ophthalmologists. [6,7] As yet there are a number or different therapies that have been proposed based on theories of pathogenesis. The goal of

treatment of chronic CME is to reduce the edema and improve the visual acuity. [8]

There are different techniques for detection of cystoid macular edema. Fundus fluorescein angiography was usually utilized to confirm the diagnosis of CME. It is a painful procedure which can cause serious complications and there is not always a correlation between the degree of hyperfluorescence and visual loss. [2,9,10] In recent years, Optical Coherence Tomography (OCT) being a non-invasive procedure is being widely used in the diagnosis of macular edema. [13,14] OCT quantifies the retinal thickness and identifies macular thickening and cysts in the macular region. OCT has proved to be as effective as fluorescein angiography to detect CME and has evidenced good reproducibility. [15,16]

The purpose of this study is to identify the incidence of cystoid macular edema after small incision cataract surgery by means of OCT.

Methodology

Study Design - This research was conducted as a prospective study.

Study Setting - The study took place at the Regional Institute of Ophthalmology (RIO) in Trivandrum.

Study Duration - The research spanned over a period of one year.

Inclusion Criteria - The inclusion criteria for this study encompassed patients aged over 40 years who were specifically presenting at the Regional Institute of Ophthalmology (RIO) in Trivandrum for cataract surgery within the stipulated one-year duration.

These individuals were required to meet specific age criteria to ensure a cohort more prone to age-related ocular conditions. Patients meeting the age threshold were evaluated for inclusion if they were scheduled for cataract surgery within the defined study period.

Furthermore, the study emphasized the importance of patient selection within this age group to obtain a representative sample susceptible to age-related ocular pathologies like cataracts and potential complications such as Cystoid Macular Edema (CME) following small incision cataract surgery. This criterion was essential for maintaining uniformity in the patient population and ensuring a standardized analysis of postoperative outcomes related to CME in the context of age-related ocular conditions.

Exclusion Criteria

The exclusion criteria for this study involved several specific conditions and circumstances.

Patients were excluded if they had been diagnosed with cystoid macular edema (CME) prior to cataract surgery due to causes other than those being investigated in this study. Additionally, individuals who underwent phacoemulsification, extracapsular cataract extraction (ECCE), or were left aphakic post-surgery were not included in the study. The exclusion of patients with refractive errors greater than 6D and intraocular pressure exceeding 21 mm of Hg aimed to eliminate potential confounding variables. Furthermore, individuals with pre-existing macular lesions such as macular hole, age-related macular degeneration (ARMD), or diabetic macular edema, as well as those who had diabetes with macular involvement prior to surgery, were also excluded. Patients who had undergone previous laser therapy or were not willing to participate in the study were not included. These exclusion criteria were vital to ensure a focused and specific study population, reducing confounding factors and enabling a more accurate assessment of CME occurrence specifically associated with small incision cataract surgery.

Sample Size Determination - A sample size of 325 was determined based on the calculated incidence of Cystoid Macular Edema at specific postoperative intervals.

Methodology Overview - After obtaining informed consent, 325 eligible patients for cataract surgery underwent thorough pre-operative evaluations. These assessments included detailed medical history, ocular examination, and screening for diabetic retinopathy or pre-existing macular lesions. Postoperative small incision cataract surgery was conducted, and complications were noted. Medication was administered and tapered over a six-week period.

Postoperative Evaluations - Patients were followed up at specific intervals (1st week, 6th week, 12 weeks, and 6 months post-surgery). These evaluations involved BCVA checks, fundus examinations, and OCT assessments for the detection of cystoid macular edema.

Diagnosis of Macular Edema - Cystoid macular edema was diagnosed through OCT images showing a central foveal thickness greater than the mean thickness + 2SD in corresponding areas of healthy subjects. In this study, macular edema was diagnosed if the macular thickness within a 1 mm central circle was more than 200 microns, displaying cystic spaces.

Statistical Analysis - Data analysis was conducted using SPSS software (version 10). Frequency, percentage, mean, and standard deviation were employed for data expression. Chi-square tests were used for associations and comparisons between different parameters. Additionally,

Student’s t-test was employed for comparisons between groups, considering a significance threshold of $p < 0.05$ for all statistical evaluations.

Result

The distribution of the study participants based on age categories shows a comprehensive representation of various age groups. Among the total cohort of 325 individuals involved in the study, the largest proportion was observed in the age bracket of 60 to 69 years, constituting 142 participants, which accounts for 43.7% of the total sample. Following this, the 50 to 59 age group encompassed 92 individuals, representing 28.3% of the total population.

Additionally, the 70 to 79 age category included 76 participants, making up 23.4% of the sample. Comparatively smaller groups were observed in the 40 to 49 and over 80 age ranges, consisting of 9 individuals (2.8%) and 6 individuals (1.8%) respectively. This diverse age distribution within the study’s sample population ensures a representation across a spectrum of ages, allowing for a more comprehensive analysis of the incidence and characteristics of Cystoid Macular Edema following small incision cataract surgery within different age demographics shown in Table 1 to Table 8 and Figure 1 to Figure 7.

Table 1: Demographics of the Study

Age	Frequency	Percent
40 - 49	9	2.8
50 - 59	92	28.3
60 - 69	142	43.7
70 - 79	76	23.4
>= 80 yrs	6	1.8
Total	325	100

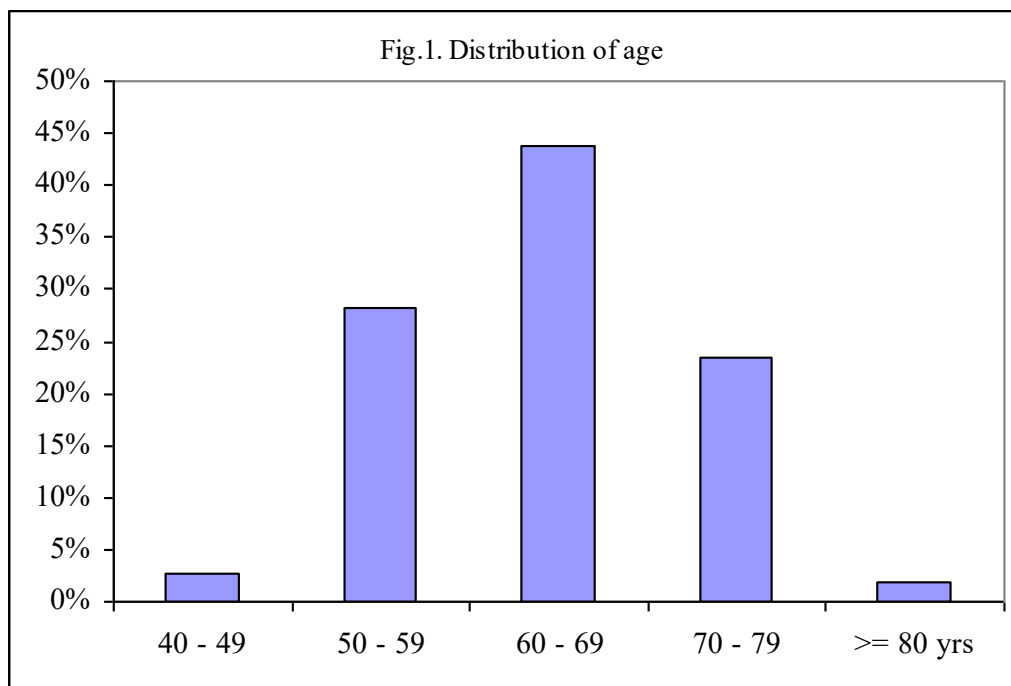


Figure 1: Distribution of Age

Table 2: Gender distribution

Gender	Frequency	Percent
Male	132	40.6
Female	193	59.4
Total	325	100

59.4% of the study population was females and 40.6% of the subjects were males.

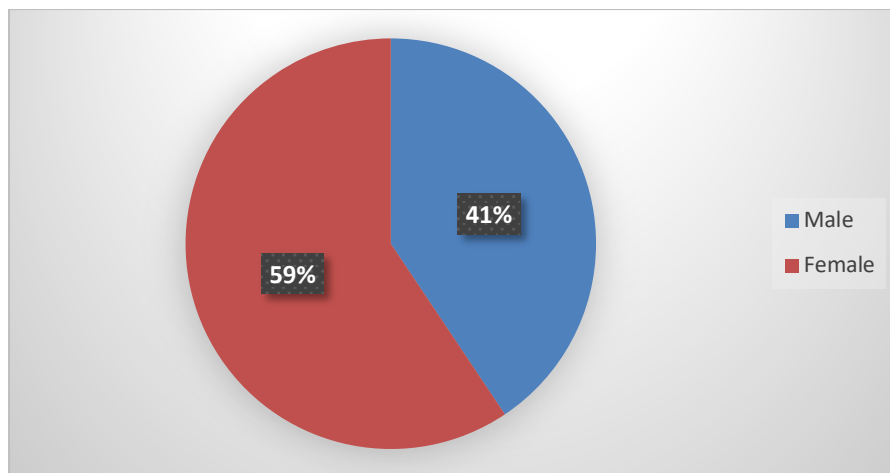


Figure 2: Gender distribution

Table 3: Eyes Evaluated

Eye	Frequency	Percent
Right	181	55.7
Left	144	44.3
Total	325	100

Of the 325 eyes included in the study, in 181 subjects, the right eye was evaluated and in 144 subjects the left eye was evaluated for the development of cystoid macular edema.

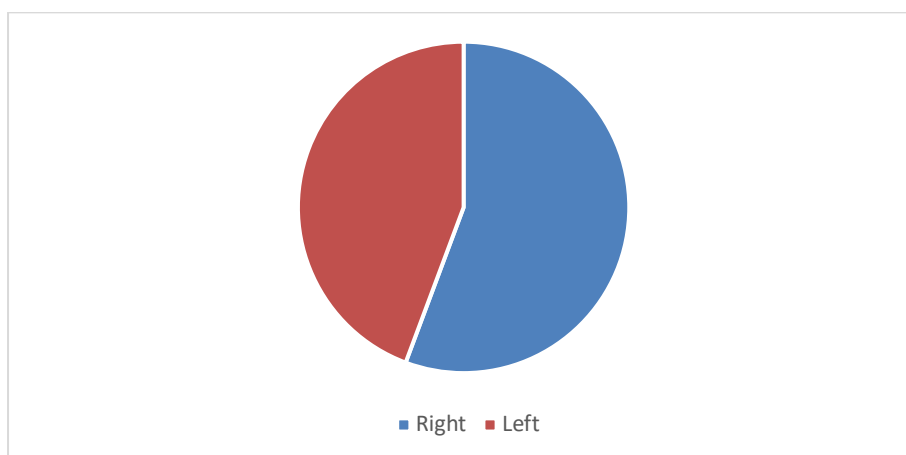


Figure 3: Eyes Evaluated

In the study population, 72% were not diabetic. 21.8% were diabetic, but did not have diabetic retinopathy. 1.5% had mild non proliferative diabetic retinopathy, 3.1% had moderate non proliferative diabetic retinopathy, and 1.5 % had severe diabetic retinopathy. Proliferative diabetic retinopathy was not present among the study population.

Table 4: Diabetic status

Diabetic status (ETDRS)	Frequency	Percent
Diabetic ,no DR	71	21.8
Mild NPDR	5	1.5
Moderate NPDR	10	3.1
Severe NPDR	5	1.5
Not diabetic	234	72
Total	325	100

Table 5: Incidence of Cystoid Macular Edema

CME	Post OP 1st Week		Post OP 6th Week		Post OP 3rd Month		Post OP 6th Month	
	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
No	325	100.0	264	81.2	282	86.8	308	94.8
Yes	0	0	61	18.8	43	13.2	17	5.2
Total	325	100	325	100	325	100	325	100

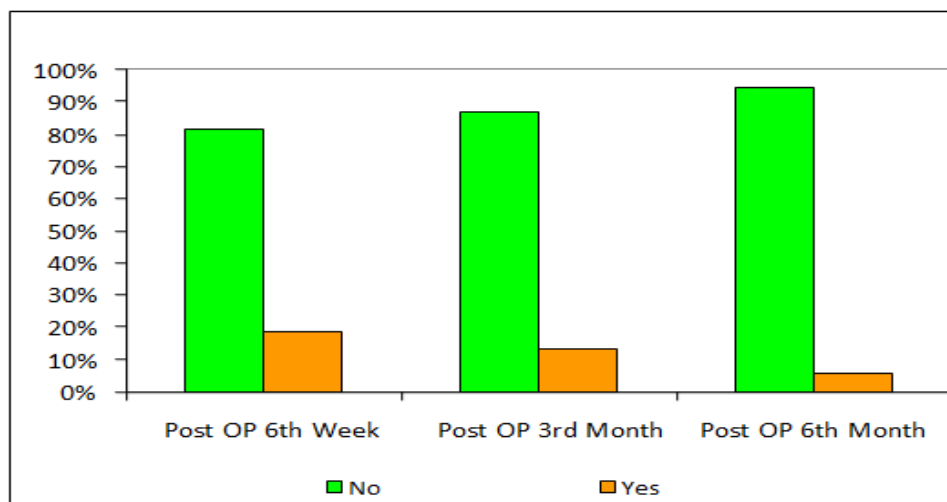


Figure 4: Incidence of CME

Cystoid macular oedema was not noted in any of the study population in the first postoperative week. After 6 weeks, 61 patients developed cystoid changes in the macula with oedema. After 3 months of surgery, only 43 patients had cystoid macular edema. After 6 months only 17 subjects had cystoid macular edema. The incidence of cystoid macular edema was maximum 6 weeks after surgery.

Table 6: Incidence of Clinically Significant Cystoid Macular Edema

Clinically Significant CME	Post OP 1st Week		Post OP 6th Week		Post OP 3rd Month		Post OP 6th Month	
	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
No	325	100.0	312	96.0	321	98.8	323	99.4
Yes	0	0	13	4.0	4	1.2	2	0.6
Total	325	100	325	100	325	100	325	100

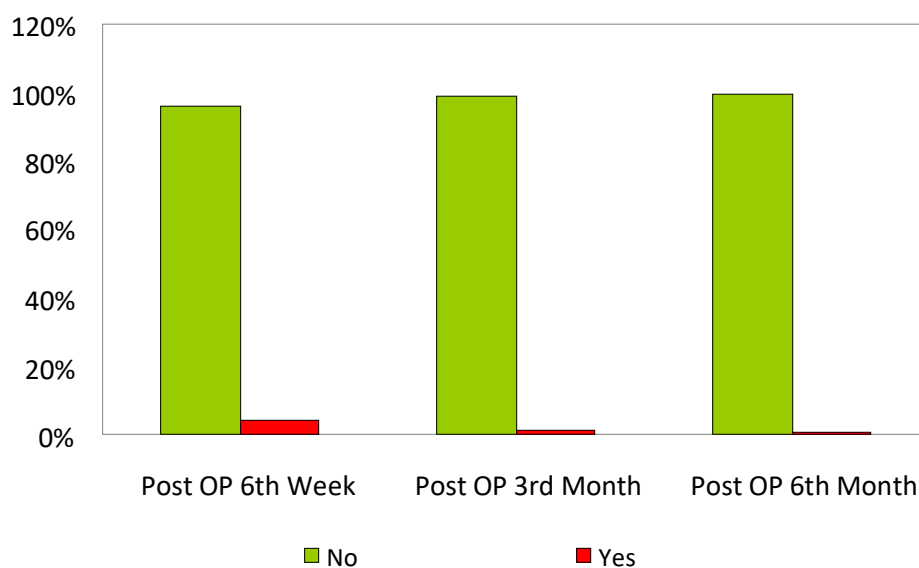


Figure 5: Clinically significant CME

Cystoid macular oedema was not noted in any of the study population in the first postoperative week. After 6 weeks, 13 patients developed cystoid changes in the macula with oedema and decrease in vision. After 3 months of surgery, only 4 patients had clinically significant cystoid macular edema. After 6 months only 2 subjects had clinically significant cystoid macular edema.

Table 7: Incidence of CME in Diabetic Patients

CME	Diabetes Mellitus		Total	Chi Square	P value
	No DM	DM			
Post OP 1st Week	0	0	0	0.000	> 0.05
	0.00%	0.00%	0.00%		
Post OP 6th Week	30	31	61	19.397	< 0.001
	12.80%	34.10%	18.80%		
Post OP 3rd Month	16	27	43	29.754	< 0.001
	6.80%	29.70%	13.20%		
Post OP 6th Month	6	11	17	11.988	< 0.01
	2.60%	12.10%	5.20%		

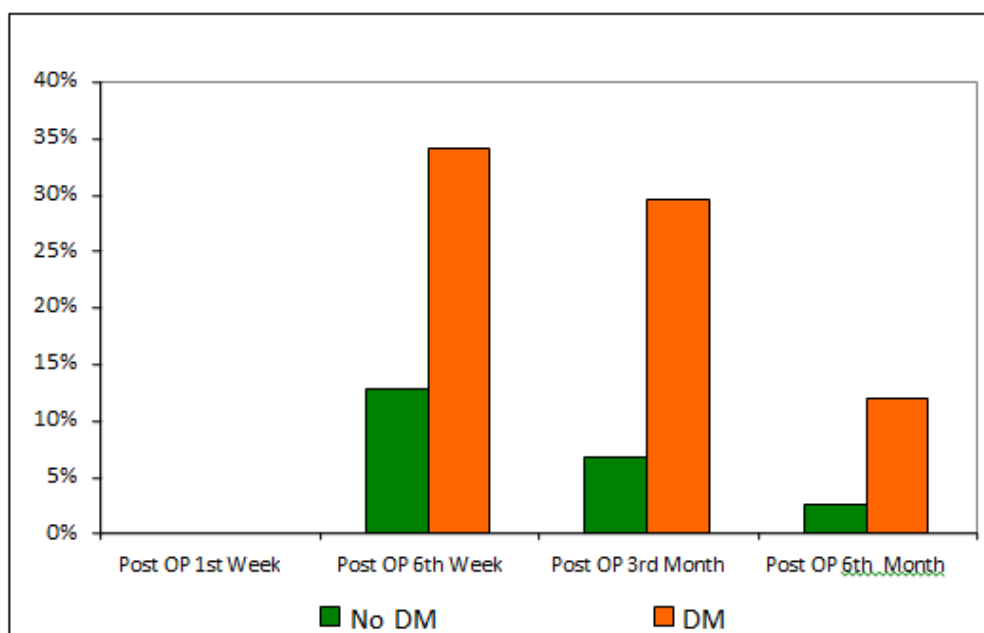


Figure 6: CME and DM

In the study population, none of the subjects developed CME in the first postoperative week. In the 6th post-operative week, 34.10% diabetic patients developed CME while only 12.8% of the non-diabetic patients developed CME. In the third month after surgery, 29.7% of the diabetic patients developed CME, while only 6.8% non-diabetic patients had CME. After 6 months, 12.10% of the diabetic patients had CME while only 2.6% had CME among the non-diabetic patients. The differences were statistically significant.

Table 8: Tincidence of Clinically Significant CME in Diabetic Patients

Clinically Significant CME	Diabetes Mellitus		Total	Chi Square	P value
	No DM	DM			
Post OP 1st Week	0	0	0	0.000	> 0.05
	0.00%	0.00%	0.00%		
Post OP 6th Week	4	9	13	11.419	< 0.01
	1.70%	9.90%	4.00%		
Post OP 3rd Month	1	3	4	4.438	< 0.05
	0.40%	3.30%	1.20%		
Post OP 6th Month	1	1	2	0.483	> 0.05
	0.40%	1.10%	0.60%		

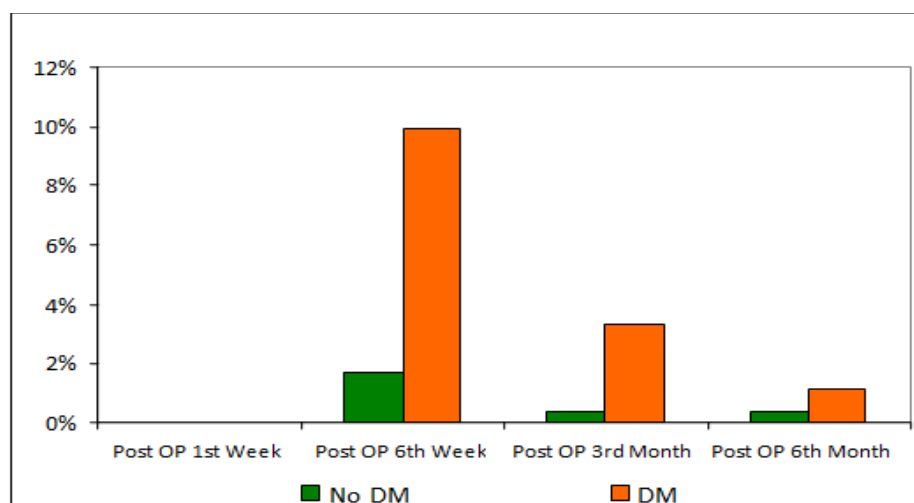


Figure 7: Clinically Significant CME and DM

Discussion

The higher occurrence of CME in the age group of 60-69 is consistent with previous findings that suggest an increased risk of developing CME with age. Elderly patients might have predisposing factors such as reduced retinal vascular perfusion and compromised blood-retinal barrier integrity, contributing to the higher incidence of CME post-cataract surgery in this age group.

The higher percentage of females experiencing CME following cataract surgery in this study is noteworthy. It aligns with existing literature suggesting hormonal differences or variations in ocular anatomy between genders as potential contributing factors to the different rates of postoperative CME. The association between diabetes and CME following cataract surgery is well-documented. Diabetic individuals, especially those with diabetic retinopathy, are at an increased risk of developing CME post-surgery due to compromised retinal vasculature and increased inflammation.

Understanding the demographic characteristics and diabetic status of patients prone to developing CME post-cataract surgery is crucial for clinical management. It emphasizes the need for vigilant preoperative assessment, close postoperative monitoring, and tailored interventions to mitigate the risk of CME, especially in high-risk groups such as elderly individuals, females, and those with diabetic retinopathy.

The study's analysis of Cystoid Macular Edema (CME) following small incision cataract surgery at various postoperative intervals sheds light on the temporal dynamics and severity of this complication. In the immediate postoperative period, specifically in the first week, there were no reported instances of CME among the study population. This absence of CME aligns with the typical early recovery phase following cataract

surgery, where acute complications such as CME may not manifest. However, a significant rise in CME occurrence was noted in the subsequent weeks. At the 6-week mark, 61 patients, constituting 18.8% of the subjects, presented with signs of CME. This substantial increase suggests a delayed onset of macular edema following cataract surgery, which is a critical finding for postoperative patient care and follow-up. Over the subsequent months, there was a notable decline in the incidence of CME.

By the 3-month postoperative assessment, only 43 patients (13.2%) exhibited signs of CME. This decreasing trend continued, with only 17 patients (5.2%) displaying CME at the 6-month evaluation. The progressive decline in CME incidence indicates a resolving or self-limiting nature of this complication over time in a majority of cases. In a similar study by Dimpy Gothwal et al, the incidence of CME was found to be 30% at 4 weeks, 32% at 8 weeks, and 14% at 3 months following manual small incision cataract surgery. [17]

Additionally, the study investigated clinically significant CME, a more severe form of macular edema that may have a more pronounced impact on vision and require specific intervention. Notably, no instances of clinically significant CME were observed in the immediate postoperative phase. However, at the 6-week assessment, 13 patients (4.0%) presented with clinically significant CME.

This suggests that while the overall incidence of CME decreases over time, the proportion of severe cases also follows a similar trend, albeit at a smaller magnitude, implying a parallel resolution pattern. In a similar study by Eriksson U et al, 6 weeks after cataract surgery, there was a significantly low visual acuity among the diabetic patients when compared to the control group. [18]

By the 3-month and 6-month assessments, the incidence of clinically significant CME continued

to decrease, with 4 patients (1.2%) and 2 patients (0.6%) respectively showing signs of this severe form of macular edema. This decreasing trend in clinically significant CME, mirroring the overall CME incidence, reinforces the notion that, over time, a significant portion of postoperative CME cases tend to resolve or become less severe.

The comparison of Cystoid Macular Edema (CME) incidence between diabetic and non-diabetic patients following small incision cataract surgery is a pivotal aspect of understanding the postoperative complications in these distinct patient groups. The findings present a striking contrast in the occurrence of CME at various postoperative intervals.

During the initial phase, in the first postoperative week, neither diabetic nor non-diabetic patients showed any instances of CME. However, as the postoperative period progressed, a significant discrepancy in CME rates became evident. By the 6th week following surgery, a substantial difference emerged. While only 12.80% of non-diabetic patients developed CME, a notably higher proportion, accounting for 34.10% of diabetic patients, exhibited signs of CME. This early divergence signifies a heightened vulnerability to CME among diabetic individuals within the initial months post-cataract surgery.

Moreover, as time progressed, the disparity persisted and even amplified. At the 3-month assessment, 29.70% of diabetic patients were afflicted by CME, contrasting sharply with the 6.80% incidence among non-diabetic individuals. This persistent elevation in CME prevalence among diabetic patients underlines the on-going risk they face in developing this postoperative complication. Even at the 6-month evaluation, the disparity remained evident.

While the incidence of CME decreased in both groups, diabetic patients still showed a markedly higher prevalence, with 12.10% experiencing CME compared to the 2.60% among non-diabetic patients. The statistical significance of these differences underscores the consistent and substantial association between diabetes and the increased likelihood of developing CME following cataract surgery.

The study's comprehensive analysis of Cystoid Macular Edema (CME) following small incision cataract surgery reveals pivotal insights into its temporal occurrence and association with diabetic status. The results demonstrate a clear trend in CME development, notably absent in the first postoperative week, gradually escalating by the 6th week, and gradually declining thereafter at the 3rd and 6th months.

Furthermore, a distinct disparity emerges between diabetic and non-diabetic patients, with diabetic individuals consistently exhibiting higher rates of CME across all postoperative intervals. The statistically significant association between diabetes and increased CME risk post-cataract surgery underscores the need for targeted monitoring and intervention strategies for diabetic patients, emphasizing the critical importance of tailored postoperative care to mitigate the impact of CME on visual outcomes. These findings offer valuable guidance for clinical management, emphasizing the necessity for early identification and proactive measures specifically designed for diabetic patients undergoing cataract surgery to minimize the risk and consequences of CME.

The study on Cystoid Macular Edema (CME) following small incision cataract surgery, while informative, has several limitations. The absence of a control group for comparative analysis restricts the ability to directly contrast the incidence of CME in individuals who did not undergo cataract surgery. Additionally, the study's sample size and duration might limit the generalizability of the findings to broader populations and longer-term outcomes. Moreover, the lack of detailed information on factors like pre-existing ocular conditions or variations in surgical techniques might affect the comprehensive understanding of CME development. Addressing these limitations in future research could provide a more comprehensive and nuanced understanding of CME post-cataract surgery.

Future research in the field should focus on expanding the current study's scope by including a control group for comparative analysis, investigating additional risk factors such as pre-existing ocular conditions and variations in surgical techniques, and conducting longitudinal studies with larger sample sizes to assess long-term trends and late-onset Cystoid Macular Edema (CME) post-surgery. Evaluating tailored interventions for high-risk groups, particularly diabetic individuals, would also be beneficial in understanding and mitigating CME's impact on postoperative visual outcomes.

Conclusion

The study on Cystoid Macular Edema (CME) following small incision cataract surgery provides crucial insights into the temporal pattern of CME occurrence and its association with diabetic status. The findings reveal a distinctive escalation of CME after the 6th postoperative week, gradually declining by the 3rd and 6th months. Notably, diabetic patients consistently exhibited higher CME rates across all intervals, signifying a significant association between diabetes and increased CME risk post-cataract surgery. These results underscore

the necessity for targeted monitoring and intervention strategies for diabetic individuals, emphasizing the critical importance of tailored postoperative care to mitigate the impact of CME on visual outcomes. Addressing the limitations and embracing future recommendations could refine our understanding and clinical management of CME following cataract surgery, offering avenues for more effective interventions and improved patient outcomes.

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