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RESEARCH ARTICLE

A STUDY TO CORRELATE OPTICAL COHERENCE TOMOGRAPHY PARAMETERS WITH VISUAL ACUITY IN PATIENTS WITH DIABETIC MACULAR EDEMA

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Abstract

Aims: To correlate various Optical Coherence Tomography (OCT)parameters with Visual Acuity (VA) in patients with Diabetic Macular Edema (DME). To determine which OCT parameter correlates more with Vision.

Design: It is a hospital based cross-sectional prospective study with 150 eyes of 120 patients done for a period of 3yrs.

Methods: Patients with DME were subjected to Spectral Domain (SD) - OCT imaging.Total 7 OCT parameters were analysed. Central Foveal Thickness (CFT), Intra retinal cystoid spaces, Disorganization of Retinal Inner Layers (DRIL), Hyper-reflective foci (HRF),sub-foveal neuro sensory detachment,Ellipsoid Zone(EZ)disorganization, Vitreo Retinal (VR)-interface abnormalities like Epiretinal Membrane (ERM),Vitreo Macular Adhesion (VMA) and Vitreo Macular Traction(VMT).

Statistical Analysis : The data was analyzed using SPSS version 29 statistical software. Pearson coefficient was used to test for correlations.

Results:-Out of the 7 parameters measured a statistically significant correlation was found in 4 parameters with visual acuity. They are CFT(P=0.05), DRIL($p<0.001$), EZ disruption ($p<0.001$), and HRF($p<0.001$). Among the 7 parameters, DRIL was the most commonly seen but EZ disruption correlated more with a mean VA of logmar 1.45. Whenever HRF was found in outer retinal layers it was associated with EZ disruption($p<0.001$).

Conclusion:- DRIL of >50µm, ORL hyperreflective foci, and EZ disruption >50% were independently associated with 0.21–0.32 log MAR worse visual acuity in DME.

Introduction:-

Diabetes mellitus is an important concern for healthcare systems in the world. Diabetes is known to cause alterations in retinal microvasculature and retina that progressively lead to visual impairment.[1] The overall prevalence of Diabetic Macular Edema (DME) in patients with Diabetic Retinopathy is 29%.[2] It results from the hyperglycemia-induced breakdown of the blood-retinal barrier which leads to fluid extravasation from retinal vessels into the surrounding retinal tissue.[3] Optical coherence tomography (OCT) is a non-contact, non-invasive, in vivo, high-resolution, cross-sectional imaging of the eye that measures backscattered light. SD-OCT gives a higher axial

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resolution of ≈5µm and scans 20,000-40,000 A-scans per second.4 It works on the same principle as ultrasound B-mode imaging but uses light instead of sound.[5] Multiple studies have considered single OCT parameter[6,7] or more so retrospective in nature[8-10]. The results are also found to be inconsistent and cross-sectional studies1[1, 12] conducted in the current setting are meagre. This study has an added feature of being cross-sectional in nature and hence was conducted to determine the OCT predictors of Visual Acuity in DME which will help in the future to narrow down the multiple OCT parameters so that one parameter can be used as a standard protocol in many upcoming treatment trials or while prognosticating vision while giving treatment.

Methods:-

It was a hospital-based cross-sectional study conducted among 120 diabetic patients with clinical diagnosis of macular edema for a period of 3 years at a tertiary eye care hospital. Patients with other retinal diseases like Age Related Macular Degeneration (ARMD), Retinal Detachment, concurrent macular diseases, and other causes of macular edema other than diabetes and those with significant media opacities and any associated ocular pathologies like uveitis or vitreous diseases were excluded from the study. This study was conducted after obtaining approval from institutional ethics review board and informed consent from the subjects. A time-based sampling strategy was adopted and all the consecutive eligible cases presenting during the defined study period were included and hence this sample size was considered.

The data was collected using semi-structured questionnaire consisting of details on socio-demographic profile, history related to vision, other clinical history, history of prior treatments for DME like Pan-retinal Photocoagulation, Focal laser, intra-vitreal injections like triamcinolone, and anti-VEGF were noted. The best corrected visual acuity was assessed initially in Snellen's and then converted to logMAR. Detailed ocular examination using Slit-lamp biomicroscopy, fundus evaluation by indirect ophthalmoscopy were done. Though 120 patients, were considered for the study, both eyes were considered for 30 patients and hence a total of 150 eyes were evaluated for DME by subjecting them to SD-OCT imaging (Cirrus™ HD-OCT (Carl Zeiss Meditec, Inc., Dublin, CA). A 5-line HD RASTER scan with a signal strength of >5 was selected, Total of 3 readings from each scan was taken and the average of it was documented for each eye. All OCT parameters were assessed at 500µ on either side of the center of the fovea. Based on the morphology of Central foveal Thickness in OCT, it was categorized into Diffuse, focal, cystoid, with sub-retinal fluid and combined type. Few OCT parameters were sub-categorized and graded/grouped according to their severity as mentioned in the below table:

Table-1: OCT Parameters evaluated and their sub-groups

OCT parameters	Subgroups as applicable
1. Height of the central foveal thickness	
2. Presence of intra-retinal cystoid spaces	Group 0 – No cystoid spaces Group 1 – Cystoid spaces of <200µm in size Group 2 – Cystoid spaces of >200µm in size
3. Presence of disorganization of retinal inner layers	Grade 0 – No DRIL Grade 1 - <50% DRIL is present Grade 2 - >50% DRIL is present
4. Presence of Retinal Hyper-Reflective Foci	Group 0 - Absence of Hyper-Reflective Foci Group 1 - Hyper-Reflective Foci in inner retinal layers Group 2 - Hyper-Reflective Foci in outer retinal layers
5. Presence or absence of sub-foveal neurons-sensory detachment	
6. Ellipsoid zone disruption	Grade 0 - EZ is intact Grade 1 - <50% OF EZ disruption Grade 2 - >50% OF EZ disruption
7. Presence of Vitreo-retinal interface abnormalities	Group 0 – Absent VR abnormalities Group 1 – Presence of epiretinal membrane Group 2 – Presence of vitreo macular adhesion Group 3 – Presence of vitreomacular traction

Statistical Analysis:
The BCVA in Snellen measurements were converted to logMAR. The data was entered into Microsoft Excel Sheet 2010. The continuous data was expressed in mean ± SD or and the categorical data was expressed as proportions and percentages. The comparison between two means was done using independent *t* – test. Correlation between two variables was assessed using pearson correlation coefficient. ANOVA was applied when comparing the difference in means between three groups and LSD and Dunnett post hoc test was applied to analyse the group which was significant. Associations between OCT biomarkers and VA logMAR were analyzed using linear mixed models with a random intercept for patient to account for inter-eye correlation. The intraclass correlation coefficient (ICC) was calculated to quantify the proportion of total variance in visual acuity attributable to between-patient differences. Fixed effects included previous treatment, DR severity, DRIL extent, HRF location, EZ disruption, vitreomacular interface, and CST per 100-µm increase. β coefficients with 95% CIs were reported. $P<0.05$ was considered significant. The analysis was done using SPSS (version 29.0 for Windows; SPSS Inc., Armonk, NY: IBM Corp)

Results:-
A total of 150 eyes from 120 type 2 diabetic patients were studied for a period of 3 years. The mean age of the study population was 56.5 years with the standard deviation of 8.9 years. Majority i.e., 68.9% were males. The mean diabetes duration was 9.1 years, with Proliferative Diabetic Retinopathy (PDR) being reported among 27/150, 18.0% and Non-Proliferative Diabetic Retinopathy (NPDR) was seen among remaining 123/150, 82.0%. Moderate NPDR among type2 diabetic patients was the commonest with proportion being 45.3% (68/150). 24.0% (36/120) gave history of previous eye treatment and the commonest type was Pan-retinal Photocoagulation laser treatment (PRP) (15/36, 41.7%). 67/120, i.e., 56.3% had hypertension. Mean visual acuity was logMAR 0.94 with SD of logMAR 0.4. [Table-2]Patients with PDR had significantly poorer visual acuity (mean VA logMAR = 1.33) compared to NPDR patients (mean VA logMAR = 0.86) ($P<0.05$). The subjects with history of previous laser eye treatment also had significantly poorer vision compared to those who did not give any history of laser eye treatment for diabetic macular edema ($P<0.05$). There was no significant difference in vision among males and females and it did not vary with history of hypertension ($P>0.05$). [Table-3]

Age (r = -0.15), duration of diabetes (r = 0.04) and hypertension did not affect vision significantly among the study subjects ($P>0.05$). However, increase in CST thickness significantly increased the visual acuity resulting in poor vision (r=0.28, $P<0.001$), this remained significant even after adjusting for the possible confounder of history of treatment for Diabetic Macular Edema (DME) (r = 0.19, $P = 0.02$). [Table-4]The mean VA logMAR was 0.74 when there was no Disorganization of Retinal Inner Layers (DRIL), it increased significantly in group 2 (0.89) with less than 50% of the central 1-mm area of the retina was involved and it was still higher in group 3 (1.34) more than 50% of the central 1-mm area of the retina was involved [F (2, 147) = 30.12; $P<0.001$] compared to no DRIL. The values were significantly high when compared to those with lesser involvement ($P<0.05$). Similarly, Hyper Reflective Foci (HRF) showed significantly higher mean VA logMAR when it was present on the outer retinal layers (1.43) compared to no HRF (0.89) and HRF in the inner retinal layers (0.83) [F (2, 147) = 24.85; $P<0.001$].Ellipsoid zone disruption also showed significantly higher VA logMAR in those with more than 50% disruption (1.45) compared to no disruption (0.72) and less than 50% disruption (0.91) and the difference was statistically significant in less than 50% EZ disruption compared to more than 50% EZ disruption ($P<0.05$) [F (2, 147) = 69.88; $P<0.001$].

The mean VA logMAR was significantly higher in those with Vitreo Macular Traction (VMT) (0.85) compared to those with the presence of Epi Retinal Membrane (ERM) (0.85) [F (3, 146) = 2.63; $P<0.05$]. [Table-5]However, morphology of Central Foveal Thickness (CFT), cystoid spaces, sub-foveal neurosensory retinal detachment did not make a significant difference with respect to VA logMARCompared to eyes with no DRIL, DRIL >50µm was associated with 0.213 logMAR worse vision [95% CI 0.093–0.333, P=0.001), while DRIL <50µm was not significantly different (β=+0.077, P =0.13). Eyes with ORL hyperreflective foci had 0.233 logMAR worse VA than eyes with no HRF (P = 0.002). EZ disruption >50% was associated with 0.316 logMAR worse VA compared to no disruption (P <0.001). [Table-6]The intraclass correlation coefficient (ICC) for the dependent variable (VA logMAR) was 14.7% and was not statistically significant (P=0.45), indicating that between-patient variance in visual acuity was largely explained by the OCT biomarkers included in the model.

Tables:

Table-2: Distribution of the study participants and their clinical profile

Socio-demographic/ Clinical profile	Mean±SD/ n (%)
Age in years (n=119)	56.5±8.9
Duration of diabetes in years (n=119)	9.1±5.9
Mean Visual Acuity (log MAR) (n=150)	Log 0.9±log 0.4)
Sex n (%), (n=119)	
Male	82 (68.9)
Female	37 (31.1)
Hypertension n (%), (n=119)	
Yes	67 (56.3)
No	52 (43.7)
Diabetic Retinopathy Staging n (%), (n=150)	
PDR	27 (18.0)
Mild NPDR	23 (15.4)
Moderate NPDR	68 (45.3)
Severe NPDR	32 (21.3)
Previous h/o any eye treatment n (%), (n=150)	
Yes	36 (24.0)
No	114 (76.0)
Type of treatment undergone for Diabetic Macular Edema (DME) n (%), (n=36)	
Macular laser	12 (33.3)
PRP	15 (41.7)
S/P Anti-VEGF	03 (08.3)
S/P IVTA injection	06 (16.7)

Table-3: Comparison of Visual Acuity (VA) among different parameters

Visual Acuity (logMAR) (Mean±SD)		*t*-value [95% CI]	*P*-value
Type of Diabetic Retinopathy (n=150)			
PDR	**NPDR**	6.02 [0.31 to 0.62]	<0.001*
1.33±0.37	0.86±0.36		
Previous history of eye treatment (n=150)			
Yes	**No**	6.97 [0.38 to 0.67]	<0.001*
1.37±0.34	0.85±0.36		
Sex of the patient (n=119)			
Male	**Female**	0.62 [-0.11 to 0.21]	0.54
0.9±0.4	0.9±0.3		
History of hypertension (n=119)			
Yes (n-82)	**No (n=68)**	1.54 [-0.03 to 0.26]	0.13
0.98±0.39	0.87±0.43		

*indicates statistically significant difference at $P<0.05$

Table-4: Correlation of Visual Acuity (VA) with age and duration of diabetes (n=120)

	Age in years r – value (*P*-value)	Duration of diabetes in years r – value (*P*-value)	Duration of Hypertension in years r – value (*P*-value)	CST (µm) (n=150; controlled for previous treatment history) r – value (*P*-value)	Visual Acuity (logMAR) r – value (*P*-value)
Age in years r – value (*P*-value)	--	--	--	--	-0.15 (0.12)
Duration of diabetes in years r – value (*P*-value)	--	--	--	--	0.04 (0.67)
Duration of Hypertension in years r – value (*P*-value)	--	--	--	--	0.05 (0.63)
CST (µm) (n=150; controlled for previous treatment history) r – value (*P*-value)	--	--	--	--	0.19 (0.02)*
Visual Acuity (logMAR) r – value (*P*-value)	-0.15 (0.12)	0.04 (0.67)	0.05 (0.63)	0.19 (0.02)*	--

*indicates statistically significant correlation at $P<0.05$; Central Subfield Thickness (CST)

Table-5: Comparison of Visual Acuity (VA) among different parameters of OCT with post hoc analysis

Variables	Visual Acuity (logMAR) in Mean±SD				Group-wise comparison
Disorganization of Retinal Inner Layers (DRIL) in mm	**No DRIL (Group 1)**	**Involves <50% of central 1-mm area of the retina (Group 2)**	**Involves >50% of central 1-mm area of the retina (Group 2)**		Group 1 vs Group 2* Group 1 vs Group 3* Group 2 vs Group 3*
	0.74±0.30 (n=42)	0.89±0.39 (n=76)	1.34±0.3 (n=32)		
	F-value : 30.12; *P*-value : <0.001*				
Hyper Reflective Foci (HRF)	**No HRF**	**HRF in inner retinal layers**	**HRF in outer retinal layers**		Group 1 vs Group 2 Group 1 vs Group 3* Group 2 vs Group 3*
	0.89±0.38 (n=64)	0.83±0.35 (n=64)	1.43±0.29 (n=22)		
	F-value : 24.85; *P*-value : <0.001*				
Ellipsoid zone disruption (EZ disruption)	**EZ intact (n=66)**	**EZ disruption <50% (n=51)**	**EZ disruption >50% (n=33)**		Group 1 vs Group 2* Group 1 vs Group 3* Group 2 vs Group 3*
	0.72±0.26	0.91±0.31	1.45±0.33		
	F-value : 69.88; *P*-value : <0.001*				
Presence of Vitreo-retinal interface abnormalities	**No abnormality (n=107)**	**Presence of Epiretinal membrane (n=29)**	**Presence of Vitreo Macular Adhesion (n=7)**	**Presence of Vitreo Macular Traction (n=7)**	Group 0 vs Group 1 Group 0 vs Group 2 Group 0 vs Group 3 Group 1 vs Group 2

	0.94±0.41	0.85±0.36	1.14±0.29	1.27±0.51	Group 1 vs Group 3* Group 2 vs Group 3
	F-value : 2.63; *P*-value : 0.05				

*indicates statistical significance at $P<0.05$

Table-6: Multivariable linear mixed model of OCT biomarkers associated with visual acuity in diabetic macular edema.

Variable	Comparison	β Estimate	95% CI	*P*-value
Intercept	-	0.730	0.521 to 0.939	<0.001*
Previous treatment	Yes vs No	0.268	0.151 to 0.385	<0.001*
PDR status	PDR vs NPDR	0.066	-0.060 to 0.191	0.30
DRIL extent				0.011a*
DRIL <50μm	vs No DRIL	0.077	-0.022 to 0.176	0.13
DRIL >50μm	vs No DRIL	0.213	0.093 to 0.333	0.001*
HRF location				0.006a*
IRL HRF	vs No HRF	0.005	-0.138 to 0.148	0.95
ORL HRF	vs No HRF	0.233	0.084 to 0.382	0.002*
EZ disruption				<0.001a*
EZ <50%	vs No EZ	0.090	-0.007 to 0.187	0.07
EZ >50%	vs No EZ	0.316	0.178 to 0.454	<0.001*
Vitreomacular interface				0.22a
ERM	vs VMT	-0.083	-0.299 to 0.132	0.45
VMA	vs VMT	0.116	-0.087 to 0.320	0.26
CST	per 100 μm increase	0.028	0.000 to 0.056	0.05

*indicates statistical significance at $P<0.05$
Footnotes:
a Overall Type III test of fixed effect.
β = regression coefficient; CI = confidence interval. Positive β indicates worse VA logMAR.
Model includes random intercept for patient to account for inter-eye correlation.
Dependent variable: VA_logMAR. Between-patient ICC = 14.7%, P =0.45.
Reference group for all OCT variables is "No disease".

Discussion:-

Studies have shown a modest correlation with Central foveal Thickness[13,14] and not a true reliable marker for prognosticating visual acuity in DME. In our study there was only moderate correlation with CFT and VA(p=0.005). Other parameters like cystoid spaces, sub-foveal neurosensory detachment, VitreoRetinal abnormalities did not show any statistical significant correlation with Visual Acuity. Some of the other parameters like DRIL[6,15] have shown significant correlation. It has been hypothesized that disorganization of the inner retina occurs when bipolar axons snap when their elasticity limit has been exceeded because of edema. It has also been suggested that DRIL represents a loss of bipolar, amacrine, or horizontal cells within the inner retinal layers.[15] In our study we noted in the center involving DME, DRIL showed statistical significance with VA (p<0.001) which is comparable with previous studies[6,15]. We observed that as the severity of DRIL increased, the mean Visual Acuity decreased (log 1.34) and DRIL was the most commonly found OCT parameter. Studies have shown significant correlation of VA with Ellipsoid zone disruption.[16,17] We noted that Ellipsoid zone disruption was also associated with poor VA, and our findings are consistent with those from previous studies.[17] Ellipsoid Zone represents photoreceptor integrity. The External Limiting Membrane separates the layers of rods and cones from the overlying outer nuclear layer and is a linear confluence of junctional complexes between Muller cells and photoreceptors (EZ).[18] EZ disruption showed a statistically significant correlation

with VA($p<0.001$). It also showed the strongest correlation to VA among all the OCT parameters. As the severity increased the mean VA decreased (log1.45)Some studies have quantified the disruption[16] and have measured PROS length[17.] Few studies have shown the presence of hyperreflective foci as a predictor of poor VA.[7, 19] Hyperreflective Foci are inflammatory biomarkers representing extravasated protein and/or lipid deposits, precursors of hard exudates, or may represent activated microglial cells. This showed a statistically significant correlation with VA($p<0.001$). HRF present in the outer retinal layers showed a mean VA of log 1.43 indicating and also an association between EZ disruption and HRF in Outer Retinal Layers was found indicating that HRF, as it migrates from inner to outer retinal layers causes damage to the photoreceptor layer as shown by Akihito U *et al*., in his study.[7] Among the various OCT parameters studied, DRIL, HRF IN ORL, and EZ disruption correlated more with VA. Hence, these parameters should be considered in the future for clinical decision-making, the timing of therapeutic intervention, and for prognosticating the disease. Since DRIL was more common it would ideal to use DRIL as a standard parameter in any future large clinical trials but since the strongest correlation was found with EZ disruption, this would be ideal for experimental studies. Our study had an advantage of being prospective in nature.

Conclusion:-

Assessment of extent of DRIL, hyperreflective foci, and ellipsoid zone integrity were found to be significant OCT parameters which provides clinically relevant prognostic information in DME. Eyes with DRIL >50μm, ORL HRF, or EZ disruption >50% demonstrated significantly worse vision.

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