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Original Article

Ophthalmology Section

Incidence, Clinical Features and Risk Factors for Cystoid Macular Oedema following Cataract Surgery: A Prospective Cohort Study

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ABSTRACT

Introduction: Pseudophakic Cystoid Macular Oedema (PCME) remains an important cause of delayed visual recovery after cataract surgery. The use of Optical Coherence Tomography (OCT) has increased the detection of milder and subclinical postoperative macular oedema, making local incidence estimates and risk profiling clinically relevant.

Aim: To estimate the incidence of PCME within 3 months after cataract surgery and to evaluate the clinical and operative risk factors associated with its occurrence.

Materials and Methods: The present prospective cohort study was conducted in the Department of Ophthalmology, Adichunchanagiri Institute of Medical Sciences, BG Nagara, Karnataka, India, during a 12-month study period from January 2025 to January 2026. A total of 155 eyes of 155 patients aged 40 years and above undergoing small-incision cataract surgery or phacoemulsification were analysed. Baseline systemic and ocular variables, operative details, postoperative anterior chamber reaction, Best-Corrected Visual Acuity (BCVA), and OCT-derived central macular thickness were recorded. PCME was defined on OCT by intraretinal cystic changes with increased central macular thickness. Categorical variables were analysed by Chi-square test or Fisher's exact test, continuous variables by Student's t-test, and within-group CMT change by paired t-test after assessment of distribution. Exploratory multivariable logistic regression was used to identify associated predictors. A p-value of <0.05 was considered statistically significant.

Results: PCME was identified in 18 of 155 eyes (11.6%). Diabetes mellitus, hypertension, operative duration >20 minutes, intraoperative complications, and anterior chamber inflammation grade ≥2 at one week were more frequent in the PCME group. Mean central macular thickness increased from 252±22 µm preoperatively to 320±25 µm at six weeks in eyes with PCME (p<0.001), whereas the change in non-PCME eyes was not statistically significant (250±20 µm to 240±18 µm, p=0.052). 3-month BCVA remained poorer in the PCME group (LogMAR 0.5±0.2 vs 0.3±0.1, p=0.008). In exploratory multivariable analysis, diabetes mellitus, operative duration >20 minutes, and intraoperative complications remained associated with PCME.

Conclusion: OCT-detected PCME occurred in approximately one in nine operated eyes in this cohort. Diabetes mellitus, greater operative stress, and intraoperative complications were the strongest associated predictors. Early OCT surveillance may therefore be justified in eyes with a higher postoperative inflammatory or metabolic risk profile.

Keywords: Macula lutea, Optical coherence, Postoperative complications, Pseudophakia, Retinal oedema, Tomography

INTRODUCTION

Cataract surgery is one of the most frequently performed ophthalmic procedures, and most patients expect a rapid and uncomplicated visual recovery. When vision improves more slowly than anticipated despite a clear cornea, a centred intraocular lens, and an otherwise satisfactory anterior segment examination, the macula becomes the principal site of concern. PCME, also referred to as Irvine-Gass syndrome, remains one of the common causes of such delayed recovery [1,2].

The pathophysiology of PCME is thought to be predominantly inflammatory. Surgical manipulation induces prostaglandin release and disrupts the blood-retinal barrier, which increases perifoveal vascular permeability and allows fluid to accumulate within the retinal layers [2,3]. OCT has changed the clinical landscape by detecting small intraretinal cysts and subclinical increases in central macular thickness that may not be evident on routine slit-lamp biomicroscopy or indirect ophthalmoscopy [3,4]. Consequently, the reported incidence varies widely across studies depending on whether diagnosis is based on angiography, clinical examination, or OCT criteria [2-4].

The risk of postoperative macular oedema is not evenly distributed. Diabetes mellitus, diabetic retinopathy, hypertension, posterior capsule rupture, vitreous disturbance, and prolonged operative manipulation have repeatedly been associated with a higher likelihood of PCME [1,2,5]. Large database studies have shown that even after modern cataract surgery, clinically relevant macular oedema continues to occur, particularly in eyes with pre-existing retinal or systemic vulnerability [2,6].

Interest has therefore shifted from treatment alone to selective prevention and early detection. Published review literature and the European Society of Cataract and Refractive Surgeons (ESCRS) PREvention of Macular EDema after cataract surgery (PREMED) randomised trial programme have supported the role of topical anti-inflammatory prophylaxis, particularly in eyes considered at greater risk [4,5,7,8]. However, the frequency of OCT-confirmed PCME and the relative contribution of systemic versus operative risk factors may vary across institutions because technique mix, case complexity, and follow-up practices are not uniform.

Indian studies addressing post-cataract macular thickening, PCME occurrence after small-incision cataract surgery, and treatment response in acute PCME are available, but prospective Indian cohort data that simultaneously report OCT-defined incidence, systemic profile, operative variables, and 3-month visual outcome remain comparatively limited [9-11]. The present study was therefore

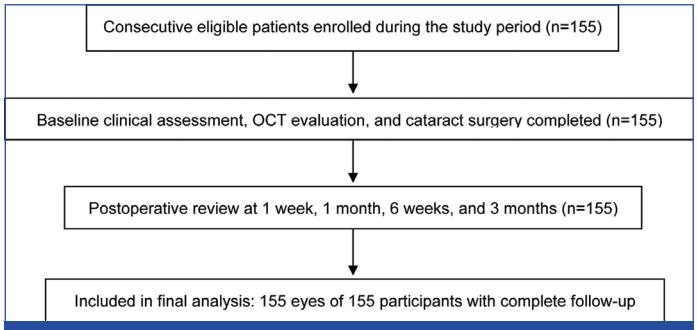
undertaken to estimate the incidence of OCT-detected PCME within 3 months after cataract surgery and to identify the clinical and operative risk factors associated with its occurrence. It was hypothesised that clinical and operative risk factors would be associated with a greater risk of postoperative OCT-detected PCME.

MATERIALS AND METHODS

The present prospective cohort study was conducted in the Department of Ophthalmology, Adichunchanagiri Institute of Medical Sciences, BG Nagara, Karnataka, India, over a 12-month study period from January 2025 to January 2026. The study was designed to document the incidence of PCME after cataract surgery and to evaluate the associated clinical and operative risk factors. The manuscript was prepared with reference to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance for cohort studies [12]. The study was approved by the Institutional Ethics Committee of Adichunchanagiri Institute of Medical Sciences. Written informed consent was obtained before enrolment. Patient confidentiality was maintained throughout the study. The institutional ethics committee registration number available in the study records was EC/NEW/INST/2023/KA/0382.

Inclusion and Exclusion criteria: Patients aged 40 years and above who were scheduled for cataract extraction by either small-incision cataract surgery or phacoemulsification and who consented to postoperative OCT-based follow-up were considered eligible. Only one eye per participant was included in the final analysis to avoid within-subject correlation. Eyes with pre-existing macular pathology, retinal disease likely to alter central macular thickness, previous intraocular surgery in the study eye, media opacity precluding reliable OCT acquisition, or incomplete follow-up up to 3 months were excluded. The final analysed cohort comprised 155 eyes with complete 3-month follow-up.

Sample size calculation: Consecutive recruitment was followed. The sample size was justified using the formula $n=Z^2p(1-p)/d^2$, assuming an anticipated CME incidence of 10%, 95% confidence level, and absolute precision of 5%. The calculated minimum sample size was 139. To allow for possible incomplete follow-up and to preserve adequate analytical precision, the target sample was increased to 155 participants. All eligible patients presenting during the study period and completing the scheduled follow-up were included in the final analysis [Table/Fig-1].



[Table/Fig-1]: Participant flow of the analysed cohort.
Flowchart depicts enrolment, scheduled follow-up, and the final analysed cohort

Study Procedure

Clinical assessment and surgery: A standard preoperative assessment was performed for all participants and included demographic details, systemic history with specific documentation of diabetes mellitus and hypertension, visual acuity, refraction, slit-lamp examination, dilated fundus evaluation, and baseline OCT assessment of the macula. Cataract surgery was performed as either small-incision cataract surgery or phacoemulsification according to surgeon judgement and case factors. The recorded operative variables included surgical technique, operative duration using a >20-minute threshold, intraoperative complications defined as posterior capsule rupture or vitreous disturbance, and intraocular lens implantation details. Intraoperative complications were analysed as a binary composite surgical-stress variable because the total number of such events was small.

Postoperative follow-up and outcome definition: Participants were reviewed at one week, one month, six weeks, and 3 months after surgery. Each visit included BCVA assessment, slit-lamp examination with grading of anterior chamber reaction according to the Standardisation of Uveitis Nomenclature (SUN) anterior chamber cell grading approach, fundus evaluation, and OCT-based evaluation of central macular thickness and macular morphology [13]. For the comparative thickness analysis, preoperative and six-week central macular thickness values were used. PCME was defined as postoperative intraretinal cystic changes on OCT accompanied by an increase in central macular thickness consistent with cystoid macular oedema.

STATISTICAL ANALYSIS

Categorical variables were summarised as frequency and percentage, whereas continuous variables were expressed as mean±Standard Deviation (SD). Normality for continuous variables and within-group CMT differences was assessed using the Shapiro-Wilk test. Between-group comparisons between eyes with PCME and those without PCME were performed using Chi-square test or Fisher's exact test for categorical variables and Student's t-test for normally distributed continuous variables. Within-group change in central macular thickness from baseline to six weeks was assessed using paired t-test because the paired CMT differences were treated as approximately normally distributed. Variables that were clinically important and not judged to represent postoperative mediators were taken forward into an exploratory multivariable logistic regression model to identify associated predictors of PCME. As there were 18 PCME events, the 3-predictor model provided approximately six events per variable; therefore, multivariable estimates were interpreted cautiously. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 155 eyes of 155 participants with complete 3-month follow-up were analysed. The mean age of the cohort was 65.4±8.2 years. Women constituted 55.5% of the study population, and 65.8% of participants were from rural areas. Diabetes mellitus was present in 48 participants (31.0%), while hypertension was present in 63 participants (40.6%) [Table/Fig-2].

Variables	Values
Mean age (years)	65.4±8.2
Sex (male/female)	69 (44.5%) / 86 (55.5%)
Residence (urban/rural)	53 (34.2%) / 102 (65.8%)
Diabetes mellitus	48 (31.0%)
Hypertension	63 (40.6%)

[Table/Fig-2]: Baseline demographic and clinical characteristics of the study cohort (N=155).
Values are presented as mean±standard deviation or number (percentage)

The PCME was detected in 18 of 155 eyes, giving a cumulative incidence of 11.6% over the 3-month follow-up period. Comparative analysis between eyes with and without PCME is shown in [Table/Fig-3]. Diabetes mellitus, hypertension, operative duration >20 minutes, intraoperative complications, greater early postoperative inflammation, and poorer 3-month visual acuity were more common in the PCME group. Surgical technique distribution in the overall cohort was 116 eyes (74.8%) for small-incision cataract surgery and 39 eyes (25.2%) for phacoemulsification. Technique-wise outcome comparison was not used as a formal subgroup analysis because the PCME event count was small and the study was not powered for a stable procedure-specific outcome model.

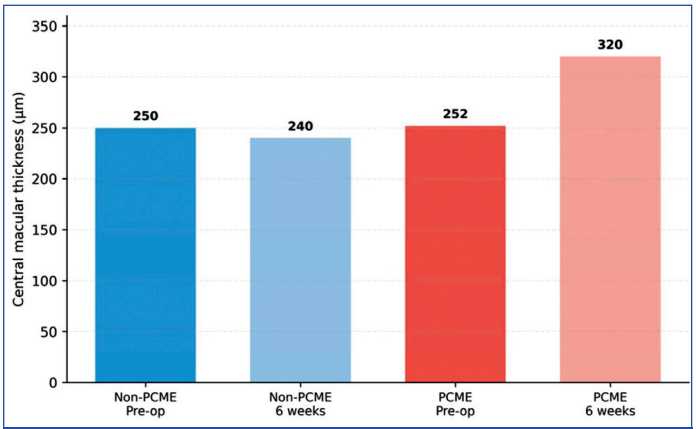
Variables	PCME (n=18)	Non-PCME (n=137)	p-value
Age (years), (Mean±SD)	67.1±7.9	65.2±8.2	0.296
Male sex	9 (50.0%)	60 (43.8%)	0.619
Rural residence	13 (72.2%)	89 (65.0%)	0.544
Diabetes mellitus	10 (55.6%)	38 (27.8%)	0.023*
Hypertension	12 (66.7%)	51 (37.2%)	0.017*
Diabetic retinopathy	3 (16.7%)	10 (7.3%)	0.165
Pseudoexfoliation	1 (5.6%)	5 (3.6%)	0.672
Operative duration >20 minutes	7 (38.9%)	20 (14.6%)	0.012*
Intraoperative complications	2 (11.1%)	2 (1.5%)	0.045*
BCVA at 3 months (LogMAR), mean±SD	0.5±0.2	0.3±0.1	0.008*

[Table/Fig-3]: Comparison of baseline, operative, and postoperative outcome variables between eyes with and without PCME (N=155).
PCME: Pseudophakic cystoid macular oedema; BCVA: Best-corrected visual acuity; LogMAR: Logarithm of the minimum angle of resolution; SD: Standard deviation. *Statistically significant

Anterior chamber inflammation at one week showed a clear between-group difference. Grade ≥2 reaction was recorded in 61.1% of eyes with PCME compared with 18.2% of eyes without PCME. OCT-based central macular thickness analysis at the scheduled six-week assessment also diverged across groups. In the PCME group, mean central macular thickness increased from 252±22 µm preoperatively to 320±25 µm at six weeks (paired t-test, p<0.001). In the non-PCME group, the corresponding change from 250±20 µm to 240±18 µm did not reach statistical significance (paired t-test, p=0.052) [Table/Fig-4,5].

Parameters	PCME (n=18)	Non-PCME (n=137)	p-value/note
Anterior chamber inflammation at 1 week: Grade 0-1	7 (38.9%)	112 (81.8%)	<0.001
Anterior chamber inflammation at 1 week: Grade ≥2	11 (61.1%)	25 (18.2%)	<0.001
CMT preoperative (µm), mean±SD	252±22	250±20	-
CMT at 6 weeks (µm), mean±SD	320±25	240±18	-
Within-group CMT change, preoperative vs 6 weeks	Significant increase	No significant change	PCME: paired t-test p<0.001; Non-PCME: paired t-test p=0.052

[Table/Fig-4]: Early postoperative inflammation and OCT-based central macular thickness analysis.
CMT: Central macular thickness; OCT: Optical coherence tomography; SD: Standard deviation



[Table/Fig-5]: Central macular thickness at baseline and six weeks in eyes with and without PCME.
Mean values are displayed above the bars. Shades of blue indicate the non-PCME group and shades of salmon indicate the PCME group

The exploratory multivariable logistic regression model retained diabetes mellitus, operative duration >20 minutes, and intraoperative complications as associated predictors of PCME [Table/Fig-6]. Hypertension and anterior chamber inflammation were not retained in the final model because the number of outcome events was limited, and anterior chamber reaction was interpreted as an early postoperative correlate rather than a baseline preoperative predictor.

Predictor	Odds ratio	95% confidence interval	p-value
Diabetes mellitus	2.8	1.2-6.4	0.015
Operative duration >20 minutes	2.5	1.1-5.9	0.028
Intraoperative complications	3.5	1.1-11.2	0.032

[Table/Fig-6]: Exploratory multivariable logistic regression analysis for predictors of PCME.
With 18 PCME events and 3 retained predictors, the model had approximately six events per variable. The confidence interval for intraoperative complications should therefore be interpreted cautiously.

DISCUSSION

The present study found an OCT-detected incidence of PCME of 11.6% within 3 months after cataract surgery. This estimate is higher than rates derived from registry or clinically coded series, but it remains consistent with the broader literature showing that OCT-based surveillance identifies more subclinical and mildly symptomatic oedema than diagnosis based on clinical examination alone [2,3,6]. A recent systematic review also emphasised that the apparent incidence of postoperative macular oedema changes substantially with the diagnostic definition used and the timing of imaging [14].

Diabetes mellitus emerged as the most consistent systemic predictor in the present cohort. More than half of the eyes that developed PCME belonged to patients with diabetes, and the association remained significant after adjustment. This finding agrees with earlier risk-factor studies and with recent database work showing that diabetic retinal vulnerability continues to shape postoperative oedema risk even in the era of modern cataract surgery [1,2,6,15]. Meta-analytic evidence has similarly shown that prophylactic strategies in diabetic eyes need to be considered separately from routine low-risk cataract surgery because the underlying susceptibility is different [8,16].

Hypertension was also more common in the PCME group on univariate analysis. Although it was not retained in the exploratory regression model, the direction of association was clinically plausible. A 2024 retrospective case-control study in eyes without pre-existing fundus disease also reported higher systolic blood pressure among patients who developed clinical PCME after otherwise uneventful phacoemulsification [17]. In the present cohort, hypertension likely reflected the broader vascular and metabolic milieu rather than acting as fully independent determinant once stronger operative and diabetic factors were considered.

Operative stress markers behaved as expected. Eyes that required more than 20 minutes of surgery and eyes with intraoperative complications were more likely to develop PCME, and both remained associated with the outcome on exploratory multivariable analysis. Similar observations have been reported in classic clinical series and in subsequent multicentre database studies, where prolonged manipulation, posterior capsular events, and vitreous disturbance amplified the postoperative inflammatory cascade and increased the risk of macular oedema [1,2]. These findings support the view that the burden of surgical trauma still matters even when postoperative care is otherwise standardised.

The early inflammatory signal was also striking. At one week, anterior chamber reaction grade ≥2 was seen much more often in eyes that subsequently demonstrated PCME. Although this variable was not treated as a baseline predictor in the final model, it provides a clinically useful postoperative warning sign. The same inflammatory sequence was reflected in the OCT measurements. Central macular thickness increased markedly in the PCME group, whereas the change in the non-PCME group remained statistically non-significant. OCT-based longitudinal studies after uncomplicated phacoemulsification have

shown comparable transient or progressive thickening patterns, especially when postoperative inflammation is more pronounced [18].

The functional implication was evident at 3 months, when mean BCVA remained poorer in the PCME group. This does not necessarily imply permanent visual loss, but it does indicate delayed rehabilitation and a longer recovery trajectory. Such behaviour has been described previously in both observational and review-based literature, where some cases settle with topical therapy whereas others require closer structural monitoring and occasionally escalation of treatment [3,5,14].

From a practice perspective, the present findings favour risk-stratified follow-up rather than uniform postoperative surveillance. Contemporary prophylaxis literature has shown benefit from topical non-steroidal anti-inflammatory drugs, either alone or in combination with corticosteroids, particularly in higher-risk eyes [4,7,8,16,19,20]. The findings of this study do not establish causation, but they do support earlier OCT evaluation when diabetes, prolonged surgery, or intraoperative complications are present.

Limitation(s)

The study has certain limitations. It was conducted at a single centre, and the follow-up period was restricted to 3 months. The relatively small number of PCME events limited the complexity of multivariable modelling. Specifically, 18 outcome events and 3 retained predictors yielded approximately six events per variable, below the conventional threshold of ten events per predictor; the odds ratios, particularly for intraoperative complications where the total number of complication events was four, should therefore be interpreted as exploratory rather than definitive. Subtype-specific breakdown of the composite intraoperative complication variable was not available for reliable tabulation, so this variable should be read as a broad surgical-stress marker. Detailed regimen-level analysis of postoperative anti-inflammatory therapy and manufacturer-specific OCT acquisition details were also not available. These limitations should be considered while interpreting the strength and generalisability of the associations.

CONCLUSION(S)

OCT-detected PCME occurred in 11.6% of eyes within 3 months after cataract surgery in this prospective cohort. Diabetes mellitus, operative duration >20 minutes, and intraoperative complications were the strongest associated clinical and operative risk factors in exploratory multivariable analysis. Eyes with more intense early postoperative inflammation also showed greater macular thickening and poorer 3-month visual acuity. These findings support closer OCT-based follow-up in eyes with higher metabolic or operative risk.

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Authors' contribution: SNK contributed to study conception, methodology, clinical supervision, interpretation of findings, critical revision of the manuscript, and final approval. SSK contributed to participant recruitment, clinical follow-up, data collection, literature review, statistical coordination, initial manuscript drafting, and final approval. Both authors agreed to be accountable for the integrity and accuracy of the work.

Use of Artificial Intelligence (AI)-assisted technologies: A generative AI tool was used for language assistance such as grammar and punctuation during manuscript preparation. The scientific content, interpretation, and final approval remained the responsibility of the authors.

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