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Original Research Article

Macular thickness comparison in type II diabetic patients using optical coherence tomography: A case control study

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ABSTRACT

Aims: A case control approach was done in which the primary outcome was to measure and to compare detect any significant changes in the macular thickness of normal controls Versus Type II diabetic patients or with their subgroups of with and without diabetic retinopathy and a secondary outcome to correlate the visual acuity of distance and near with central macular thickness.

Materials and Methods: Two hundred ten study subjects were included in this case-control study has been conducted over a pool of overall 210 participants were further divided into 7 groups such as normal controls, no diabetic retinopathy, mild non-proliferative diabetic retinopathy, moderate non-proliferative diabetic retinopathy, severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, clinically significant macular edema was taken and each group having 30 patients (60 eyes in each group) using spectral-domain - OCT. Selected participants enrolled using sampling size ($n = k\{Z_a+Z_b\}^2 \times \{s_1^2+s_2^2\}/d^2$) and confidence interval being capped at 95%. An automated algorithm of OCT scanned the central retinal region having a variable thickness in three concentric circles primary central circle 1 mm of the macula. Four major quadrants (superior, nasal, inferior, temporal) was scanned from center (1mm) to inner (3 mm) and an outer circle (6 mm).

Results: To evaluate the result, overall 210 participants with each group having 30 patients in 7 groups (mean age 54.54 ± 9.67 years) were analyzed by one way ANOVA and independent sampling T-test method. The results were evenly distributed in terms of gender-wise sampling, duration/severity of the disease, and changes in visual acuity. A substantially increased macular thickness ($p < 0.05$) was observed among severe forms of diabetic retinopathy compared with the control group.

Conclusion: This study conclude that the there is an increased in the macular thickness of all quadrants especially in PDR and CSME group which may be masked by changes in vascular permeability triggering thickening of the retinal layers from early to severe diabetic changes of the macula, using optical coherence tomography for diabetic patients Type II with and without diabetic retinopathy. Although central macular thickness and Log Mar visual acuity distance as well as near are moderately strong correlated.

1. Introduction

During the 6th century BC, Sushruta had categorized Diabetes as 'Madhumeh,' and in 1425, the term 'Diabetes' in English was introduced, still acting as a significant

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cause of preventable blindness. Thomas, in 1675, introduced an accession of Latin American term 'Mellitus' to this hyperglycemic condition "affecting a majority of human organs, by suggesting the term as "Honey," referring to the sweetness of urine. The worldwide prevalence of diabetes mellitus, a major global hazard of the 21st century, is projected to grow up to 300 million individuals by 2025 at an alarming level within two decades.[1–3] Besides the microvascular complications, including diabetic retinopathy, nephropathy, and neuropathy, it also aids in substantial morbidity and mortality of macrovascular illnesses such as cardiovascular anomalies and obesity.[4] The very first Federal study about the Incidence of Type II diabetes mellitus in India has been conducted involving 1972 to 1975 from the Indian Council Medical Research (ICMR, New Delhi) where the incidence rate was 2.1% among the metropolitan populace and 1.5% among rural dwellers whereas in people preceding 40 decades old, the prevalence had a drastic upshoot of 5% in urban and 2.8% in rural locations.[5] Though since the late 90s, numerous peer-reviewed publications have concluded the substantially inclining incidence rate (11.6%) of Diabetes mellitus-II within five decades, the accelerated trend, however, is highly rooting for the aged individuals while affecting the Southern Indian region more in comparison to its counterpart.[6,7] Consequently, the ailment is strongly linked to the systemic parameters (not limited to obesity). Hence, crucial issues such as comprehensive education for minimizing risk, frequency of observing discrete parameters, esteem tracking of continual complications inpatients who have Diabetes and opting medically innovative goals of varied parameters are suggested for constraining diabetes.[8] In terms of ophthalmic science, diabetic retinopathy a secondary complication of Diabetes (Type I and II) which at first can result in no signs or merely mild vision issues, has an irreversible detrimental effect on the retinal blood vessels, which can lead to blindness.[9]

In severe vitreous hemorrhage cases, blood may ooze out into the vitreous cavity and entirely obstruct the vision.[11] Although vitreous hemorrhage alone does not cause irreversible vision loss and blood often clear out in just a couple of weeks, the chronic irreversible changes often lead to increased bloodvessels that further excite the establishment and growth of the cottonwool spots, hard exudates, as well as acute hemorrhages.[9,12] Eventually, the series of reactions may wrench the retina, elevate intraocular pressure damaging the optic nerve, and induce acute or absolute vision loss.[13] Clinically significant macular edema (CSME) additionally plays a substantial role in vision reduction when there's a thickening of the central and adjacent 500 μm retinal region and formation of hard exudates (macula).[14] Besides, highly equivalent effects are inescapable whether there's variation in retinal thickening of a particular disc area or surrounding significant portion, some segment which will be contained in a single disc diameter of the central retina.[15] But it's crucial to comprehend that most visual loss occurs when macular edema includes the central part of the retina.[16] As stated by the International medical Diabetic Macular Edema Disease Severity Scale, when DME occurs, it gets distributed into mild (some retinal thickening or hard exudates from the posterior pole, however scarce in the middle of the macula), medium (retinal thickening or hard exudates progressing towards the central macula, however, keeping it untouched), also acute (concerning retinal thickening or hard exudates in the center).[14,17] Therefore, the current research will investigate the differences in the macular thickness of Normal Controls vs Type - II diabetic patients having diabetic retinopathy and explore the other discrete parameters such as age, gender, etc., of a randomly selected pool of participants.

Table 1: Diabetic retinopathy disease severity scale[10]

No Diabetic Retinopathy	No abnormalities were seen.
Mild Non-Proliferative Diabetic Retinopathy	Microaneurysms only.
Moderate Non-Proliferative Diabetic Retinopathy	More than just microaneurysms but less than severe non-proliferative diabetic retinopathy
Severe non-proliferative diabetic retinopathy	Any of the following: more than 20 intraretinal hemorrhages in each of 4 quadrants; definite venous beading in 2 quadrants; Prominent intraretinal microvascular abnormalities in 1 quadrant and no signs of proliferative retinopathy
Proliferative Diabetic Retinopathy:	One or more of the following: neovascularization, vitreous/pre-retinal hemorrhage.

2. Materials and Methods

The case-control study has been conducted over a pool of 210 participants (420 eyes) in which it was further divided into equally in 7 groups and each group having 30 patients (60 Eyes) of the out-patient department of Maharishi Markandeshwar Institute of Medical Science and Research, Mullana, Ambala (Haryana), which was concluded after employing a simple random sampling strategy ($n = k\{Z_a+Z_b\}^2\times \{s_1{}^2+s_2{}^2\}/d^2$).[18] All the participants (normal control and Type II Diabetic (Non-Insulin dependent)) were grouped as shown in Table 2 after evaluating them under careful inclusion criteria, which additionally involved the age range between 40 and 80 years old and history of no or insignificant previous ocular pathology. The participants with hazy ocular media or opacities, angle-closure glaucoma suspected or suffering from Type - I Diabetes was excluded from the study.

Table 2: Diabetic retinopathy groups [10]

Group 1	Normal Controls	Patients	Eyes
Group 2	Type II Diabetic patients without diabetic retinopathy	30	60
Group 3	Type II Diabetic patients with Mild Non-Proliferative diabetic retinopathy (NPDR)	30	60
Group 4	Type II Diabetic patients with Moderate Non-Proliferative diabetic retinopathy (NPDR)	30	60
Group 5	Type II Diabetic patients with Severe Non-Proliferative diabetic retinopathy (NPDR)	30	60
Group 6	Type II Diabetic patients with Proliferative diabetic retinopathy (PDR)	30	60
Group 7	Type - II Diabetic patients with Clinically significant Macular Edema (CSME)	30	60

The investigation and inclusion were carried out after obtaining the written consent from all participants. The included participants were thoroughly evaluated by recording previous medical history, visual assessment, correction, slit lamp examination, and fundus evaluation (Carl Zeiss Visucam 700). The Optical Coherence Tomography (Zeiss Spectral Domain Cirrus^{TM} HD-OCT MODEL-5000) was performed as ETDRS macular map having 9 quadrants (Figure 1) using Macular Cube 512 X 128 Scanning Protocol (6 mm square grid by acquiring a series of 128 horizontal scan lines, each composed of 128 A-scans).The precision of Diabetes among included participants was maintained by opting vigorous blood sugar investigation strategy.

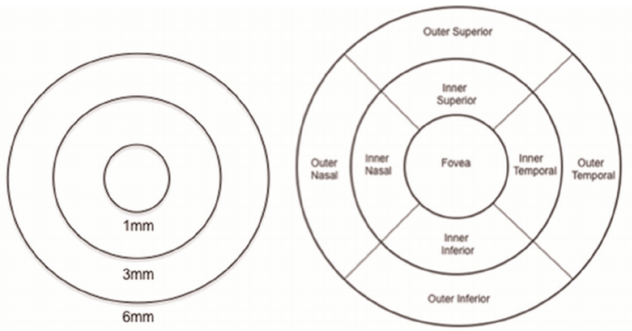

Figure 1: ETDRS macular mapping [9]

3. Results

Statistical analysis was performed utilizing the Statistical Package for the Social Sciences (SPSS) Version 23.0 (IBM Corp., United States). 210 patients or 420 eyes (360 - Type - II Diabetic and 60- Control with mean age 54.54 ± 9.67 years) were included in the study. The gender-wise distribution (Figures 2 and 3) (Non-diabetics- male 33.3%, female 66.7% and type - ii diabetic male 52.2%, female 47.8%) was taken into consideration.

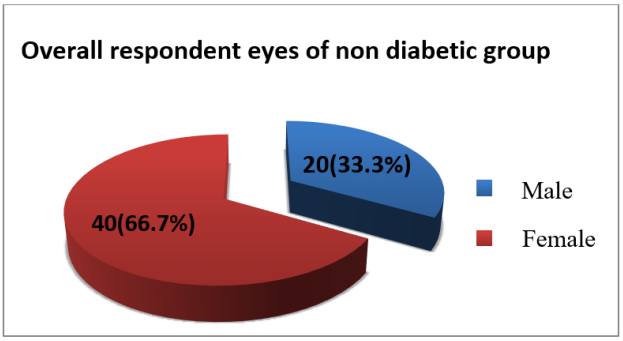

Figure 2: Non - diabetic group

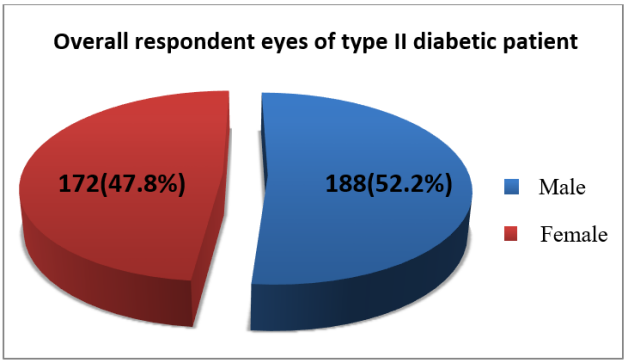

Figure 3: Type - II diabetic group

Among diabetic participants, most patients (30%) listed their diagnosis of Type - II diabetes mellitus stretching for more than 10 years, and (44.17%) of patients reported the condition extending from 0-5 years. The rest of the limited participants (25.83%) had a diabetes history between 6-9 years, as depicted in (Figure 4).

Above Scatter plot depicting LogMAR distance on X-axis and central mean macular thickness on Y-axis was drawn. It showed a linear association (r^2=0.232) between the two parameters, which means that LogMAR distance visual acuity measurement changed proportionally to a change in central mean macular thickness. The Pearson correlation coefficient value was 0.481 with P-value < 0.001, which indicates a moderately strong correlation between the LogMAR distance visual acuity and central mean macular thickness.

Another Scatter plot depicting LogMAR Near visual acuity on X-axis and central mean macular thickness on Y-axis was drawn. It showed a linear association (r^2=0.185) between the two parameters, which mean that LogMAR near visual acuity measurement changed proportionally to a change in central mean macular thickness. The Pearson

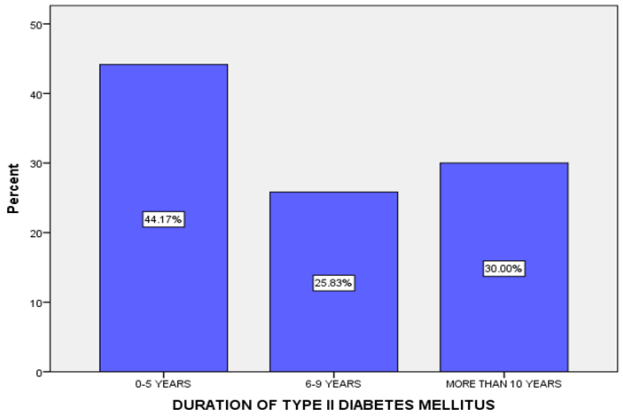

Figure 4: Duration distribution of Type - II diabetes mellitus among participants

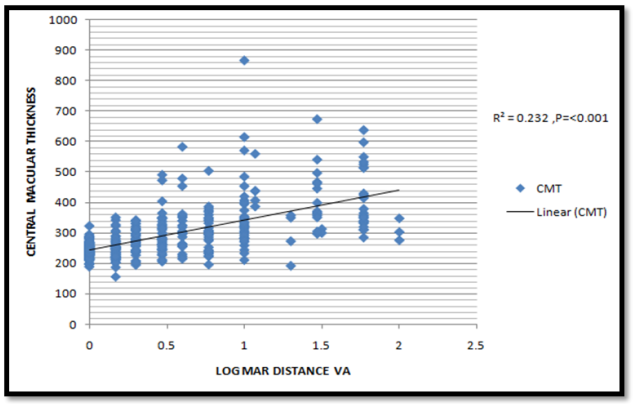

Figure 5: Linear association between Log Mar distance and central macular thickness

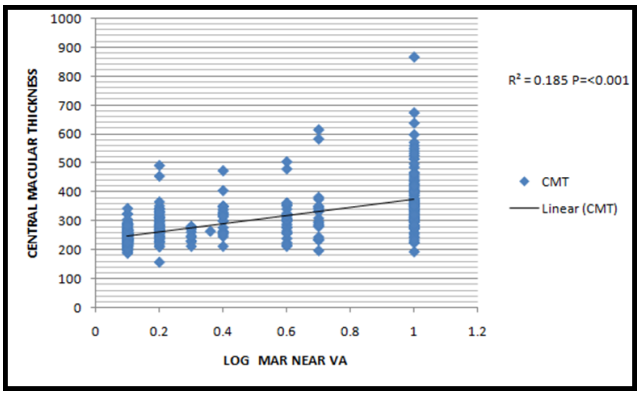

Figure 6: Showing Linear association between Log Mar Near and central macular thickness

correlation coefficient value was 0.430 with P-Value < 0.001, which indicates a moderately strong correlation between the LogMAR near visual acuity and mean central mean macular thickness in (Figure 6).

The result has shown no difference between the normal groups versus No diabetic retinopathy in Type - II Diabetes Mellitus patients. A statistically significant increase in thickness was found between Central macular thickness (p =0.016), superior outer macular (p 0.04) while comparing Normal controls with Mild NPDR. On the other hand, while comparing Normal Control versus Severe NPDR, all the macula quadrants showed a significant increase in the thickness of the macula (P<0.0001) except in the inferior inner macula. A statistically significant increase in thickness was found between comparing Normal controls with Proliferative Diabetic Retinopathy & CSME in all the quadrants of macula (P<0.001) in (Table 3).

4. Discussion

Since diabetic retinopathy is a familiar complication in recent times with booming prevalence, even an early identification and appropriate approach can decrease the sight-threatening situation.[1,19] The OCT device used in evaluating the current study has proved to be an appropriate instrument for a repeatable and straightforward retinal examination.[19] The current research has contemplated an evenly dispersed random sample of diabetic males (159 eyes) and females (172 eyes). Macular thickness levels, however, were statistically insignificant among these patients. Similar trends were also observed by,[20,21] in a study sample of nearly equal variants. On the contrary side,[22] revealed greater foveal thickness for men as compared to females. Even though[23] did not attain any association between retinal thickness, the variation was substantial in another research conducted by,[16] who affirmed the enhanced vascular permeability as can be acause in chronic diabetic patients. A highly significant (p < 0.001) and a steady decline in visual acuity was observed with an escalation in the severity of diabetic retinopathy, including CSME patients. Macular edema stands as the controlling factor for reduced visual acuity in diabetic retinopathy, resulting in considerable visual acuity reduction,[24] a high macular thickness level was observed among the control group compared to Mild Non-proliferative diabetic retinopathy participants with no diabetic retinopathy group showing statistically insignificant effect. The outcome has demonstrated a comparable trend of thin macular thickness among diabetic retinopathy participants, as discussed by[25,26] A myriad of factors are in place, not limited to the reduction of neuronal tissue, which commences from the early phases of Diabetes and thus was responsible for thinner macula in diabetic subjects.[27] Identical significant growth of macular thickness can be seen among eyes with moderate NPDR in few

Table 3: Mean macular thickness statistical distribution among control vs. different groups of diabetic retinopathies

Group	CMT± SD	TIM± SD	SIM± SD	NIM± SD	IIM± SD	TOM± SD	SOM± SD	NOM± SD	IOM± SD	CUBE VOL.	CUBE AVG.
Normal controls	239 17.9	303 14.6	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
NODR	238 21.15	308 18.73	305 11.53	313 13.54	305 17.73	253 11.68	269 13.59	288 17.43	259 13.36	9.61 0.48	269 13.73
P Value	0.71	0.07	0.06	0.89	0.057	0.09	0.13	0.58	0.17	0.09	0.09
Normal Controls	239 17.97	303 14.63	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
MILD NPDR	250 29.96	308 13.49	305 13.76	316 20.56	308 18.03	257 18.77	277 15.67	292 14.98	264 16.03	9.69 0.47	271 13.54
P Value	0.016	0.06	0.07	0.54	0.25	0.73	0.04	0.43	0.38	0.48	0.47
Normal Controls	239 17.97	303 14.63	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
Moderate NPDR	259 37.09	305 28.48	317 17.32	319 32.04	310 27.92	267 33.05	285 24.62	301 35.85	273 27.04	10.01 0.82	280 22.99
P Value	< 0.001	0.52	0.04	0.26	0.79	0.02	< 0.001	0.02	0.006	0.02	0.02
Normal controls	239 17.97	303 14.63	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
Severe NPDR	275 49.69	331 40.06	327 41.40	324 29.70	320 30.16	298 38.74	309 31.50	317 30.35	300 33.32	10.65 0.80	297 22.26
P Value	< 0.001	< 0.001	0.005	0.01	0.053	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Normal controls	239 17.97	303 14.63	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
PDR	299 48.33	330 54.80	328 59.23	331 28.67	340 53.95	313 70.05	319 43.14	338 70.59	309 60.90	10.78 1.64	300 45.14
P Value	< 0.001	< 0.001	0.02	< 0.001.	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Normal controls	239 17.97	303 14.63	310 17.52	313 16.03	311 14.52	256 11.93	272 10.92	290 12.82	262 9.52	9.74 0.35	272 9.84
CSME	464 123.28	429 97.45	436 107.53	429 105.36	432 117.84	363 88.93	365 100.92	376 93.85	354 96.94	12.21 2.27	341 63.71
P Value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

quadrants.[28] Additionally, the results stayed substantially same when compared with the severe forms of NPDR and PDR group and, CSME group (except Inferior Inner Macula for NPDR) that subsequently reflects increased serous leakage at the macular level, which might boost the retinal thickness in these Type of conditions.[27] A variation of the blood-retinal barrier in these stages can alleviate perifoveal and macular capillaries.[29] Alternatively, a possible mechanism for increased central macular thickness in patients with moderate or severe NPDR is interstitial edema, which lies secondary to perifoveal capillary loss, occurring in the course of diabetic retinopathy.[30,31]

5. Conclusion

The current study has been in a position to yield substantial results while comparing Normal control vs diabetic retinopathy groups. This study conclude that the there is an increased in the macular thickness of all quadrants especially in PDR and CSME group which may be masked by changes in vascular permeability triggering thickening of the retinal layers from early to severe diabetic changes of the macula, using optical coherence tomography for diabetic patients Type II with and without diabetic retinopathy. Although central macular thickness and visual acuity (distance as well as near are moderately strong correlated). However, insignificant lapses can be altered in future studies. Further enhancement to this study can be achieved by employing additional parameters such as dietary customs, professional environment, the metabolic state of participants. Additionally, the factors can be altered by including the relationship between choroidal thickness and choroidal blood circulation. In diabetic retinopathy, Spectral-domain OCT can be a useful device to evaluate blood flow changes in the choroid. To comprehend the choroidal role and variation among subgroups in diabetic retinopathy, more prospective studies should be done.

6. Recommendation and Limitation

More studies with greater sample size are required to find out the association between severity of diabetic retinopathy with reduction in macular thickness.The limitations of this study included the predominantly homogenous subject group a self-reported duration of disease, and a relatively small sample size, which may have increased the bias of the study. Larger and case-control studies are necessary to verify these results**.**

7. Source of Funding

This research did not receive any outside funding or support.

8. Conflict of Interest

None.

9. Ethical Approval

The study got its ethical clearance from the ethical committee of Maharishi Markandeshwar Institute of Medical Science and Research, Mullana, Ambala

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