A Comparative Study in Diabetic Patients to Assess Retinal Thickness with or without Clinically Significant Macular Oedema Visiting Tertiary Care Centre, Jharkhand

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ABSTRACT

Introduction: Diabetic retinopathy is one of the sights threatening disease. Timely diagnosis and intervention can minimize the potential risk of visual loss in susceptible patients. Retinal thickness was measured using Optical coherence tomography allowing to assess the type and severity of Diabetic Macular oedema and as it is a non-invasive technique it is useful in post treatment follow-up.

Material and Methods: This hospital based, prospective and observational study was done in a tertiary care centre of Jharkhand between June 2013 to June 2014. 140 eyes of 70 patients were examined in which 135 eyes were diagnosed with diabetic retinopathy. Age, sex, vision and central macular thickness was assessed in both cases of Diabetic Retinopathy with and without Clinically Significant Macular Edema.

Results: 140 eyes of 70 patients were examined in which 135 eyes were diagnosed with diabetic retinopathy. 73 eyes were diagnosed with Diabetic Retinopathy without Clinically Significant Macular Edema and in 62 eyes Diabetic Retinopathy with Clinically Significant Macular Edema by optical coherence tomography. Diabetic Retinopathy without Clinically Significant Macular Edema and with Clinically Significant Macular Edema in males was 27(38.6%), 30(42.9%) and in females, it was 9(12.9%), 4(5.7%) respectively. The incidence of Diabetic Retinopathy with and without Clinically Significant Macular Edema was prevalent in the age group of 56-65 years, minimum in the age group of 26-35 and in patients aged >75 with prevalence more in males as compared to females.

Conclusion: Optical Coherence Tomography was found to be a useful technique for quantitative measurement of retinal thickness in patients with diabetes. A significant correlation between foveal thickness and visual acuity was also established. Our study also suggested that despite normal findings in slit lamp bio-microscopy, early changes in retinal thickness can be detected by Optical Coherence Tomography.

Keywords: Clinically Significant Macular Oedema (CSME), Diabetic Retinopathy (DR), Diabetic Macular Oedema (DME), Diabetes Mellitus (DM), Optical Coherence tomography (OCT)

INTRODUCTION

Diabetic retinopathy is predominantly a microangiopathy in which small blood vessels are particularly vulnerable to damage from hyperglycemia[1]. According to WHO, 41.9 million people were affected by diabetes in India which is forecasted to have an estimated prevalence of 79.4 million people living with DM by 2030[2-4]. Currently India has got the largest number of diabetics and is being called as diabetic capital of the world[5]. As per the recent epidemiological survey conducted at Aravind Eye hospital, Theni has shown that there are 47.8million of diabetics in India[6].

Severe vision loss (Best corrected visual acuity 5/200 or worse) due to diabetic eye disease largely results from proliferative diabetic retinopathy (PDR), while moderate vision loss (doubling of the visual angle) primarily results from diabetic macular oedema[7]. Ninety percent of diabetics in America have Type 2 DM, and since DME is more common than PDR in the individuals, a greater number of people suffer vision loss from DME than PDR[8]. DR is the leading cause of vision loss in working-age adults, and DME is the most frequent cause of vision loss related to diabetes[9]. HD-OCT evaluates the integrity of the inner-outer segment (IS/OS junction) which is seen as hyper-reflective line just above the photoreceptors. It has been already established that disruption in the IS/OS junction indicates damage to macular photoreceptors. Maheshwari et al[10] have shown a direct relationship between percent disruptions of the IS/OS junction and visual acuity in DME. It also helps in establishing the prognosis of visual outcomes in these DME patients prior to treatment. Objective quantification of retinal thickness is advantageous not only for improving diagnostic accuracy, but also for monitoring change over time.

MATERIAL AND METHODS

It is a hospital based, prospective and observational study conducted in patients attending ophthalmology OPD and IPD in a tertiary care center of Jharkhand between June 2013 to June 2014. In this study, 140 eyes were examined in which 135 eyes were diagnosed with diabetic retinopathy.

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Inclusion criteria

1. Diagnosed cases of diabetes mellitus
2. Cases with features of diabetic retinopathy

Exclusion criteria:

1. All cases of cataract >grade II (LOCS III classification)
2. History of previous Intraocular surgery
3. Corneal opacity involving pupillary region
4. Media opacities like vitreous haze
5. Patients who received Anti VEGF treatment and laser photocoagulation

The general examination included physical and laboratory examination. In our study fasting blood glucose levels above 100mg/dl and postprandial i.e., 2 hours after taking 75gm of glucose, above 140mg/dl was considered as hyperglycemia. It also included Urine analysis and Glycosylated Hemoglobin (HbA1c) estimation.

The ocular examination included visual assessment using Snellen's chart. The eyes were examined under slit lamp bio microscopy, direct and Indirect Ophthalmoscopy. Intraocular pressure was measured with non-contact tonometry. Fundus Fluorescein Angiography was done in all selected cases followed by examination under optical coherence tomography.

After minimum pupillary dilatation of 5 mm diameter, using the 512 x 128 scan pattern of Cirrus™ HD-OCT scanning was performed. A 6mm x 6mm macular grid was scanned with 128 horizontal B-scan lines, where each consisted of 512 A-scans per line (total of 65,536 sampled points). We obtained a total of three "high-quality" scans; which were defined as scans with a signal strength of ≥ 6 exhibiting correct delineation of the ILM and RPE which was detected automatically by the intrinsic software segmentation algorithm. During OCT scanning, macular grid was centered on the intrinsic fixation target, and decentration of the grid was done by the technician as an attempt to centre the grid on the fovea was not allowed. Hence the centre of the macular grid was maintained at the patient's point of fixation. The measurements were obtained for three parameters: macular grid (6mm x 6mm), the central subfield (1 mm diameter), as well as for the central foveal point (0.33mm diameter). The software provided by the manufacturer helped in Macular thickness measurements.

The macular thickness compares the measured macular thickening to age-matched data in Cirrus RNFL Normative Database. The age-matched normative data to the patient appears after performing the macular thickness analysis, done on all patients 18 years of age or older. A White-green-yellow-red colour code is used as macular normative database, which is seen as legend over the right side, indicating the normal distribution percentiles.

In the normal population of same age individuals, the percentiles applied to each particular macular thickness measurement along the calculation circle are as follows:

- The red area indicates the thinnest 1% of measurements. Measurements in red are considered outside normal limits (red <1%, outside normal limits).
- The yellow area or below indicates the thinnest 5% of measurements (1%≤ yellow <5%, suspect)
- The green area consists of 90% of measurements (5% ≤ green ≤95%)
- The white area is the thickest 5% of measurements (white > 95%).

The quadrants were divided as superior outer (SO), nasal outer (NO), inferior outer (IO), temporal outer (TO), superior inner (SI), nasal inner (NI), inferior inner (II), temporal inner (TI) and foveal thickness. The average macular thickness was also calculated.

RESULTS

The study comprised of 140 eyes of the 70 patients out of which 135 eyes were diagnosed with DR. These eyes were subsequently categorized into two groups according to the presence or absence of CSME. As a result, there were 73 eyes without CSME and 62 eyes with CSME.

The basic characteristics of the diabetic eyes without and with CSME is shown in Table 1.

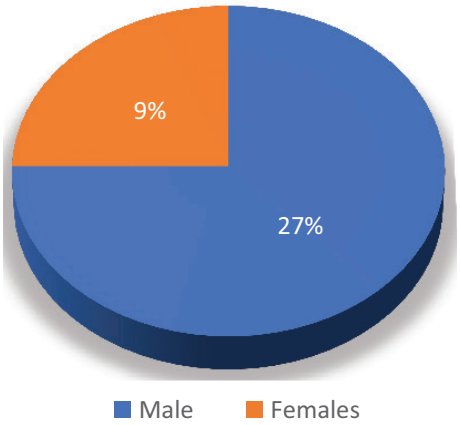
Eyes with CSME were compared to those without CSME in retinal thickness by student's t-test with unequal variances. The correlation between foveal thickness and visual acuity was also determined by student's t-test. Significance level was set at $p<0.05$.

	Eyes without CSME (n=73)	Eyes with CSME (n=62)	P value
Age (Year)	60±12.10	50±12.40	0.417
LogMAR visual acuity	0.16±0.17	0.45±0.58	0.086
Refractive power (dioptre)	0.14±1.31	0.75±2.63	0.439
NPDR/PDR	73/4	62/2	0.682
Mean duration of DM	9.0±7.4	12.80±6.9	0.043

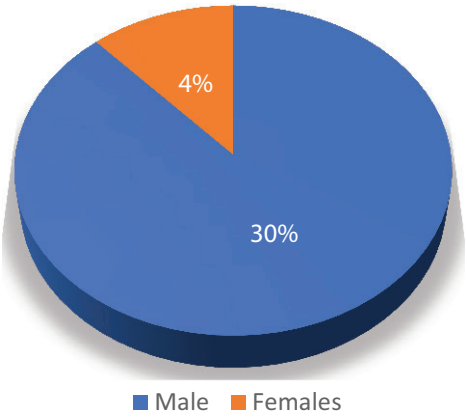
DR without CSME in males was 27(38.6%) and in females it was 9(12.9%) [Graph 1]. DR with CSME in males was 30(42.9%) and in females it was 4(5.7%) [Graph2]. We concluded that DR with and without CSME is more prevalent in males as compared to females.

The incidence of DR without CSME and DR with CSME was much more prevalent in the age group of 56-65 years and minimum in the age group of 26-35 and in patients aged >75. The incidence of DR without CSME is depicted in Graph 3 and DR with CSME in Graph 4.

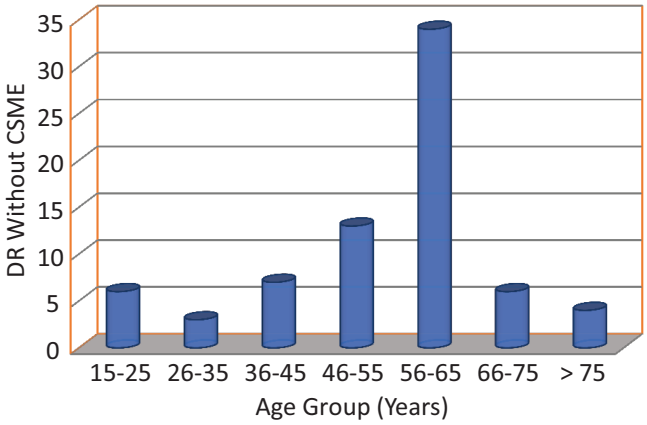
Comparison of macular thickness (mean ± standard deviation in mm) measured using optical coherence tomography



Graph-1: Males and Females without CSME



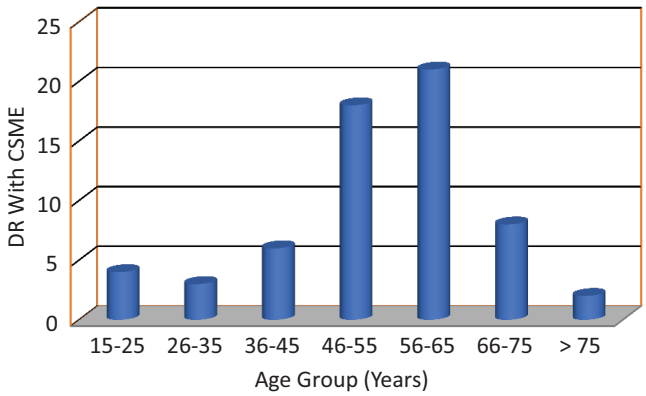
Graph-2: Males and Females with CSME



Graph-3: DR without CSME

between diabetic eyes with CSME and without CSME is shown in Fig.1 and Fig.2.

Standard deviation (SD) of the average thickness of the six tomograms at the central fovea was found to be less than 10% of the measured foveal thickness, with about 18.0µm and 16.9µm in eyes with CSME and without CSME, respectively. In eyes with CSME the SD was slightly larger, which did not significantly differ from that in eyes without CSME(P=0.970). In eyes with CSME the mean ± SD foveal thickness was 492.10 ± 79.90µm, and 230 ± 12.40µm in eyes without CSME(P=0.970). Eyes with CSME generally had thicker retina than those without CSME on locations outside the central fovea, the difference being statistically significant



Graph-4: DR with CSME

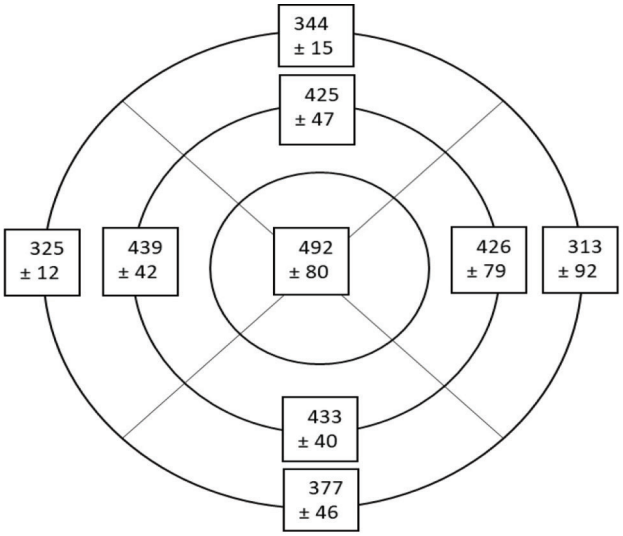


Figure-1:

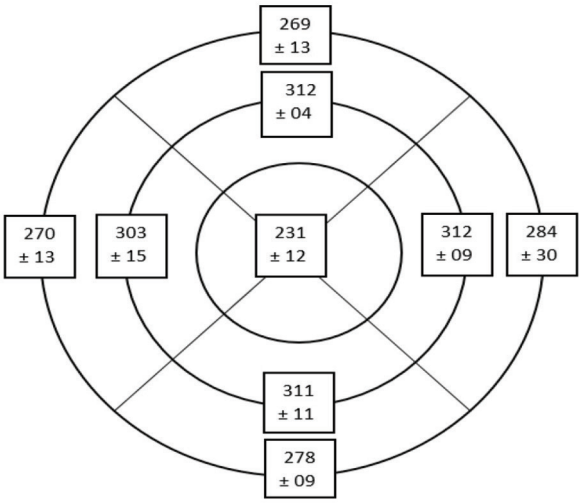


Figure-2:

within 3 rings of the inferior quadrant (P<0.01), the inner rings of the superior quadrant (P<0.05), and the middle rings of both the nasal and temporal quadrants(P<0.05).

In 73 eyes without CSME(P=0.905), foveal thickness and best corrected visual acuity did not have significant correlation, the result was statistically not significant at P<0.05. There was a positive correlation between the foveal

thickness and the logMAR visual acuity (P<0.00001) of 62 eyes with CSME, the result was significant at P<0.05.

DISCUSSION

The most sensitive parameter related to diabetic macular oedema (DME) is precise measurement of macular thickness[11]. OCT is an accurate technique for quantifying macular thickness in patients with DME[12]. OCT studies have consistently revealed retinal structural changes and increased retinal thickness in patients with DME[13]. In this study, 140 eyes were examined in which 135 eyes were diagnosed with diabetic retinopathy, which consisted 73 eyes without CSME and 62 eyes with CSME. There was a significant retinal thickening in diabetic eyes with CSME as compared to those without CSME. Fovea and parafoveal areas, especially the inferior quadrant showed retinal thickening in eyes with CSME. Histologically, there is higher density of Muller cells at the foveal floor than at the retinal edges[14]. In this study eyes with CSME generally had thicker retina than those without CSME on locations outside the central fovea, the difference being statistically significant within 3 rings of the inferior quadrant (P<0.01), the inner rings of the superior quadrant (P<0.05), and middle rings of both the nasal and temporal quadrants (P<0.05). In eyes, with CSME the SD was slightly larger, which did not significantly differ from that in eyes without CSME(P=0.970). In eyes with CSME the mean ± SD foveal thickness was 492.10 ± 79.90µm, and 230 ± 12.40µm in eyes without CSME(P=0.970). Chang -Sue Yang et al[15] stated that the mean ± standard deviation foveal thickness was 255.6 ± 138.9µm in eyes with CSME, and 174.6 ± 38.2µm in eyes without CSME (P=0.051). We concluded that DR with and without CSME is more prevalent in males as compared to females. E A Gale et al[16] stated that men seem more susceptible than women to the consequences of indolence and obesity, possibly due to differences in insulin sensitivity and regional fat deposition. The prevalence of diabetes increased with age, reaching its peak at 70–89 years of age in Chinese and Japanese subjects, and at 60–69 years of age followed by a decline at 70 years of age in Indian subjects according to Decoda study group[17] which is consistent with our present study that the incidence of DR without CSME and DR with CSME was much more prevalent in the age group of 56-65 years and minimum in the age group of 26-35 and in patients aged >75.

CONCLUSION

We concluded that OCT played a useful technique in the assessment of retinal thickness in diabetic patients. Our study fully supports previous suggestions that early changes in retinal thickness can be detected by OCT despite normal findings in slit lamp bio microscopy. In addition, our results suggested that abnormal macular thickening may be suspected if the foveal thickness measures more than 180 µm on OCT, indicating patient to be a candidate for more frequent and detailed follow-up. Future long-term studies are required to investigate whether patients with areas of subclinical retinal thickening in specific regions are at higher risk for the development of retinopathy than those with normal OCT findings.

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