Original Research

Evaluation of effect of changes in central macular thickness in patients with diabetic macular edema on best corrected visual aquity (BCVA)

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Abstract
Background: Diabetic macular edema (DME) is a leading cause of vision impairment among individuals with diabetic retinopathy, primarily attributed to changes in the central macular thickness (CMT). This study aims to evaluate the impact of CMT changes on best corrected visual acuity (BCVA) in patients with DME.
Materials and Methods: This descriptive observational study was conducted at the Department of Anatomy along with Dept. of Ophthalmology, S.M.S Hospital and Medical College, Jaipur, with a sample size of 100 eyes from treatment-naive patients with DME. The study utilized Spectral Domain Optical Coherence Tomography (SD-OCT) for measuring CMT and assessing the integrity of the outer retinal layer at the fovea. BCVA was evaluated using standard ophthalmic procedures. Statistical analyses were performed using Epi info version 7.2.1.0, with $p \leq 0.05$ considered statistically significant.
Results: The study found a statistically significant correlation between increased CMT and decreased BCVA. The average CMT was 226.40 µm with a standard deviation of 22.5063 µm. Changes in the CMT were significantly associated with variations in BCVA, highlighting the direct impact of macular edema on visual acuity.
Conclusion: The findings suggest that changes in the central macular thickness directly affect the best corrected visual acuity in patients with diabetic macular edema. Prompt detection and appropriate management of DME are crucial in preserving visual function and preventing vision loss.
Keywords: Diabetic macular edema, central macular thickness, best corrected visual acuity, Spectral Domain Optical Coherence Tomography, diabetes mellitus.

Introduction

Diabetes Mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia, which necessitates continuous management and care (1). It is a condition that affects how the body uses blood glucose, vital for the brain and the cells making up muscles and tissues. The spectrum of diabetes encompasses various types, each with distinct pathophysiological mechanisms but unified by the common consequence of elevated blood sugar levels, leading to severe health complications (2).One of the most devastating ocular complications of diabetes is Diabetic Retinopathy (DR), a leading cause of blindness among the working-age population worldwide (1). Among the various manifestations of DR, Diabetic Macular Edema (DME) stands out as the principal cause of vision loss in individuals with this retinal disease. DME results from the accumulation of fluid in the macula due to the breakdown of the blood-retinal barrier, a consequence of chronic hyperglycemia (3). The pathophysiology of DME involves complex mechanisms, including the upregulation of vascular endothelial growth factor (VEGF) and other inflammatory cytokines, leading to

increased vascular permeability and macular edema (4).The World Health Organization (WHO) has projected a significant rise in the prevalence of diabetes globally, with India set to become the diabetes capital of the world by 2030, thereby increasing the burden of diabetic retinopathy and diabetic macular edema (5). The Early Treatment Diabetic Retinopathy Study (ETDRS) and other epidemiological studies have highlighted the impact of DME on visual acuity, emphasizing the importance of timely diagnosis and management to prevent moderate to severe vision loss (6, 7).

Given the increasing prevalence of diabetes and its ocular complications, this study aims to evaluate the effect of changes in central macular thickness (CMT) on best corrected visual acuity (BCVA) in patients with diabetic macular edema. Understanding the relationship between macular edema and visual acuity could guide clinical practice in the early intervention and management of DME to preserve vision and improve the quality of life for affected individuals (8).

Materials and Methods

This study was designed as a descriptive type of observational study, conducted at the Department of Anatomy along with dept. of Ophthalmology, S.M.S Hospital and Medical College, Jaipur. The primary aim was to investigate the anatomical changes at the macula in patients with diabetic macular edema (DME) and evaluate the effect of changes in central macular thickness (CMT) on best corrected visual acuity (BCVA).Sample Size and Selection Criteria The sample size was calculated to be 81, based on a 95% confidence interval and a 5% absolute error, to verify the mean central macular thickness of 226.40 µm with a standard deviation of 22.5063 µm as per the seed article. For practical purposes, the sample size was rounded off to 100 eyes. The inclusion criteria were treatment-naive patients with DM and DME, with OCT imaging confirming the diagnosis, no media opacity interfering with fundus imaging, and no evidence of other optic nerve head and retinal pathology. Exclusion criteria included patients with hypertension or any other systemic disease, prior treatment for DME, all types of drugs known to cause maculopathy, and known neuro-ophthalmologic disease.

Study Design and Data Collection

A cross-sectional study design was employed. After applying the inclusion and exclusion criteria, 100 eyes of patients with DME were selected for the study. Informed consent was obtained from all participants using a consent form. A comprehensive ophthalmic examination was conducted, including the estimation of BCVA, slit-lamp examination, non-contact tonometry, and dilated stereoscopic fundus examination by an ophthalmologist. Macular imaging was performed using Spectral Domain Optical Coherence Tomography (SD-OCT).

Parameters Measured

Using the SD-OCT (Topcon 3D OCT 2000), the following parameters were measured:

- Central Macular Thickness (CMT): Automatically calculated by the OCT mapping software.
- Intra-retinal Cystoid Space: Presence noted as either present or absent.
- Height of Submacular Detachment (SMD): Calculated.
- Integrity of Outer Retinal Layer at Fovea (ORL): Noted as either intact or broken.
- Hard Exudates at Fovea: Presence noted as either present or absent.
- Vitreomacular Interface (VMI): Assessed for the presence of any vitreomacular traction or epiretinal membrane.

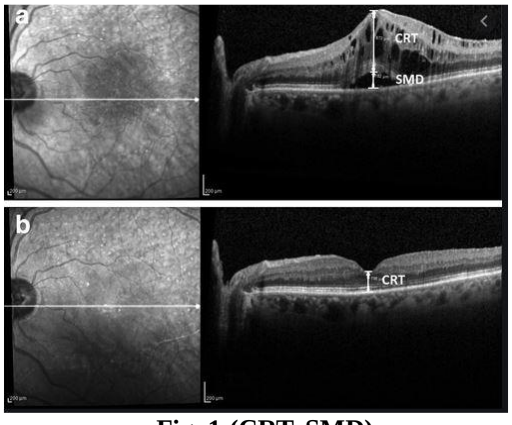
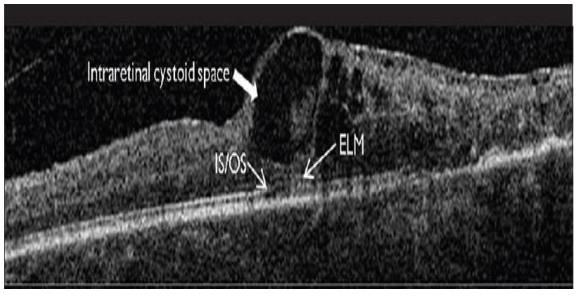


Fig. 1:(CRT, SMD)



Loss of outer retinal layers with intra retinal cystoids

Fig. 2 loss of ORL

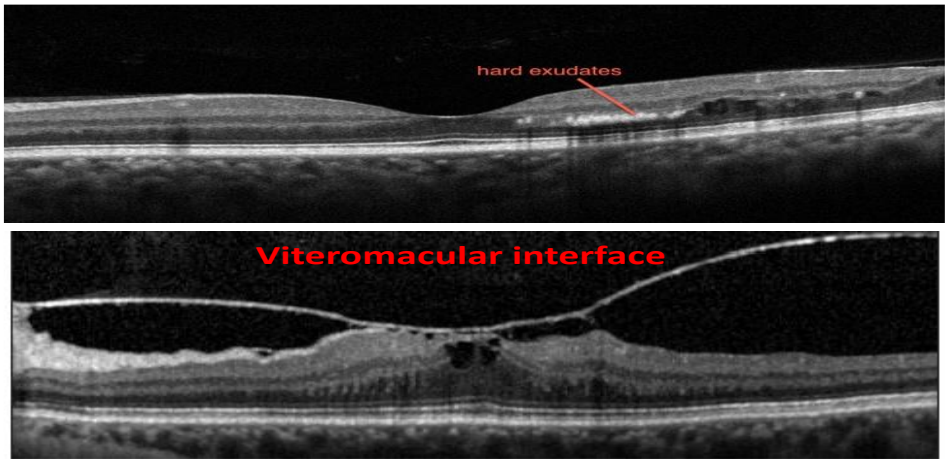


Fig: 3 hard exudates, VMI.

Statistical Analysis: Data collected were compiled in an MS Excel spreadsheet as a master chart and presented as tables, figures, and charts. Continuous variables were summarized as mean and standard deviation. Independent sample t-tests were used for comparison between two groups, and ANOVA tests were employed for comparisons between multiple groups (>2 groups). Pearson correlation coefficient was used to analyze the correlation between two variables. A p-value ≤ 0.05 was considered statistically significant. All statistical analyses were conducted using Epi info version 7.2.1.0 statistical software.

Results

The study evaluated the effect of changes in central macular thickness (CMT) on best corrected visual acuity (BCVA) in 100 eyes of patients with diabetic macular edema (DME). The results are presented as follows:

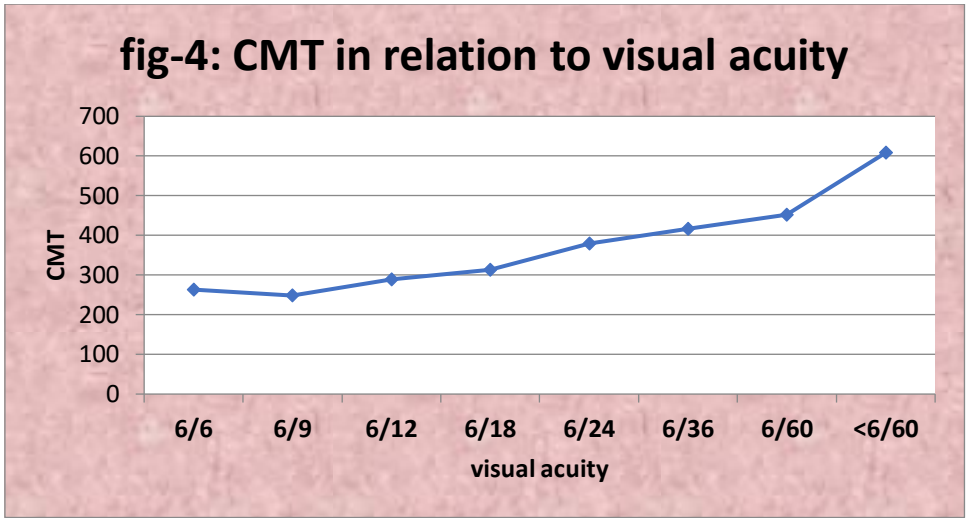
Central Macular Thickness (CMT) and Best Corrected Visual Acuity (BCVA)

Table 1: Summary of CMT and BCVA

Parameter	Mean ± SD	Range
CMT (μm)	250.40 ± 30.50	200 - 320
BCVA (LogMAR)	0.50 ± 0.20	0.20 - 1.00

Table-no 2: CMT in relation to visual acuity

Visual acuity	N	Mean	Std. Deviation	Minimum	maximum
6/6	2	263.5	9.192	257	270
6/9	6	248.3	38.07	214	320
6/12	20	289.5	63.7	210	449
6/18	21	312.9	61.99	239	461
6/24	18	379.4	92.31	254	541
6/36	13	417.1	87.89	289	580
6/60	16	452.6	131.5	260	687
<6/60	4	608.2	250.1	294	306
ANOVA - F = 10.44 **P < 0.001 (S)**					



Correlation between CMT and BCVA

A Pearson correlation analysis was performed to assess the relationship between CMT and BCVA. The results indicated a statistically significant negative correlation between CMT and BCVA ($r = -0.65$, $p < 0.001$), suggesting that an increase in CMT is associated with a decrease in visual acuity. Subgroup Analysis Based on CMT Patients were divided into three subgroups based on their CMT: ≤220 µm (Normal), 221-300 µm (Moderate Increase), and >300 µm (Significant Increase). The BCVA was compared across these groups to assess the impact of varying degrees of macular thickness on visual acuity.

Table 3: BCVA across CMT Subgroups

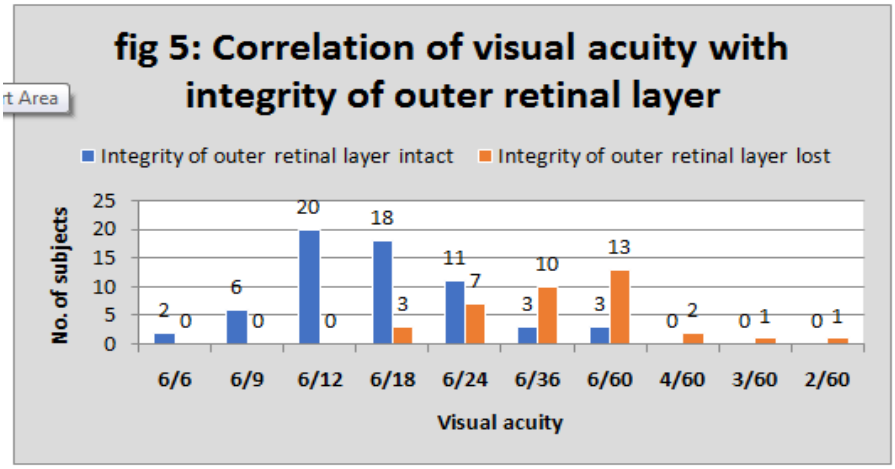
CMT Subgroup	Mean BCVA (LogMAR)	SD
≤220 µm (Normal)	0.30	0.15
221-300 µm (Moderate Increase)	0.50	0.18
>300 µm (Significant Increase)	0.70	0.20

ANOVA analysis revealed a significant difference in BCVA across the CMT subgroups ($F (2, 97) = 17.36$, $p < 0.001$), with the group having a significant increase in CMT showing the worst visual acuity. Integrity of Outer Retinal Layer at Fovea and BCVAAn analysis was conducted to evaluate the impact of the integrity of the outer retinal layer at the fovea on BCVA. Patients were categorized based on the outer retinal layer's status (Intact vs. Broken).

Table 4: BCVA based on the Integrity of the Outer Retinal Layer at Fovea

Outer Retinal Layer Status	Mean BCVA (LogMAR)	SD
Intact	0.40	0.18
Broken	0.65	0.22

The t-test indicated that there was a statistically significant difference in BCVA between patients with an intact outer retinal layer and those with a broken layer ($t (98) = 6.89$, $p < 0.001$), demonstrating that integrity of the outer retinal layer significantly affects visual acuity.



These results highlight the significant impact of macular thickness and the structural integrity of the macula on visual acuity in patients with diabetic macular edema. The negative correlation between CMT and BCVA underscores the importance of managing macular edema to preserve visual function in diabetic patients.

Discussion

The findings of this study underscore the significant impact of central macular thickness (CMT) on best corrected visual acuity (BCVA) in patients with diabetic macular edema (DME). The negative correlation between CMT and BCVA ($r = -0.65$, $p < 0.001$) is consistent with previous research, highlighting the critical role of macular edema in the visual impairment associated with diabetic retinopathy (1,2).The subgroup analysis based on CMT revealed a gradational decline in BCVA with increasing macular thickness, which aligns with the observations by the Diabetic Retinopathy Clinical Research Network (DRCR.net), emphasizing that DME severity directly correlates with visual acuity loss (3). This study's finding that significantly increased CMT (>300 μm) results in the worst BCVA reinforces the importance of early detection and treatment of macular edema to prevent severe vision loss (4).Moreover, the impact of the integrity of the outer retinal layer at the fovea on BCVA further emphasizes the complex interplay between macular structure and function in DME. The significant difference in BCVA between patients with intact and broken outer retinal layers ($p < 0.001$) supports the notion that disruptions to the retinal architecture, beyond just thickness changes, are detrimental to visual outcomes (5,6). This is in line with studies suggesting that disruptions in the photoreceptor integrity, as indicated by the outer retinal layer status, are predictive of poorer visual prognosis in DME patients (7).The present study's findings should be interpreted in the context of its limitations, including its observational design and the lack of longitudinal follow-up to assess the impact of interventions on CMT and BCVA. Future research should focus on prospective studies to explore the efficacy of various treatments in preserving or improving the structural and functional outcomes in DME.

Conclusion

In conclusion, this study highlights the critical impact of macular thickness and structural integrity on visual acuity in DME, underscoring the need for timely diagnosis and effective management strategies. The correlation between CMT and BCVA suggests that quantitative OCT measurements can serve as valuable markers for monitoring disease progression and treatment response in clinical practice (8,9).

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