International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Study of Changes in Central Macular Thickness in Patients with Diabetes Mellitus Before and After Cataract Surgery

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Abstract

Purpose: To study the changes in central macular thickness (CMT) in diabetic patients before and after cataract surgery using optical coherence tomography (OCT) and compare on the basis of grades of diabetic retinopathy (DR).

Methods: This is a prospective observational, single centre hospital based study including 94 patients with diabetes mellitus undergoing phacoemulsification surgery at our hospital. The pre-op stage of DR, best corrected visual acuity (BCVA), CMT, glycosylated hemoglobin (HbA1c) levels were recorded and the data compared with post-op BCVA, CMT measured at one week, four weeks and three months post-op. ANOVA: Two factor without multiplication and Karl Pearson's correlation coefficient were used for statistical analysis.

Results: A total of 6.4% (6) patients developed post-operative clinically significant macular edema (CSME) out of which 9% had moderate non proliferative diabetic retinopathy (NPDR), 16.6% had severe and very severe NPDR. 58.5% (55) were found to have sub clinical macular edema (SCME) detected by OCT-macula, which includes 11 (45.8%) no DR cases; 14 (58.3%) cases of mild NPDR; 14 (63.63%) cases of moderate NPDR; 16 (66.67%) cases of severe and very severe NPDR (p=0.000133). The post-operative BCVA at week four, for patients with no DR; mild NPDR; moderate NPDR; severe and very severe NPDR is 20/25; 20/30; 20/40; 20/40 respectively showing lesser BCVA in patients with higher grades of diabetic retinopathy than those with mild NPDR or no DR. Among the patients who had either SCME or CSME post-operatively, it was found that 17 had pre-op SCME of which 4 had moderate NPDR and 13 had severe or very severe NPDR. The maximum rise in central macular thickness, was observed in patients with pre-operative moderate, severe and very severe NPDR and those having pre-operative sub-clinical macular oedema. Among those developing CSME, 100% had uncontrolled blood sugar (UCBS) levels, and those with SCME, only 29.09% had controlled blood sugar (CBS) while rest 70.91% had UCBS.

Discussion: It was found that those patients with an UCBS, pre-existing severe DR and SCME developed a significant increase in central macular thickness, following cataract surgery. It can be concluded that in diabetic patients the blood sugar levels and pre-operative stage of DR are important prognostic factors in determining post-operative macular thickness and visual recovery post cataract surgery.

Keywords: Diabetic Retinopathy; Cataract surgery; Central macular thickness; Optical coherence tomography

Introduction:

Diabetes mellitus and cataract are among the highly prevalent diseases in India, affecting a large group of population.[1,2] It is well established that diabetes or raised blood sugar level leads to varying grades of diabetic retinopathy. Although various studies have shown that proper glycaemic control reduces the risk of new onset diabetic retinopathy and also arrests further progression of diabetic retinopathy that has set in.[3] It has been observed in some studies that diabetic macular oedema worsens after cataract surgery, although there remains a controversy as to the incidence and degree of worsening.[4,5] There are two types of worsening reported: transient psuedophakic oedema which was caused by the surgery itself and the actual progression of diabetic maculopathy.[6] This study was conducted to observe and document the changes in central macular thickness post phacoemulsification surgery and compare them based of severity of diabetic retinopathy (DR), graded according to Early Treatment Diabetic Retinopathy Study (ETDRS).[7] Patients with cataract were graded according to LOCS III (Lens opacities classification system) classification.[8] Central macular thickness (CMT) has been observed to increase in diabetic patients post cataract surgery according to several studies which is the parameter used to document macular edema.[9] Although the relation between diabetic retinopathy and increase in post cataract CMT affecting final best corrected visual acuity (BCVA) has been established in many studies, data on the comparison of increase in CMT based on severity of diabetic retinopathy in Indian population is not abundant.[10-13] In the present study it was also aimed to find the correlation between blood sugar level and central macular thickness in diabetic patients using Optical coherence tomography macula (OCT-macula)[14,15]

Methods:

During the study period of 15 months from December 2022 to February 2024, patients who visited the ophthalmology OPD of this hospital and fulfilled the inclusion criteria were included in the study. The procedures that the patients underwent had been explained to them beforehand, after which they were made to sign informed consent forms regarding the same. The study was conducted after receiving clearance from the institutional ethical committee. All the patients presenting with features suggestive of cataract and history of diabetes mellitus (DM) were further examined to check for their eligibility to be included in the present study, which are as follows:

Inclusion criteria: Patients more than 40 years of age, history of diabetes mellitus, patients with cataract upto grade three (cortical, nuclear, posterior sub-capsular) according to LOCS III (Lens opacities classification system) classification, who agreed to undergo phacoemulsification, patients who continued follow up till atleast three months post-operatively ;

Exclusion criteria: Less than 40 years of age, patients lost to follow up, history of ocular pathology other than diabetic retinopathy and cataract, pre-operative clinically significant macular edema (CSME) or proliferative diabetic retinopathy (PDR), history of any ocular intervention in the eye included for the study, higher grades of cataract rendering visualization of fundus difficult. The visual acuity of all participants was measured with the help of Snellen's chart. Their uncorrected, best corrected and pin-hole visions were noted down. The anterior segment of all participants was examined with the help of Appasamy slit lamp bio-microscopy and the grade of their cataract was established on the basis of LOCS

III . Later for posterior segment examination, the patient's pupils were dilated with the help of eye drops-tropicamide+phenylephrine. The subjects then underwent Fundus examination with the help of Volk 90D lens and Indirect ophthalmoscopy, which was followed by OCT-Macula examination, on Appasamy SD OCT instrument.[16] On the basis of fundus examination, we divided the patients into four groups, patients with no diabetic retinopathy; patients with mild NPDR, moderate NPDR, severe and very severe NPDR according to ETDRS classification of diabetic retinopathy (DR).[17]The duration for which they had diabetes was noted along with their glycosylated hemoglobin (HbA1c) levels. Accordingly those patients were divided into two groups, the patients who had controlled blood sugar (CBS) and the patients with uncontrolled blood sugar (UCBS).[18] Through OCT-Macula, Central Macular thickness (CMT) was recorded and based on DRCR.net study, number of patients having sub-clinical macular edema (SCME) was noted i.e. CMT between 225 - 299µm, those with clinically significant macular edema were excluded from the study.[6] All the patients underwent phacoemulsification. After all the surgeries were concluded, uneventfully by the same surgeon, the best corrected visual acuity (BCVA) of the patients was again assessed with the help of Snellen's chart the next day and at one week, four weeks and three months. OCT-Macula was used to record the central macular thickness; and fundus examination was again repeated post-operatively at one week, four weeks and three months. The central macular thickness of the post-operative values is then compared with that of the pre-operative values among the patients with different grades of DR. Later we compare all values to see if there is any correlation between HbA1c values, diabetic retinopathy status of the patient pre-operatively and development of post operative clinically significant Macular oedema and sub-clinical macular oedema.[19]

Statistical Analysis:
The data has been collected and entered in MS excel (latest version). Two null hypotheses have been formed: 1) H_0: Average CMT of all kinds of patients is equal i.e. there is no significant difference between average CMT of patients with different grades of DR. 2) H_0: Average CMT of all patients remains same before and after the operations. ANOVA: Two factor without multiplication (to either confirm or reject the null hypotheses) and Karl Pearson's correlation coefficient were used for statistical analysis.

Results:
A total of 94 patients were included in the present study. The pre operative characteristics and demographic details are mentioned in Table one. It is observed that, out of 94 patients, 49(52.13%) were females and 45(47.87%) were males. A total of 24(25.5%) patients had no diabetic retinopathy (DR), 24(25.5%) had mild NPDR; 22(23.4%) had moderate NPDR; 24(25.5%) had severe and very severe NPDR. The mean HbA1c of patients with no diabetic retinopathy, mild NPDR, moderate NPDR, severe and very severe NPDR are, 5.8; 6.2; 6.8 and 7.4 respectively. The mean pre-operative BCVA of patients with no diabetic retinopathy, mild NPDR, moderate NPDR, severe and very severe NPDR is 20/120; 20/200; 20/400; 20/400 respectively.
Table two shows changes in CMT and best corrected visual acuity (BCVA) measured at one week, four weeks and three months post operatively among patients with different grades of diabetic retinopathy. The post-operative BCVA at week four, for patients with no DR; mild NPDR; moderate NPDR; severe and very severe NPDR is 20/25; 20/30; 20/40; 20/40 respectively showing lesser BCVA in patients with higher grades of diabetic retinopathy than those with mild NPDR or no DR.

It was found that a total of 6 patients developed post-operative clinically significant macular edema (CSME) according to DRCR.net study (i.e. CMT more than 299µm) out of which 2 (9%) had moderate NPDR and 4 (16.67%) had severe & very severe NPDR. 55 (patients were found to have sub-clinical macular oedema, of which 11 (45.83%) had no DR; 14 (58.33%) had mild NPDR; 14 (63.63%) had moderate NPDR; 16 (66.67%) had severe & very severe NPDR. Among the patients who had either SCME or CSME post-operatively, it was found that 17 had pre-op SCME of which 4 had moderate NPDR and 13 had severe or very severe NPDR. The maximum rise in central macular thickness, was observed in patients with pre-operative moderate, severe and very severe NPDR and those having pre-operative sub-clinical macular oedema illustrated in figure one.

Two null hypotheses are formed: 1) H_0: Average CMT (Central macular thickness) of all kinds of patients is equal i.e. there is no significant difference between average CMT of patients with different grades of diabetic retinopathy. 2) H_0: Average CMT of all patients remains same before and after the operations. Summary of values of pre-op and post-op CMT and number of patients with different grades of retinopathy is mentioned along with their variance in table three which forms the basis for ANOVA: Two factor without replication calculations which is depicted in table four.. As p-values are < 0.05 we reject both the null hypotheses, therefore indicating that: 1) there is significant difference between average CMT of patients with different grades of DR; 2) there is significant difference between pre op and post op CMT.

Table five shows distribution of patients having macular edema post-op (either SCME or CSME) with respect to their pre-op HbA1c levels. HbA1c <5.7% was categorized as controlled blood sugar (CBS) whereas HbA1c >5.7% as uncontrolled blood sugar (UCBS) . Out of the patients with CBS, 16 had SCME of which 5 (20.83%) had no DR; 8 (33.33%) had mild NPDR; 5 (23%) had moderate NPDR; 6 (25%) had severe or very severe NPDR. None of those with CBS developed CSME post op whereas among the 6 patients who developed CSME, all had uncontrolled blood sugar. Out of those, 2 (9%) had moderate NPDR; 4 (16.67%) had severe or very severe NPDR. 39 patients with UCBS had sub-clinical macular oedema; out of which 6 (25%) had no DR, 11 (46%) had mild NPDR, 12 (54.5%) had moderate NPDR and 10 (42%) had severe or very severe NPDR. The Karl Pearson Correlation coefficient between HbA1c and pre-operative CMT is 0.98 (approx.) which indicates that higher value of HbA1c is positively correlated with raised central macular thickness.

Discussion:

It has been observed in previous studies that patients with diabetes mellitus undergoing cataract surgery have a higher incidence of development of post operative, clinically significant macular oedema. In several studies, observations were made that the peak of post-operative macular oedema was observed between three months to six months.[22] According to these observations, the central macular thickness started reducing after six months. In this study it was observed that the central macular thickness rises and peaks at four weeks post-operatively and reduces by three months.[23] The post operative macular oedema observed after cataract surgeries is generally pseudophakic cystoid macular oedema, which tends to resolve spontaneously, however similar outcomes have not been observed with diabetic macular oedema which persists or even increases post-operatively.[25] The risk for development of post operative macular oedema is higher in diabetics with higher grades of diabetic retinopathy as well as pre-existing sub-clinical macular oedema. No differences were observed in the central macular thickness between patients with no diabetes mellitus and diabetic patients without diabetic retinopathy, pre-operatively in other studies. In the present study it was observed that those patients who have uncontrolled blood sugar levels had developed

post-operative macular oedema. Although some studies have found that such a correlation between HbA1c and post-operative central macular thickness does not exist. Raised blood sugar levels have also been found to be associated with with pre-operative grades of diabetic retinopathy like non-proliferative diabetic retinopathy .

In the present study it has been evaluated that the central macular thickness of all 94 patients pre-operatively and observed that the thickness was comparatively more in the group of patients who had higher grades of diabetic retinopathy. Also all the patients with higher central macular thickness were observed to have uncontrolled blood sugar. Higher grades of cataract have also been found to have a correlation with development of post operative macular oedema but in the present study only the patients with cataract upto grade three (LOCS III) have been included so as to eliminate its confounding effect.

Correlation between higher levels of HbA1c and development of post-operative macular oedema was also observed by Varma et al.[3] According to a study conducted by Henricsson M. patients with raised blood sugar levels for over thirty years were the ones developing diabetic retinopathy which in turn became the most implicated factor for the development of post-operative clinically significant macular oedema.[21] Similar observations were also made in the present study where there was a significant correlation of post-operative macular oedema with long standing diabetes mellitus. Central macular thickness increased significantly in patients who already had higher grades of retinopathy before undergoing cataract surgery at fourth week. In the studies conducted by Mittra A. R. et al a progression of higher grades of diabetic retinopathy as well as an increase in macular oedema was observed post surgically, similar to findings in the present study.[23]

In a study conducted by Gallego-Pinazo R. et al and other studies, the development of post-operative macular oedema was heavily dependant on the grade of diabetic retinopathy and macular oedema that the patient had pre-operatively as has been observed in the present study as well.[24].

Other findings that were similar to ours were from the study by Garcia-Martin E. et al that studied the patients with diabetic retinopathy before and after cataract surgery with the help of Cirrus and Spectralis OCT and have shown that in patients who had pre-operative Diabetic retinopathy, there were increased chances of developing post-operative macular oedema.[20]

Conclusions

In this study, it was found that those patients with an UCBS, pre-existing severe DR and SCME developed a significant increase in central macular thickness, following cataract surgery. It can be concluded that in diabetic patients the blood sugar levels and pre-operative stage of DR are important prognostic factors in determining post-operative macular thickness and visual recovery post cataract surgery.

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Tables and figures:

Table 1- Pre op characteristics and demographic details

Table 2- Changes in Central macular thickness and BCVA after surgery with respect to grades of Diabetic Retinopathy

Table3: Summary of values of pre-op and post-op CMT and number of patients with different grades of retinopathy and their variance.

Table4: ANOVA table

Table 5: Macular edema in grades of Diabetic Retinopathy in relation to blood sugar levels.

Figure1: Pre-op and post-op macular edema in different grades of diabetic retinopathy

		No DR	Mild NPDR	Moderate NPDR	Severe & Very Severe NPDR
No. of eyes		24 (25.5%)	24 (25.5%)	22 (23.4%)	24 (25.5%)
OD (Right eye)		14 (58%)	15 (62.5%)	11 (50%)	13 (54.2%)
Age (mean ± SD)		57±1.45	61±1.67	68±1.59	72±206
Gender	M	11	14	13	11
	F	13	10	9	13
Duration of DM (Mean years ± SD)		7.8±1.5	11.1±2.8	18.3±6.9	21.7±9.3
HbA1c in % (mean ± SD)		5.8±1.27	6.2±1.02	6.8±0.97	7.4±1.89

BCVA (Snellen) (mean)	20/120	20/200	20/400	20/400
CMT (µm) (mean ± SD)	209±10	213±11	219±16	238±22
No. of cases with SCME (CMT = 225-299µm)	0	0	4	13

Table 1- Pre op characteristics and demographic details

DR- Diabetic Retinopathy,NPDR- non-proliferative diabetic retinopathy, BCVA- Best corrected visual acuity, CMT- central macular thickness, DM- Diabetes Mellitus, SCME: sub-clinical macular oedema; SD - Standard deviation

	No DR	Mild NPDR	Moderate NPDR	Severe & Very Severe NPDR
CMT Pre-Op(µm) [Avg]	209	213	219	238
CMT PostOp 1 week(µm) [Avg]	222	234	237	267
CMT PostOp 4 weeks(µm) [Avg]	235	266	271	282
CMT PostOp 3 months(µm) [Avg]	228	241	264	279
Pre-Op BCVA (Mean)	20/120	20/200	20/400	20/400
PostOp BCVA 1week (Mean)	20/20	20/25	20/30	20/36
PostOp BCVA 4week (Mean)	20/25	20/30	20/40	20/40
PostOp BCVA 3months (Mean)	20/23	20/24	20/30	20/40

Table 2- Changes in Central macular thickness (CMT) and Best corrected visual acuity (BCVA) after surgery with respect to grades of Diabetic Retinopathy

CMT - Central macular thickness; DR - diabetic retinopathy; NPDR - Non-proliferative diabetic retinopathy; BCVA - Best corrected visual acuity; Avg - Average

SUMMARY	*Count*	*Sum*	*Average*	*Variance*
CMT Pre-Op(µm) [Avg]	4	879	219.75	164.9167
CMT PostOp 1 week(µm) [Avg]	4	960	240	366
CMT PostOp 4 weeks(µm) [Avg]	4	1054	263.5	405.6667
CMT PostOp 3 months (µm) [Avg]	4	1012	253	522
No DR	4	894	223.5	121.6667
Mild NPDR	4	954	238.5	477.6667
Moderate NPDR	4	991	247.75	582.25

Severe & very severe NPDR	4	1066	266.5	403

Table 3: Summary of values of pre-op and post-op CMT and number of patients with different grades of retinopathy and their variance.

CMT - Central macular thickness; DR - Diabetic retinopathy; NPDR - Non-proliferative diabetic retinopathy; Avg - Average

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Rows (Pre and post op.)	4261.188	3	1420.396	25.95318	0.000091	3.862548
Columns (Diabetes mellitus)	3883.188	3	1294.396	23.65093	0.000133	3.862548
Error	492.5625	9	54.72917			
Total	8636.938	15				

Table 4: ANOVA table

SS- Sum of square; df - degree of freedom; MS - Mean sum of square; F crit - Formula critical

		No DR	Mild NPDR	Moderate NPDR	Severe & Very Severe NPDR
CBS PostOp	CSME	0	0	0	0
	SCME	5(20.83%)	3(12.5%)	2(9%)	6(25%)
CBS No PostOp ME		7(29.2%)	8(33.33%)	5(23%)	4(16.67%)
UCBS PostOp	CSME	0	0	2(9%)	4(16.67%)
	SCME	6(25%)	11(46%)	12(54.5%)	10(42%)
UCBS No PostOp ME		6(25%)	2(8.33%)	1(4.5%)	0
HbA1c (mean)		5.8	6.2	6.8	7.4
CMT (PreOp) (mean)		209	213	219	238
Correlation coefficient		0.979386614			

Table 5: Macular edema in grades of Diabetic Retinopathy in relation to blood sugar levels.

DR- Diabetic retinopathy; NPDR- Non-proliferative diabetic retinopathy; Post-op ME - Post-operative macular oedema, CSME- Clinically significant macular oedema, SCME- sub-clinical macular oedema, CBS- controlled blood Sugar[<5.7%], UCBS- uncontrolled blood Sugar[>5.7%]; CMT - Central macular thickness