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Occurrence of cystoid macular edema after uneventful phacoemulsification in diabetic patients without retinopathy: A hospital-based comparative study

Lipika Mehra, Anita Minj, Swati Samant, Pradeep Kumar Panigrahi *, Ramesh Chandra Mohapatra

Department of Ophthalmology, Institute of Medical Sciences and SUM Hospital, Siksha O Anusandhan (deemed to be) University, Bhubaneswar, India

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ABSTRACT

This study aims to determine the incidence of CME after uneventful phacoemulsification in diabetic patients without any signs of retinopathy and nondiabetic patients in early post-operative periods. The present study was a prospective, comparative, hospital-based study conducted from December 2019 to December 2020 in the Ophthalmology department of a tertiary care referral hospital in Eastern India. All patients aged between 50 to 80 years of either sex with cataract grade nuclear sclerosis II–III with or without cortical cataract and early posterior subcapsular cataract undergoing uncomplicated phacoemulsification surgery by a single surgeon were included in the study. The patients were divided into 2 groups. Group 1 consisted of Type 2 diabetes mellitus patients with cataracts with no retinopathy changes on funduscopy and group 2 included healthy non-diabetic patients with cataracts. Comprehensive baseline evaluation including central retinal thickness (CRT) measurement using optical coherence tomography was done in all cases. Best corrected visual acuity (BCVA) and CRT were assessed 1 week and 6 weeks following surgery. Seventy-four patients were included in the study. Both the groups consisted of 37 cases each. The mean age in group 1 and group 2 was 62.24 ± 6.36 and 63.30 ± 6.39 years respectively. One patient in each group developed clinical CME in the postoperative period. The incidence of CME in our study was 2.7%. Improvement in BCVA was comparable in both groups and statistically insignificant. An increase in CRT was found to be statistically significant (P= 0.047) in group 1 at the 6th week follow-up. Visual outcomes in diabetic patients without retinopathy are similar to normal patients following uncomplicated phacoemulsification surgery.

1. Introduction

Cystoid macular edema (CME) is a well-documented complication following cataract surgery. Over the years, advancements in instrumentation and surgical techniques have led to tremendous improvement in surgical outcomes. These days, phacoemulsification is the preferred technique owing to its small corneal incision, less astigmatism, and early rehabilitation. Visual outcomes are usually good after uneventful phacoemulsification surgery. But like any other surgery, even phacoemulsification can be associated with post-surgical complications of which CME is one of the common causes leading to unsatisfactory post-operative vision (Linebarger et al., 1999).

CME is identified by the development of intra-retinal cysts along with fluid accumulation within the retinal layers. Various theories have been put forward explaining the pathogenesis of PCME of which post-surgical release of prostaglandins leading to inflammation and breakdown of the blood-retinal barrier is widely accepted (Ursell et al., 1999; Miyake and Ibaraki, 2002). The incidence of PCME after uneventful phacoemulsification in the healthy population is around 0.1-2.3% (Chu et al., 2016; Yoon et al., 2018). Various risk factors such as any chronic inflammation, uveitis, any preexisting maculopathy, previous ocular surgery and diabetes can affect the development of CME apart from surgical complications. Diabetic retinopathy is a

* Corresponding Author.
Email Address: doc.pkp25@gmail.com (P. K. Panigrahi)
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Corresponding author's ORCID profile:
https://orcid.org/0000-0003-1236-2845

common microvascular complication of diabetes that leads to increased permeability of retinal vessels due to higher release of Vascular Endothelial Growth Factor (VEGF) and other inflammatory cytokines which can predispose a patient to develop macular edema even after an uncomplicated surgery (Hartnett et al., 2009; Hayashi et al., 2009). Nonetheless, diabetes even without any clinical signs of retinopathy can be a risk factor for PCME when compared to a healthy population as found in a few studies (Chu et al., 2016; Oyewole et al., 2017; Katsimpris et al., 2012).

Although fluorescein angiography still has an important role in the diagnosis and confirmation of PCME as well as to differentiate from other causes of macular edema, it's an invasive procedure that can have serious complications and the findings do not always co-relate to the amount of vision loss. Optical Coherence Tomography (OCT) is a non-contact, non-invasive mode of investigation for the human retina which is well established for diagnosing various macular and vitreoretinal interface diseases (Hee et al., 1998; Puliafito et al., 1995). Few studies have tried to characterize PCME on an OCT which reported localized perifoveal edema with cystic spaces mainly at the level of the inner nuclear layer which may be accompanied by a neurosensory detachment (Dysli et al., 2019). OCT has been used to study changes in macula after uncomplicated cataract surgery with heterogeneous results; retinal thickness was found to be increased in some studies (Von Jagow et al., 2007; Nicholas et al., 2006) whereas in others no changes were seen in the early postoperative period (Georgopoulos et al., 2008).

In our present study, we aimed to find the incidence of CME after uneventful phacoemulsification in diabetic patients without any signs of retinopathy and nondiabetic patients in early post-operative periods and also compare the changes in macular thickness and visual outcomes after the surgery in our study population.

2. Materials and methods

This was a prospective, comparative, hospital-based study conducted from December 2019 to December 2020 in the Ophthalmology department of a tertiary care referral hospital in Eastern India. We studied the incidence of CME after uneventful phacoemulsification surgery in diabetic patients without DR and compared it with non-diabetic patients undergoing the same procedure. Informed written consent was obtained from all patients before entering the study. The study adhered to the basic tenets of the Helsinki Declaration. Institutional ethical committee clearance was obtained before starting the study (Ref No DMR/IMS-SH/SOA/180371 dated 29/11/2019).

All patients aged between 50 to 80 years of either sex with cataract grade nuclear sclerosis II –III with or without cortical cataract and early posterior subcapsular cataract undergoing uncomplicated phacoemulsification surgery by a single surgeon (AM) were included in the study. The patients were divided into 2 groups. Group 1 consisted of Type 2 diabetes mellitus patients with no retinopathy changes on funduscopy with cataracts and group 2 included healthy non-diabetic patients with cataracts. Exclusion criteria included diabetic patients with retinopathy changes, patients with other systemic illnesses causing retinopathy, preexisting macular pathology of any other etiology, history of any past intraocular surgery or trauma, intra-operative complications during phacoemulsification surgery, history of intake of medications that can lead to maculopathy, inferior quality OCT scans and patients unwilling to participate in the study. Raosoft™ sample size calculator was used to calculate the sample size. Using a confidence limit of 95%, a sample size of 74 was deemed adequate for the study. Thirty-seven diabetic patients without retinopathy and 37 nondiabetic patients with cataracts were included in the study.

After obtaining informed written consent, detailed history regarding the patient's name, age, sex, occupation, address, presenting symptoms, progression, and associated condition was taken. Detailed history in diabetic patients such as type of diabetes, duration, blood investigations including FBS, PPBS and HbA1c levels, and type of treatment were recorded. Good control of blood sugar was taken as FBS ≤ 126 mg/dl and/or PPBS ≤ 200 mg/dl (American Diabetes Association, 2014). A brief systemic examination was done on all patients. All patients underwent comprehensive ophthalmic evaluation at baseline and 1 and 6 weeks following surgery. Best corrected visual acuity (BCVA) was measured using Snellen's chart. Snellen's equivalents were converted into logarithm of the minimum angle of resolution (LOGMAR) for statistical purposes. Undilated anterior segment examination was done and the grade of cataract was determined in all cases. Intraocular pressure was measured using Goldmann's applanation tonometer. Pupils were dilated using a combination of 1% tropicamide and 2.5% phenylephrine hydrochloride eye drops and posterior segment examination was performed using a slit lamp biomicroscope with +78D lens and indirect ophthalmoscope. K1, K2, and axial length were recorded using Keratometer (Appasamy Associates, Chennai, India) and ophthalmic ultrasound scanner (Sonomed Inc, NY, USA) for A-scan respectively only preoperatively for IOL power calculation.

A spectral domain optical coherence tomography (OCT) scan was done using 3D-OCT Maestro (Topcon medical systems Inc., Tokyo, Japan). 3D macula scan mode with a scan length of 6 × 6 mm and scan resolution of 512 × 218 mm with macular fixation was used for measuring the central retinal thickness (CRT). Macular thickness is usually calculated in 9 regions similar to the ETDRS study from a central point. CRT refers to the average macular thickness in the central 1 mm of the ETDRS grid.

2.1. Surgical procedure

All eyes enrolled in the study underwent uncomplicated phacoemulsification cataract extraction surgery by a single experienced surgeon using the same phaco device. The surgery was done under local anesthesia by giving a peribulbar block and after topical povidone-iodine disinfection. Phacoemulsification surgery was done using WHITESTAR SIGNATURE® PRO phacoemulsification system (Johnson and Johnson Surgical Vision Inc., CA, USA). Foldable acrylic posterior chamber intraocular lens was implanted in the capsular bag in all cases. The parameter studied during the surgery was the total ultrasonic time in foot pedal position 3. All patients were treated postoperatively with topical prednisolone acetate (1%) drops in tapering dose over 6 weeks and topical Moxifloxacin (0.5%) eye drops 4 times/day for 15 days.

Criteria for pseudophakic cystoid macular edema using OCT (Dysli et al., 2019) are as follows:

1. Raised retinal thickness by more than 2 SD
2. The normal foveal contour is flattened
3. Decreased intraretinal reflectivity
4. Presence of distinct intraretinal cystoid spaces mainly at the level of the inner nuclear layer
5. Thicker foveal outer nuclear layer (mainly involving central 1mm ETDRS)
6. Associated Subretinal fluid

All patients were examined 1 and 6 weeks following the cataract surgery. At each visit, a comprehensive ophthalmic examination was done and CRT was measured using OCT in all cases

2.2. Statistical analysis

Appropriate statistical analysis was done at the end of the study period. Data were entered into an Excel sheet. Data has been represented in the form of mean, standard deviation, and percentage. Statistical analysis was done using the Z test and correlation was assessed by calculating Pearson's correlation coefficient. The test was considered statistically significant when the p-value was < 0.05%.

3. Results

A total of 74 eyes of 74 patients were included in the study. The patients were divided into 2 groups. Group 1 consisted of 37 cases of diabetes mellitus without any diabetic retinopathy on clinical examination. Group 2 included 37 age and sex-matched non-diabetic patients. The mean age in group 1 and group 2 was 62.24 ±6.36 and 63.30 ± 6.39 respectively. The majority of patients in both groups were in the 61-70 age group. Seventeen (45.94%) and 19 (51.35%) patients were males in group 1 and group 2 respectively while females contributed to 54.06% and 48.65% of the study and control groups respectively. In group 1, 17 (45.94%) of patients were diabetic for 5 – 10 years while only 9 (24.32 %) of the patients were diabetic for < 5 years. The majority of patients (75.68%) in group 1 were on oral hypoglycemic agents with the rest of the patients (24.32%) requiring insulin therapy. Mean HbA1c levels in group 1 were 7.8 ± 0.58 %. Baseline characteristics including preoperative BCVA, CRT, and mean ultrasonic time were compared between both the groups and were found to be statistically insignificant. Table 1 highlights the salient clinical and demographic characteristics of both groups.

3.1. Incidence of CME

One patient in both groups developed CME during the follow-up period. The incidence of clinical CME calculated in our study population was 2.7% with no difference being noted between groups 1 and 2 which was seen on the 6th week of the postoperative period. The patients who had developed CME in our study were started on topical non-steroidal anti-inflammatory drugs (NSAIDs) (Nepafenac 0.1%) 3 times/day. In both cases, there was a spontaneous resolution of macular edema within 1 month.

Table 1: Demographic data and baseline characteristics of the 2 groups

Variable	Group 1 N (%)	Group 2 N (%)	P-value
Mean age	62.24 ±6.36	63.30 ± 6.39	0.984
Age range			
50-60 years	14 (37.83%)	10 (27.02%)	
61-70years	20 (50.05%)	20 (54.05%)	
71-80 years	3 (8.10%)	7 (18.91%)	
Gender			
Male	17 (45.94%)	19 (51.35%)	
Female	20 (54.06%)	18 (48.65%)	
Pre op BCVA (Mean ±SD)	0.62±0.21	0.71±0.18	0.050
Pre op CRT (Mean ±SD)	212.73±14.75	213.67±15.15	0.803
Ultrasonic time in sec. (Mean ±SD)	47.51± 4.90	48.78±4.92	0.986
Duration of diabetes in years (DM pts)			
<5 years	9 (24.32%)		
5-10 years	17 (45.94%)		
>10 years	11 (29.73%)		
Types of treatment in DM Patients			
OHA	28 (75.68%)		
Insulin	9 (24.32%)		

BCVA: Best corrected visual acuity; CRT: Central retinal thickness; DM: Diabetes mellitus; OHA: Oral hypoglycemic agents

3.2. Comparison of BCVA and CRT during follow up

The visual outcome was evaluated by comparing the values of BCVA in logMAR. Fig. 1 shows the comparison of BCVA between the 2 groups. On applying the ANOVA test, in both the groups there was a significant improvement in BCVA at follow-up time intervals (p= 0.005) but the values were comparable between the groups and statistically not significant (p= 0.423). Table 2 shows the comparison of BCVA between the 2 groups. The changes in CRT were assessed and compared in both groups using the Z test. Fig. 2 highlights the comparison of CRT between the 2 groups. The increase in CRT was found to be insignificant (p> 0.05) at 1st-week post-op in both groups but was statistically significant in group 1 at 6th-week post op (p= 0.047). However, no difference was noted between the groups on any of the follow-up visits. Table 3 depicts the comparison of CRT between the 2 groups.

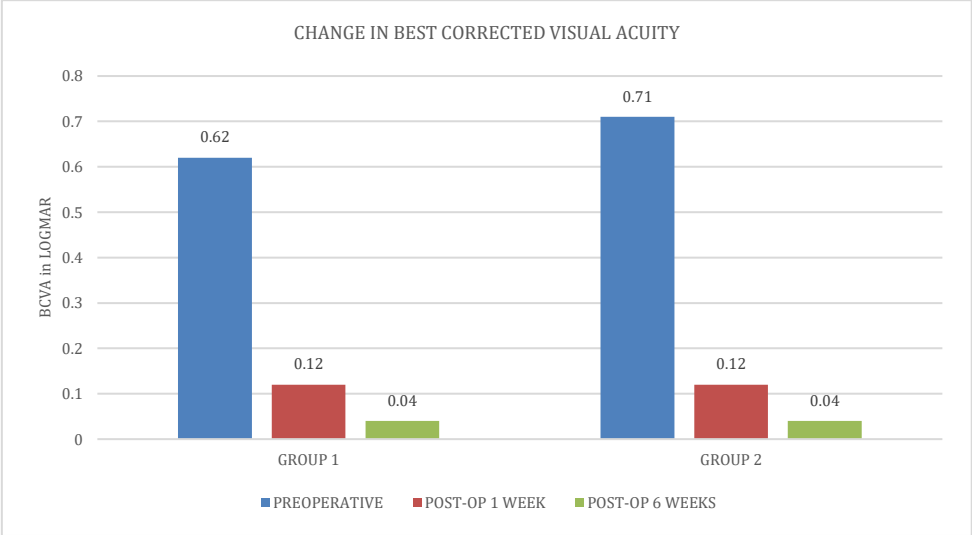

Fig. 1: Comparison of best-corrected visual acuity between the two groups

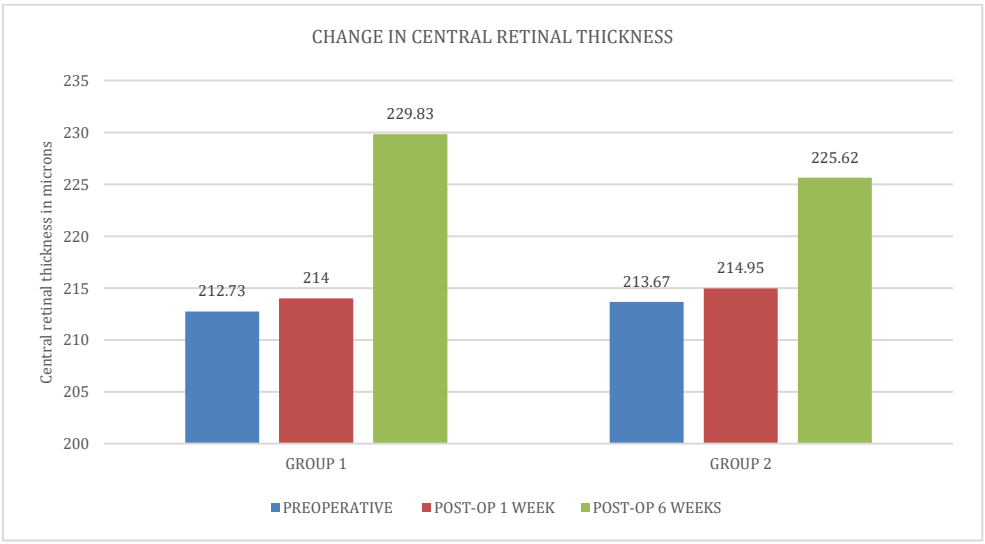

Fig. 2: Comparison of central retinal thickness between the two groups

Table 2: Comparison of BCVA between the 2 groups

Time interval	Group 1		Group 2		P-value
	mean	SD	mean	SD	
Pre-operative	0.62	0.21	0.71	0.18	
Post-op 1 week	0.12	0.10	0.12	0.10	P=0.423
Post-op 6 week	0.04	0.10	0.04	0.09	
P-value from baseline	P= 0.005		P= 0.005		

Table 3: Comparison of Central retinal thickness (CRT) between the 2 groups

TIME INTERVAL	GROUP 1		GROUP 2		P-value
	MEAN	SD	MEAN	SD	
PRE-OPERATIVE	212.73	14	213	15.15	0.803
POST-OP 1 WEEK	214	16.11	214.95	16.11	0.799
POST-OP 6 WEEKS	229.83	50.25	225.62	43.71	0.701
P-VALUE from baseline	P= 0.047		P=0.116		

A statistically significant correlation was seen between HbA1c levels and central retinal thickness preoperatively and postoperatively on both weeks one and week 6 in group 1 ($p< 0.05$ on all three occasions). No statistically significant correlation was observed between BCVA and CRT at 1-week postoperatively in both Group 1 and Group 2. Fig. 3a shows the correlation between BCVA and CRT in group 1 patients in 1st post-operative week. Fig. 3b shows the correlation between BCVA and CRT in group 2 patients in 1st post-operative week. At 6 weeks postoperatively, a statistically significant correlation was found between BCVA and CRT in both groups 1 and 2 with the p-value being extremely significant ($p< 0.001$). Figs. 3c and 3d show a statistically significant correlation between BCVA and CRT in both groups at the 6th post-operative week.

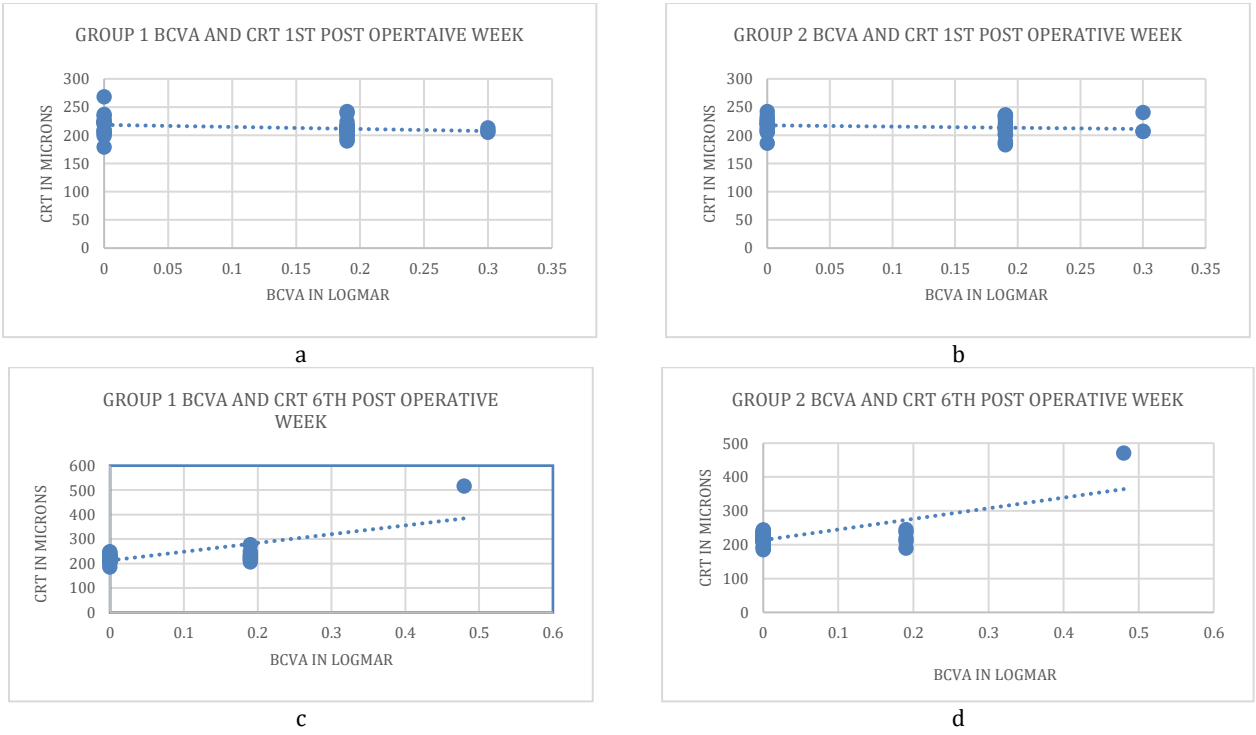

Fig. 3: (a) Correlation between BCVA and CRT in group 1 patients at 1st post-operative week. No statistically significant correlation was noted with P-value = 0.152, (b) Correlation between BCVA and CRT in group 2 patients at 1st post-operative week. No statistically significant correlation was noted with a P-value = 0.398, (c, d) Statistically significant correlation was noted between BCVA and CRT in both groups at the 6th post-operative week with $P < 0.001$

4. Discussion

Previous studies have demonstrated that clinically significant CME is generally seen 4-12 weeks following cataract surgery with a peak incidence between 4-6 weeks (Loewenstein and Zur, 2010; Yonekawa and Kim, 2012). In our prospective observational study, the patients were followed up in an early post-operative period of up to six weeks to evaluate the occurrence of cystoid macular oedema following uneventful phacoemulsification in nondiabetic patients and diabetic patients with no signs of retinopathy and assess changes in retinal thickness between the preoperative and postoperative values using an SD-OCT as the mode of investigation. Although fluorescein angiography remains the gold standard for confirming the diagnosis of CME, its invasive nature, possible side effects of the dye, and inability to quantify the leakage have led to other investigative modalities to be used which as OCT is being widely used. OCT is a non-invasive, faster, and safer technique that can assess macular changes both qualitatively and quantitatively hence was used as the investigation of choice in our study. Despite this, it comes with a share of limitations like poor signal strength due to significant media opacities like cataracts which may affect the reliability of the scans. Also, an apparent increase in retinal thickness was seen with increased signal strength following cataract extraction but this error is usually very small (Von Jagow et al., 2007). To avoid this bias, patients with only good signal strength in the preoperative OCT were included in our study.

In the present study, the average age group for diabetic eyes was 62.24 ± 6.36 years and in non-diabetic eyes was 63.30 ± 6.39 years with no significant difference between the groups. Amongst the diabetic group, maximum patients (45.94 %) had diabetes for 5-10 years of duration and 75.68% of the patients were on oral hypoglycemic agents. In their study, Pukl et al. (2017) found the mean age group in diabetics (73.5 ± 7.01) slightly higher than non-diabetics (68.8 ± 4.70). Around 75% of the diabetic patients were on oral hypoglycemic agents similar to our study. The incidence of clinically significant CME in the present study was 2.7%. This is slightly more than the incidence of 0.1-2.3% reported in other studies following uncomplicated phacoemulsification (Chu et al., 2016; Yoon et al.,

2018). However, it will be harmless to say that the incidence of PCME can depend on various factors like surgeon experience, study design, follow-up period, sample size, etc. Our results were contrary to studies conducted by Guliani et al. (2019) where no case of clinical CME was detected and Deshpande et al. (2018) where 2 patients out of 30 had developed subclinical CME. The incidence of PCME as reported by Oyewole et al. (2017) in their study was 7.6% in the entire study population which was predominantly diabetic with 34% of patients having diabetic retinopathic changes. They found a statistically significant difference in the diabetic group (10.7%) as compared to the non-diabetic group (3.5%) which was different from our study where both groups had the same incidence of 2.7%.

We compared all the baseline characteristics of the patients in between the groups preoperatively to document any intergroup preoperative disparity which may have affected the postoperative outcomes in any of the groups. No significant difference in age of presentation, ultrasonic time, and CRT was found between the 2 groups. However, BCVA was significantly higher in group 2 as compared to group 1 with a p-value of 0.047. Similar results were recorded by Katsimpris et al. (2012) and Wang and Cheng (2014) except for the BCVA which was also indifferent between the groups. Nevertheless, to the best of our knowledge, this difference in BCVA would not have affected any post-surgical results in our study. BCVA was assessed during follow-up of the patients which showed significant postoperative improvement in both diabetic and non-diabetic groups (p= 0.005) but the intergroup changes were comparable in all follow-up periods with p=0.42. Similar results were reported by Wang and Cheng (2014). However, Katsimpris et al. (2012) who followed up the patients up to 12 months post-surgery found out that the mean BCVA of the control group was stable during follow-up while the diabetic group showed a gradual decline over time with significantly lower BCVA at 12th month as compared to the 1st month.

In our study, no significant increase in CRT was noted on post-op 1 week in either of the groups while on the 6th week, the diabetic group showed a significant increase with p= 0.047 but the changes in the non-diabetic group were insignificant. However, when intergroup comparison was done, no difference was noted between the 2 groups. Similar results were obtained by Wang and Cheng (2014) in their retrospective study who found a significant increase in CRT on post-op 4th week in both non-diabetic and diabetic without retinopathy with no intergroup variability. A significant positive correlation was found between HbA1c and CRT values on all occasions in the diabetic group in our study. Singhi and Baishya (2017) who studied changes in foveal thickness in 3 groups (non-diabetic, diabetic without DR, and diabetic with DR) also reported a significant correlation between HbA1c and foveal thickness in diabetic patients with or without DR similar to our study.

The present study has a few drawbacks. The sample size is small and the results of the study cannot be extrapolated to the entire population. Studies have demonstrated that PCME can occur late in the postoperative period. Our study is limited by the shorter duration of follow-up.

5. Conclusion

Our study shows that PCME can occur as a complication even after an uneventful modern-day cataract surgery such as phacoemulsification though its incidence is much less as compared to previously performed surgical techniques. OCT is an excellent tool for diagnosis of PCME, quantifying even subtle and insignificant changes in the macula which can occur in the postoperative period. The overall incidence of macular edema, macular changes, and visual outcomes were comparable between the groups. Therefore, we could infer that in a diabetic patient, unless there are no signs of retinopathy, the visual recovery and changes in macula were as good as a healthy non-diabetic person.

Compliance with ethical standards

Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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