

## Original Research Article

# CENTRAL MACULAR THICKNESS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WITHOUT CLINICAL RETINOPATHY

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**ABSTRACT**

**Background:** Diabetes mellitus (DM) affects all parts of the eye, but it primarily causes retinal complications which are vision threatening. There is exponential rise in the number of DR patients with the rise in the prevalence of DM. A collaborative strategy for screening and management is crucial in preventing blindness from Diabetic retinopathy. This study was conducted to estimate central macular thickness in patients with type 2 diabetes mellitus without clinical retinopathy. **Aim and Objectives:** The study aims to compare the Central Macular Thickness (CMT) in patients with Type 2 diabetes mellitus without clinical retinopathy to that of normal controls, assess the relationship between CMT and the duration of diabetes mellitus in these patients, and evaluate the changes in CMT in relation to HbA1c levels in Type 2 diabetic patients.

**Materials and Methods:** A Retrospective case control study included 70 cases and 70 controls. Diabetic patients without clinical retinopathy inclusion criteria were included in the study after proper consent.

**Results:** Showed significant increase in thickness of central macula in type 2 DM patients when compared to normal controls ( $p=0.003$ ). It shows a moderate positive Correlation between HbA1c levels and CMT in cases compared to controls ( $p=0.003$ ) with Mean CMT being thicker in patients with high HbA1c.

**Conclusion:** HbA1c and duration of diabetes mellitus is the main factor affecting the mean CMT value. This study also showed that with increase in duration of diabetes there is increase in mean CMT.

**Keywords:** Diabetes mellitus; Central Macular Thickness; CMT; Clinical retinopathy; HbA1c.

**INTRODUCTION**

Amongst the largest health crisis of this century, Diabetes Mellitus has a strong foothold. According to World Health Organization (WHO), Diabetes ranks 8<sup>th</sup> among the top 10 causes leading to mortality along with others like cardiovascular causes, cancer and respiratory diseases.<sup>[1]</sup> Type 2 diabetes mellitus (T2DM) is a condition in which there is decreased insulin release from the pancreatic beta cells, increased resistance to insulin and also deficient compensatory insulin secretion.<sup>[2]</sup> Thus resulting in a metabolic disease characterized by abnormally high blood glucose levels.

"Nephropathy, neuropathy, and retinopathy are examples of microvascular complications; peripheral artery disease, stroke, and cardiovascular disease are examples of macrovascular complication."

Diabetes mellitus (DM) affects all parts of the eye, but it primarily causes retinal complications which are vision threatening. There is exponential rise in the number of DR patients with the rise in the prevalence of DM.

Diabetic retinopathy is an ocular condition caused by chronic hyperglycaemia resulting in retinal microvascular damage and neuroretinal degeneration. Diabetic retinopathy (DR) is a

common end-organ sequelae of T2DM. If left undetected and untreated, DR can cause a cascade of events in the retina, resulting in vision impairment and blindness. DR is a major cause of avoidable blindness among middle aged individuals globally. Fortunately, the possibility of serious visual loss is less than 5% with evidence-based therapy and annual screening.

Nevertheless, a large number of people with diabetes mellitus (PwDM) continue to lose their sight due to treatment delays and insufficient access to adequate treatment in several countries. Approximately 160 million individuals worldwide suffer with DR, of which 47 million have vision threatening disease.<sup>[3]</sup> Furthermore, 1 in 5 individuals with diabetes for more than 15 years have DR that could be detrimental to their eyesight. Glycaemic control is another predictor for development of DR. Every 1% reduction in HbA1c level decreases the incidence of DR by 28%.<sup>[4]</sup> DR remains a major cause of preventable blindness globally and presents a challenging scenario, especially in low to middle income countries, where access to health care service is lacking. A collaborative strategy for screening and management is crucial in preventing blindness from DR. Hence, this study was conducted to estimate central macular thickness in patients with type 2 diabetes mellitus without clinical retinopathy.

#### Aim and Objectives

1. To compare the central Macular Thickness (CMT) in patients with Type 2 diabetes mellitus without clinical retinopathy with normal controls.
2. To assess the changes in Central Macular Thickness (CMT) to the duration of diabetes mellitus in type 2 diabetic patients.
3. To assess the changes in central Macular Thickness (CMT) to the HbA1c level in type 2 diabetic patients.

## MATERIALS AND METHODS

The study was designed as a retrospective case-control study to evaluate central macular thickness in patients with type 2 diabetes. It was conducted in the Department of Ophthalmology at Navodaya Medical College and Hospital, Raichur, over a period of 18 months, from July 2023 to January 2025. The study population included patients aged 40 to 75 years diagnosed with type 2 diabetes without clinical retinopathy, attending the outpatient department of ophthalmology at the hospital. The study included 140 subjects aged 40-75 years; 70

type 2 DM patients without clinical retinopathy as cases and normal individuals as control who visited the Ophthalmology. The research adhered to the Institutional Ethics Committee guidelines and the approved study protocol, with informed consent obtained from all participants involved in the study.

#### Inclusion Criteria

1. Type 2 diabetes mellitus patients in the age group 40-75 years with no visible clinical findings of diabetic retinopathy.

#### Exclusion Criteria

1. Clinical retinopathy
2. Any other Macular pathology
3. Patients who have received Intravitreal injections.
4. Previous intra ocular surgery
5. Diagnosis of Glaucoma
6. Diagnosis of uveitis.

#### Methodology

All subjects underwent a comprehensive ophthalmic evaluation, including a detailed history and multiple diagnostic assessments. Visual acuity was measured using the Snellen chart, both with and without a pinhole, followed by the determination of best-corrected visual acuity (BCVA). A slit-lamp examination was performed, and intraocular pressure was assessed using a Reichert Auto Tonometer 7. Fundus examination was conducted after pupil dilation with Itrop Plus eye drops (Phenylephrine 5% and Tropicamide 0.8%), using an indirect ophthalmoscope (IDO) with a 20D lens, as well as a slit lamp with a 90D lens. Optical coherence tomography (OCT) scans were performed with pupils dilated to at least 5 mm. Patients were seated with their heads stabilized, and scans were conducted using an internal fixation target. Only high-quality scans with signal strengths above 7 and no artifacts were included. Retinal thickness was measured across nine sectors based on the Early Treatment Diabetic Retinopathy Study (ETDRS) grid, comprising three concentric circles of 1 mm, 3 mm, and 6 mm diameters, representing the foveal, inner, and outer rings, respectively. All measurements were obtained by a single trained examiner.

## RESULTS

The study population comprised 140 participants, divided into 70 cases and 70 controls. The mean age of the cases was  $60.59 \pm 8.12$  years, while the mean age of the controls was  $58.07 \pm 9.22$  years. There was no statistically significant difference in age between the two groups ( $t = 1.713$ ,  $p = 0.089$ ).

**Table 1: Age-Wise Distribution of Cases and Controls**

PARAMETERS	GROUP CASE (n=70)	GROUP CONTROL (n=70)	P VALUE
AGE (YEARS)	60.59+- 8.12	58.07 +- 9.22	0.089
AGE GROUP			
40-49 YEARS	7 (10.0%)	16 (22.9%)	0.096
50-59 YEARS	24 (34.3%)	24 (34.3%)	
60-75 YEARS	39 (55%)	30 (42.9%)	

The mean Central Macular Thickness in the right eye (CMT-OD) among cases was  $246.66 \pm 39.10$   $\mu\text{m}$ , while in controls, it was  $227.91 \pm 12.88$   $\mu\text{m}$ . The median CMT-OD values were 241  $\mu\text{m}$  (IQR: 217–260.75  $\mu\text{m}$ ) in cases and 228  $\mu\text{m}$  (IQR: 219–

234.75  $\mu\text{m}$ ) in controls. A statistically significant difference was observed between the two groups in terms of CMT-OD ( $p = 0.011$ ), indicating that the central macula in diabetic patients without retinopathy is thicker compared to healthy controls.

**Table 2: Descriptive statistics of Group and CMT-OD**

CMT -OD ( $\mu\text{m}$ )	GROUP CASE	GROUP CONTROL	P VALUE
MEAN (SD)	246.66 (39.10)	227.91 (12.88)	
MEDIAN (IQR)	241 (217-260.75)	228(219 -234.75)	0.011
MINIMUM - MAXIMUM	197-400	200-268	

Among the case group, 18.6% of participants had an HbA1c level below 6.5%, while 81.4% had an HbA1c level above 6.5%. In contrast, 100% of the

participants in the control group had an HbA1c level below 6.5%, with no participants in this group having an HbA1c level  $\geq 6.5\%$ .

**Table 3: Distribution of HbA1c Among Cases and Controls**

HbA1c	CASE GROUP	CONTROL GROUP	TOTAL
< 6.5 %	13 (18.6 %)	70 (100.0 %)	83 (59.3%)
$\geq 6.5$ %	57 (81.4%)	0 (0.0%)	57 (40.7%)
Total	70 (100.0%)	70 (100.0%)	140 (100.0%)

The relationship between CMT-OD ( $\mu\text{m}$ ) and HbA1c (%) in the case group shows a positive correlation. For every 1  $\mu\text{m}$  increase in CMT-OD, HbA1c increased by 0.01 units. Conversely, for

every 1% increase in HbA1c, CMT-OD increased by 6.08  $\mu\text{m}$ . This suggests that poorer glycemic control (higher HbA1c) is associated with increased CMT-OD in diabetic patients.

**Table 4: Correlation Between CMT-OD and HbA1c**

Correlation	Spearman Correlation Coefficient	P value
CMT-OD ( $\mu\text{m}$ ) vs HbA1c (%)	0.3	0.003

Similarly, for the left eye (CMT-OS), a positive correlation with HbA1c was observed. For every 1  $\mu\text{m}$  increase in CMT-OS, HbA1c increased by 0.00 units. Conversely, for every 1% increase in HbA1c, CMT-OS increased by 7.09  $\mu\text{m}$ . This further emphasizes the relationship between glycemic control and central macular thickness in patients with type 2 diabetes mellitus.

The mean central macular thickness (CMT) in T2DM patients without clinical retinopathy in this study was  $248.24 \pm 44.34$   $\mu\text{m}$ , ranging from 173 to 459  $\mu\text{m}$ . In contrast, the mean CMT in the control group was  $227.59 \pm 11.19$   $\mu\text{m}$ , ranging from 204.5 to 263  $\mu\text{m}$ . The study demonstrated that the CMT in the diabetes group was significantly thicker than that of the control group, with a p-value of 0.003, indicating statistical significance.

## DISCUSSION

In this study, 70 cases with type 2 diabetes mellitus (T2DM) without clinical retinopathy were enrolled and compared with 70 controls. The mean age of the cases was  $60.59 \pm 8.12$  years, ranging from 45 to 75 years, while the mean age of the controls was  $58.07 \pm 9.2$  years, ranging from 40 to 75 years. A significant proportion of both the cases and controls belonged to the age group of 60–75 years. Comparatively, a study conducted by Demir et al. reported a mean age of  $55.06 \pm 9.77$  years for cases and  $55.78 \pm 10.34$  years for controls.<sup>5</sup> Similarly, a study by Pokhrel U et al. included cases with a mean age of  $51.87 \pm 9.92$  years and controls with a mean age of  $45.85 \pm 8.6$  years.<sup>16]</sup>

In terms of gender distribution, 55.7% of the cases were males and 44.3% were females, which was the same for the control group. This is consistent with the findings of Sindhuja M et al., where 57.6% of the cases were females and 42.4% were males, showing a slightly different gender distribution.<sup>17]</sup>

A similar study by Demir et al. found a mean CMT of  $232.12 \pm 24.41$   $\mu\text{m}$  in T2DM patients without retinopathy and  $227.19 \pm 29.94$   $\mu\text{m}$  in controls.<sup>5</sup> While their findings also indicated a thicker CMT in cases compared to controls, the difference was not statistically significant. In contrast, the study by Pokhrel U et al. reported a mean CMT of  $236.29 \pm 40.31$   $\mu\text{m}$  in T2DM patients and  $244.25 \pm 30.51$   $\mu\text{m}$  in controls, concluding that T2DM patients had a significantly lower CMT compared to controls, which contradicts the findings of this study.<sup>16]</sup>

However, the research conducted by Lattanzio et al. supported the findings of this study, reporting a mean macular thickness of  $369.3 \pm 163.2$   $\mu\text{m}$  in T2DM cases and  $161.9 \pm 12.9$   $\mu\text{m}$  in controls, demonstrating that the central macula is significantly thicker in diabetes patients compared to controls, with statistically significant results.<sup>18]</sup> These varying findings across studies emphasize the need for further research to better understand the changes in macular thickness in diabetes patients without clinical retinopathy.

### Association of Central Macular Thickness (CMT) with HbA1c

The mean HbA1c levels in this study were  $7.33 \pm 1.21\%$  for cases and  $5.47 \pm 0.35\%$  for controls. This difference was statistically significant, with a  $p$ -value  $<0.001$ . Similarly, in a study by Demir et al., the mean HbA1c levels were reported as  $8.92 \pm 2.58\%$  in cases and  $5.07 \pm 0.70\%$  in controls, with a statistically significant difference. Another study by Murugesan et al. reported mean HbA1c levels of  $8.93 \pm 2.54\%$  among cases and  $4.57 \pm 0.56\%$  among controls, which was also statistically significant ( $p=0.00$ ).

Regarding CMT, a study by Pokhrel U et al. found a mean CMT of  $236.29 \pm 40.31 \mu\text{m}$  in patients with type 2 diabetes mellitus, compared to  $244.25 \pm 30.51 \mu\text{m}$  in controls.<sup>[6]</sup> Their findings suggested that patients with diabetes had significantly lower CMT compared to controls, which contrasts with the results of this study. However, research by Lattanzio et al. supported the findings of this study, with the mean macular thickness being  $369.3 \pm 163.2 \mu\text{m}$  in diabetic cases and  $161.9 \pm 12.9 \mu\text{m}$  in controls, indicating that the central macula was thicker in diabetes patients than in controls, with statistical significance.<sup>[8]</sup>

In this study, the mean CMT in male and female cases was  $247.65 \pm 32.67 \mu\text{m}$  and  $248.98 \pm 56.30 \mu\text{m}$ , respectively. Among controls, the mean CMT in males was  $227.21 \pm 9.91 \mu\text{m}$  and in females,  $228.08 \pm 12.77 \mu\text{m}$ . These findings indicate that while females had slightly thicker CMT compared to males, the difference was not statistically significant.

### Association of CMT with Duration of Diabetes Mellitus:

The mean CMT varied according to the duration of diabetes. For patients with a diabetes duration of 1–5 years, the mean CMT was  $230.62 \pm 27.97 \mu\text{m}$ ; for 6–10 years, it was  $240.81 \pm 27.11 \mu\text{m}$ ; and for more than 10 years, it was  $265.78 \pm 56.63 \mu\text{m}$ . A moderate positive correlation was observed between the duration of diabetes (in years) and mean CMT, with a Spearman correlation coefficient of 0.3, which was statistically significant ( $p=0.007$ ).

Contrary to these findings, a study by Demir et al. found that CMT was not affected by the duration of diabetes.<sup>5</sup> Similarly, a study by Sindhuja M et al. reported no statistically significant correlation between diabetes duration and CMT.<sup>[7]</sup>

In contrast, a study by Pokhrel U et al. showed varying mean CMT based on the duration of diabetes:  $217.19 \pm 42.22 \mu\text{m}$  for less than 1 year,  $233.49 \pm 45.69 \mu\text{m}$  for 1–5 years,  $248.5 \pm 31.37 \mu\text{m}$  for 6–10 years,  $250.89 \pm 21.62 \mu\text{m}$  for 11–15 years, and  $240.75 \pm 11.26 \mu\text{m}$  for more than 15 years.<sup>[6]</sup> This study concluded that in patients with type 2 diabetes, CMT initially decreased and then increased as the duration of diabetes progressed.

These findings collectively highlight the complex relationship between diabetes duration, glycemic control (HbA1c), and central macular thickness,

underscoring the importance of further research to explore these associations comprehensively.

## CONCLUSION

The study highlights changes in central macular thickness (CMT) in patients with type 2 diabetes mellitus (DM) and compares these findings with normal individuals. We correlated CMT with HbA1c levels (glycemic control) and the duration of diabetes. Since diabetic maculopathy is a major cause of vision loss in diabetes, optical coherence tomography (OCT) can detect changes in the central macula before the onset of clinical retinopathy. In this study, the mean CMT in type 2 DM patients without clinical retinopathy was found to be thicker than that of healthy controls, with the difference being statistically significant ( $p=0.003$ ). A positive correlation was observed between HbA1c levels and mean CMT, suggesting that patients with higher HbA1c levels tend to have increased CMT ( $p=0.003$ ). Subclinical changes in macular thickness and volume occur before macular edema develops, emphasizing the importance of early glycemic control to prevent the onset of clinical retinopathy. Additionally, the study showed a statistically significant increase in CMT with the duration of diabetes ( $p=0.007$ ). This increase in macular thickness with the duration of diabetes is associated with vascular leakage, which contributes to degeneration and an overall increase in central macular thickness.

### Limitations of This Study

- Small sample size of 140 participants.
- No follow-up to assess changes in central macular thickness over time with diabetes control.
- Comparison of central foveal region changes limited due to the absence of inner retinal layers in the fovea, requiring further studies on all macular regions.
- Lack of correlation between anatomical retinal changes and functional loss using microperimetry, which may reveal functional changes preceding clinical retinopathy.

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