Section: Ophthalmology

Original Research Article

COMPARATIVE STUDY OF CENTRAL MACULAR THICKNESS IN DIABETIC PATIENTS WITH RETINOPATHY AND WITHOUT RETINOPATHY USING SPECTRAL DOMAIN OPTICAL COHERENCE TOMOGRAPHY

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Received : 10/05/2025
Received in revised form : 16/06/2025
Accepted : 23/07/2025

Keywords:
Diabetic Retinopathy, Central Macular Thickness, Spectral Domain Optical Coherence Tomography, Diabetic Macular Edema.

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DOI: 10.47009/jamp.2025.7.4.166

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (4); 885-889

ABSTRACT

Background: Diabetic retinopathy (DR) is one of the common complications of diabetes mellitus due to microangiopathy. Macular edema is one of the important signs in patients with DR which progress to complete blindness. Macular edema can develop at any stage of DR. Optical coherence tomography (OCT) is a non-invasive third-generation imaging modality with the advantages of high resolution and speed that has been used to assess CMT and volume. Early diagnosis with screening and timely interventions can delay the sight threatening complication of DR. **Materials and Methods:** This was a cross-sectional hospital-based comparative study which was conducted in 80 diabetic patients with two groups (Group A-without DR - 40 patients, Group B with DR-40 patients). CMT was measured using SD-OCT and biochemical parameters were analyzed in all cases. The mean CMT was correlated with age and duration of diabetes. **Result:** The mean CMT was 218.80±33.89µm in without DR patients (group A) and 294.65±91.29µm in with DR patients (group B) and it was statistically significant (P value 0.001) No statistically significant association of CMT was found with age and duration of diabetes. **Conclusion:** The present study shows that CMT is more likely to be influenced by DR. The CMT was found to be high in patients diagnosed with DR.

INTRODUCTION

Diabetes mellitus is characterized by hyperglycemia which results in damage to various organs such as kidneys, brain, feet and Retina.[1] The world health organization (WHO) global burden of disease study has predicted that prevalence of diabetes is likely to increase from 451 million in 2017 to about 693 million in 2045.[2]

One of the leading cause of blindness among people aged 20 to 65 years is diabetic retinopathy.[3] The pathogenesis is a microangiopathy predominantly affecting precapillary venules and large vessels.[3] The incidence raises with the increased duration of the disease. Retinopathy is said to occur more commonly in type 2 than in type 1 diabetes mellitus. About 10% of people with diabetes are affected with macular edema who may worsen to complete blindness. Early diagnosis and initiation of treatment with reasonable metabolic control can prevent disease complications.[4]

The central macula is very susceptible part of the retina and is responsible for changes in visual acuity.[4,5] Disruption of internal blood – retinal barrier leads to leakage of lipid exudates which accumulates in the retinal layer, resulting in macular edema. It is considered a substantial cause of vision loss in diabetic Retinopathy.[4] Therefore, evaluation of central thickness of the macula is essential to prevent blindness. Thickness values of the central 1mm circular area around fovea was analyzed for the study.[5]

Noncontact imaging techniques such as optical coherence tomography (OCT) have been used to diagnose various macular disorders. It has been used to quantify thickness of macula for the diagnosis, treat and also to detect any asymptomatic thickening of macula in diabetic Retinopathy.[6] It produces an in

ISSN (O): 2687-5365; ISSN (P): 2753-6556

vivo optical biopsy of retinal layers with high reproducibility in macular thickness and volume measurements.[6,7] In spite of normal fundus findings with an ophthalmoscope OCT can detect initial alterations in retinal thickness .

The association between DR and CMT even though is a known factor, some studies has showed variable results. Some have revealed that the macula of individuals with diabetes who did not have retinopathy was thicker than that of non-diabetic controls,[8,9] Some have reported that stage 1 diabetic retinopathy had noticeably thinner pericentral macula,[10-13] Most of them compared healthy controls with either diabetics or nondiabetics.

This study was conducted to assess and compare the changes in central macular thickness (CMT) in diabetic patients with and without Retinopathy using OCT. Regular screening, diagnosing early and prompt intervention can postpone the sight-threatening complications of diabetic Retinopathy.

MATERIALS AND METHODS

The present study was conducted in the department of Ophthalmology, SMVMCH which is a tertiary care hospital located in Pondicherry in South India. It is a multidisciplinary hospital with approximately 300 diabetic patients visiting general OPD every month mostly rural areas in and around Pondicherry and Villupuram districts.

It was a Cross-Sectional Hospital-Based Comparative Study done for a period of 18 months.

Diabetic patients who visited the outpatient department of ophthalmology in Sri Manakula Vinayagar Medical College and Hospital Pondicherry were included in the study.

Sample size was calculated using open EPI version 3, with 95% confidence interval, 80% power, and Mean (M) ±standard deviation (SD) of central macular thickness in patients without diabetic retinopathy 244.55 ± 23.67 µm and with diabetic retinopathy 288.89 ±96.73 µm.1 The total sample size calculated was 80. No of patients without diabetic retinopathy were 40 and patients with diabetic retinopathy were 40. Consecutive sampling technique was used.

Inclusion criteria included all the diabetic patients visiting OPD within the age group of 20-80 years.

Patients with history of retinal laser treatment, co-existing macular pathology, previous ocular surgery, hypertension, dyslipidemia, glaucoma, and previous ocular trauma were excluded from the study.

Sampling Procedure

The Institutional research and ethical committee approval was sought for the study (Study no.EC/03/2021). The study procedures were done in compliance with tenets of the Declaration of Helsinki. The participants provided informed consent for participation in the research. The study included all diabetic patients, both male and female, aged above 20 and under 80, who visited the outpatient department (OPD) with or without retinopathy. Patients were placed in one of the two groups. Using a successive sample technique, Group A consisted of diabetic patients without retinopathy, while Group B consisted of diabetic patients with retinopathy. Detailed history of the patient regarding name, age, sex, occupation, address duration of diabetes, diabetes medical management, other comorbid conditions and past medical history was recorded. Ocular specific symptoms were also noted down. Gross systemic examination was done. HbA1C was assessed for evaluating glycemic control. Best-corrected Visual acuity was assessed using Snellen's chart. Near vision assessment done using a jaegers chart. Thorough evaluation of anterior segment was done with a Slit lamp examination. Intraocular pressure was measured by an applanation tonometer. Dilated Stereoscopic Fundus examination was done by slit lamp biomicroscopic examination with +90 D lens and indirect ophthalmoscopy.

According to Early Treatment studies for Diabetic Retinopathy Criteria, Group B patients were further divided into (1) Non-Proliferative Diabetic Retinopathy features (2) Proliferative Diabetic Retinopathy features and (3) Clinically significant Macular Edema.

After pupillary dilatation, all participants underwent macular imaging utilizing SD-OCT optical coherence tomography (Topcon 3D OCT-1 Maestro 2). The macular thickness was measured using the 3D retinal topography which is a fast macular scan protocol.

Data Analysis: IBM SPSS 26 version software was used for data analysis. Descriptive analysis was conducted on mean and standard deviation for quantitative variables, and frequency and ratio for categorical variables. Percentages were used to display categorical data. The normal distribution was evaluated using the Shapiro-Wilk test. ANOVA (>2 groups) and the independent samples t-test (2 groups) were used to compare scores that were normally distributed. P-value of <0.05 was judged to be statistically significant.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

RESULTS

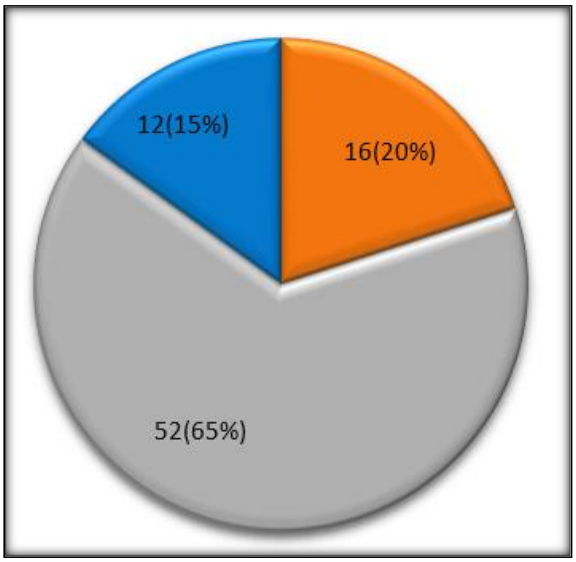

Figure 1 depicts age distribution of the study participants. The mean age of the study group was 49.10±10.18 years

For the purpose of the study, 80 individuals were chosen, 40 of whom had normal fundus and 40 of whom had diabetes with different stages of diabetic retinopathy

Majority of them in this study were in the age group of 41-60. Sixteen (20%) participants were between 20 to 40 years, 52 (65%) were between 41 to 60 years and 12 (15%) were >60 year

The ratio of male to female was 1.3: 1, among the study population. Male participants were 45 and the remaining 35 were female participants. Forty-five (56.3%) participants had a duration of diabetes less than 5years, 24 (30%) had less than 6 to 10 years and 11 (13.8%) had more than10 years. The duration of type 2 diabetes in the study group had a mean value of 6.13±5.88 years

Comparison of DM duration between group A and group B:

[Table 1] summarizes the comparison of duration between the groups. In group A 34 (85%) had a duration of diabetes up to 5 years and 6 (15%) participants had 6 to 10 years. In group B 11 (27.5%) participants had a duration of diabetes up to 5 years, 18 (45%) had 6 to 10 years and 11 (27.5%) had > 10 years duration.

Table 1: Comparison of CMT with DM duration in group A AND group B (N=80)

	DM Duration (in years)	No. of patients	CMT (µm)	P value
Group A (N=40)	<5YRS	34	217.87 ± 35.55	0.561
	6-10 YRS	6	224.08 ± 22.63	
	>10 YRS		-	
Group B (N=40)	<5YRS	11	262.36 ± 69.83	0.135
	6-10 YRS	18	311.14 ± 109.36	
	>10 YRS	11	299.95 ± 70.40	

Comparison of CMT with DM duration in group A and group B The mean CMT was 217.87 ± 35.55 µm, in patients with a duration of DM less than 5 years and 224.08 ± 22.63 µm in 6 to 10 years among Group A, but the association between DM duration and CMT was not statistically significant (P value= 0.561). The mean CMT was 262.36 ± 69.83 µm in patients with a duration of DM less than 5 years, 311.14 ± 109.36 µm in 6 to 10 years and 299.95 ± 70.40 µm in more than 10 years in group B. But the association between DM duration had no statistical significance (P value= 0.135). Mean CMT and its comparison with duration is shown in [Table 1].

The mean CMT of group A was 220.25 ± 37.29µm in ages between 20 to 40 years, 217.93 ± 34.59µm in age 41 to 60 years, and 221.83 ± 12.22µm in ages >60 years. There was no statistical difference in the CMT of different age categories (P value = 0.943). The mean CMT of group B was 263.42 ± 77.99 µm in ages between 20 to 40 years, 289.58 ± 82.31 µm in ages 41 to 60 years, and 329.56 ± 114.96µm in ages >60 years. There was mild increase in CMT in older age groups but it had no statistical significance (P value = 0.123) but when compared between the groups it was statistically significant (p value < 0.001) as shown in [Table 2].

Table 2: comparison of CMT (mean & with age) in Group A and group B (N=80)

	Age(years)	CMT (µm)	Mean CMT	P value	Total
Group A (N=40)	20-40	220.25 ± 37.29	218.80+33.89	0.943	<0.001
	41-60	217.93 ± 34.59			
	>60	221.83 ± 12.22			
Group B (N=40)	20-40	263.42 ± 77.99	294.65+91.29	0.123	
	41-60	289.58 ± 82.31			
	>60	329.56 ± 114.96			

Severity of DR among group B: [Table 3] summarizes the CMT among Group B. Moderate NPDR was found to be in the highest proportion (40%) in group B subjects. This was followed by CSME in 37.5%. Thirty percent had severe NPDR, 17.5% had mild NPDR and 12.5% had PDR. The mean CMT was 253.46 ± 70.86 in mild NPDR, 263.36 ± 44.14 in moderate NPDR, and 324.91 ± 92.77in severe NPDR among group B individuals. The association between CMT and severity of

ISSN (O): 2687-5365; ISSN (P): 2753-6556

diabetic Retinopathy was found to be statistically significant (P value < 0.001)

Table 3: comparison of CMT with DR in group A and group B (N=80)

	FUNDUS- DR	CMT(µm)	P value
Group A (N=40)	WNL	218.80 ± 33.89	-
Group B (N=40)	Mild	253.46 ± 70.86	<0.001
	Moderate	263.36 ± 44.14	
	Severe	324.91 ± 92.77	

Comparison of CMT with HBA1C in group A and group B: CMT was analyzed based on glycemic control as mild, moderate or poorly controlled. In both, the groups there was no significant correlation between CMT and HbA1c in our study with p value >0.05 (group A p value =0.300 and group B p-value=0.315) as shown in [Table 4].

Table 4: comparison of CMT with HBA1C in group A and group B (N=80)

	HbA1c	CMT(µm)	P value
Group A (N=40)	Mild (N=12)	221.25 ± 30.60	0.300
	Moderate(N=28)	210.82 ± 35.06	
	Poor(N=40)	223.65 ± 33.75	
Group B (N=40)	Mild ((N=0))	-	0.315
	Moderate(N=16)	274 ± 64.36	
	Poor(N=64)	299.81 ± 96.59	

DISCUSSION

The CMT of patients with and without DR differed significantly, according to the current study.

In both research groups, males had higher CMT than females, and in patients without diabetic retinopathy, the difference was statistically significant. A statistically significant correlation was also found between CMT and the severity of DR.

The study included participants with age ranging between 20-80years and the majority of them were in the age group of 41-60 years. The mean CMT was found to be mildly increased in those above 60 years of age in both the groups with no statistical significance. Similar results have been reported in the study done by Kashani et al which has been hypothesized due to interstitial edema occurring with capillary drop out occurring with advanced age.[10]

Previous studies which compared diabetics without DR and healthy controls showed varied results. In our research we compared diabetics with and without DR. CMT in patients without retinopathy was found to be greater in those with more than 5 years duration. We did not have any patient with more than 10 years duration in group A. In group with retinopathy CMT was found to be less for more than10 years of duration of DM than 6 to 10 years of DM with no statistical significance. Demir M et al study results also showed that in patients with Type 2 DM without retinopathy duration did not affect the CMT.[8] Asefzadeh Bet al. showed that individuals with longer durations of DM but no macular edema had thin macula which was explained due to neurodegenerative changes in diabetics.[12]

Overall in the study, patients with diabetic retinopathy had a significant increase in mean CMT. In contrast to the mild and non-DR groups, we found that patients with moderate and severe DR had higher CMT. Similar results were seen in other studies also which revealed that macular thickness increased with severity of Diabetic retinopathy.3 Murugesan et al concluded that CMT was less among type2 diabetics without DR which they explained due to neuronal damage.[4]

Whereas study done by Fritsche P et al which analyzed the retinal thickness in healthy controls and in diabetics without DR observed higher foveal thickness in diabetics.[15] When compared with HbA1c high macular thickness was found in the group with poor glycemic control, but the difference was not statistically significant.. A study by Asefzadeh B et al also did not show a significant correlation between HbA1c and macular thickness.[10] To conclude from our study CMT was not influenced by duration or glycemic control but was affected by severity of DR.

Limitations: The limitations of the study were smaller sample size, participants without a duration of diabetes mellitus longer than 20 years and no control group.

CONCLUSION

The measurement of central macular thickness using OCT is important in all diabetic patients to prevent early loss of vision. Further studies with higher sample sizes with longer duration are needed to substantiate the results found in our study.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556