Journal of Diabetes and Its Complications 36 (2022) 108131

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: www.elsevier.com/locate/jdiacomp

Prevalence and risk factors for diabetic retinopathy in prediabetes in Asian Indians

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ARTICLE INFO

Keywords:
Diabetic retinopathy
Prediabetes
HbA1c
Ultrawide field retinal photography

ABSTRACT

Aim: To assess the prevalence of diabetic retinopathy (DR) and associated risk factors in Asian Indians with prediabetes.

Methods: In a cross-sectional study conducted at two tertiary care diabetes centres in Chennai, India, clinical and biochemical assessment and nonmydriatic ultra-wide field fundus photography was performed in individuals with prediabetes (impaired fasting glucose [IFG] and/or impaired glucose tolerance [IGT]) based on oral glucose tolerance test (OGTT) and/or glycated hemoglobin (HbA1c) between 5.7% and 6.4% in 2019. The retinal photographs were graded by certified ophthalmologists. Systemic risk factors associated with DR in prediabetes were assessed.

Results: The mean age of the 192 individuals with prediabetes was 48 ± 13 years (55.2% were males). DR was present in 12 (6.3%) individuals of which nine (4.7%) had mild non-proliferative DR (NPDR) and three (1.6%) had moderate NPDR. None had severe sight-threatening DR. The Poisson multiple regression analysis showed that after adjusting for other systemic covariates, HbA1c values ≥ 6% (6–6.4%) was associated with 2 times higher relative risk of DR (Risk ratio 1.95 (95% CI 1.07–3.545, p = 0.028) in comparison to HbA1c < 6%).

Conclusion: DR was present in about 6% of the Asian Indians with prediabetes. Higher HbA1c values among individuals with prediabetes was associated with twice the relative risk for DR. Robust control of HbA1c should be encouraged even before the diagnosis of diabetes is established.

1. Introduction

Diabetic Retinopathy (DR) is a specific microvascular ocular complication associated with diabetes.[1] The global prevalence of chronic microvascular complications like DR is increasing due to the increasing prevalence of diabetes worldwide as well as the increased survival of people with diabetes.[2] Prediabetes refers to the intermediate metabolic state between normoglycemia and diabetic glucose homeostasis. People with prediabetes are defined by the presence of impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT).[3]

Glycemic threshold is mainly built on the relationship between blood glucose and development of DR as it is considered to be the most specific microvascular complication of diabetes. The fasting plasma glucose (FPG) ≥ 126 mg/dl [7.0 mmol/l], 2 h post load plasma glucose (PPG) ≥ 200 mg/dl and glycated hemoglobin (HbA1c) ≥ 6·5% criteria for diagnosis of diabetes was adopted by ADA[3] and subsequently recommended by the World Health Organization (WHO) and this was based on the risk of development of DR.[4]

Some studies have indicated that DR and other complications of diabetes could be present even at the prediabetes stage (both IGT as well as IFG).[5,6,7,8] In the Diabetes Prevention Program (DPP) at the United States of America (US)[5] and the Gutenberg Health Study in Germany,[6]

; DR, Diabetic retinopathy; IGT, Impaired glucose tolerance; IFG, Impaired fasting glucose; OGTT, Oral glucose tolerance test; NPDR, Nonproliferative diabetic retinopathy; HbA1c, Glycated hemoglobin.

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https://doi.org/10.1016/j.jdiacomp.2022.108131
Received 20 October 2021; Received in revised form 10 January 2022; Accepted 11 January 2022
Available online 23 January 2022

DR was observed in about 8% among individuals with prediabetes. DR was present in 6.7% of the participants with prediabetes in the AusDiab Study.[7] The ICMR INDIAB study showed the overall prevalence of prediabetes in all 15 states in India to be 10·3%.[9] According to National Urban Diabetes Survey, the estimated prevalence of prediabetes in India is around 14%.[10] However no major studies have been done so far to assess the prevalence of DR in prediabetes in India.

The aim of the study is to assess the prevalence of DR and associated systemic risk factors in Asian Indians with prediabetes.

2. Methods

This was a cross-sectional study done in 2019 at two separate tertiary care diabetes centres in Chennai, India.

Regular outpatients visiting the two diabetes care centres who were diagnosed as having prediabetes by oral glucose tolerance test (OGTT) conducted during the previous visit to the centres were identified from the Diabetes Electronic Medical Records (DEMR) available at the two centres. They were invited to participate in the study.

Inclusion Criteria: Individuals with prediabetes aged over 18 years, who are not on any pharmacotherapy for diabetes and willing to undergo blood tests including OGTT as well as a comprehensive eye examination and retinal colour photography, were included in the study. Prediabetes is defined as a state of intermediate hyperglycemia with two parameters namely impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) or a combination of both, based on an oral glucose tolerance test (OGTT) and/or glycated hemoglobin (HbA1c) between 5.7% and 6.4% (39–47 mmol/mol).[3] The criteria for prediabetes are shown in Table 1.

Exclusion Criteria: Individuals with known diabetes, newly diagnosed diabetes, on any pharmacotherapy for diabetes, those with HbA1c values $\geq$ 6.5%, individuals with gestational diabetes, or those not willing for fundus photography were excluded from the study. After the approval of the respective Institutional Ethics Committee (IEC) of both Institutions, the study was conducted over a period of 12 months in 2019. A written informed consent was obtained from all the participants.

Study participants underwent anthropometric measurements, measurement of blood pressure, an oral glucose tolerance test (OGTT), glycated hemoglobin (HbA1c) and serum lipid profile in the hospital laboratory and complete eye examination and ultrawide field fundus photography with Optos Daytona Plus fundus camera at the ophthalmology department.

2.1. Clinical assessment

Medical history elicited included age, family history of diabetes, history of hypertension and treatment history. Height, weight and waist circumference were measured and body mass index (BMI) was calculated as the ratio of the weight in kilograms to the square of height in meters. Blood pressure was measured using standardized technique.

2.2. Bio-chemical assessment

Blood sample (venous whole blood) was collected in the morning after at least 8 h of overnight fasting to determine fasting plasma glucose. OGTT was carried out. The biochemical parameters that were assessed included fasting plasma glucose (FPG), 1 h post-load plasma glucose, 2 h post-load plasma glucose (PPG), serum HbA1c and serum lipid profile. HbA1c was estimated by high-performance liquid chromatography using the Variant machine (Bio-Rad, Hercules, CA, USA) and the rest of the biochemical parameters were measured on Beckman Coulter AU2700 (Fullerton, CA, USA) biochemistry analyser.

Table 1
Criteria for defining prediabetes: any one of the 3 criteria would qualify as prediabetes.[3]

Impaired fasting glucose (IFG)	Fasting plasma glucose (FPG) - 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l)
Impaired glucose tolerance (IGT)	2-hour post load plasma glucose (PPG) during 75-g oral glucose tolerance test (OGTT) - 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11 mmol/l)
Glycated hemoglobin (HbA1c)	5.7–6.4% (39–47 mmol/mol)

2.3. Ophthalmic assessment

All study participants underwent a complete ophthalmic examination and retinal colour photography. Preliminary eye examination included assessment of visual acuity, intraocular pressure measurement and slit lamp examination of the anterior segment. Nonmydriatic ultrawide field fundus photography was performed using Optos Daytona Plus fundus camera [Optos Plc., UK] by a qualified optometrist. Ultrawide field (UWF™) 200° field of view optomap retinal images of both eyes were taken without dilatation. The grading of fundus photographs for presence and severity of DR was done by certified retina specialists based on the International Clinical Diabetic Retinopathy (ICDR) severity scale.[11] The minimum criterion for diagnosis of DR was the presence of at least one definite microaneurysm in any field of the retina in either eye.[12] The final diagnosis for each study participant was determined from the level of DR of the worse eye using ICDR scale.

2.4. Statistical analysis

SPSS for Windows version 24.0 was used for data analysis. Descriptive analysis was used for continuous and categorical variables. Continuous variables were expressed as mean with standard deviation (SD) and categorical variables as proportions. Chi-square test was used for categorical variables and *t*-test was used for compare the continuous variables. Univariate regression analysis was used to identify potential associated risk factors. As the prevalence of DR was low (<10%), relative risk analysis/ risk ratio (RR) was performed using Strata for assessment of systemic risk factors associated with DR. The Poisson multiple regression model was used to obtain the RR with 95% confidence interval (CI) after adjusting for systemic covariates. P value $<$ 0.05 was considered statistically significant.

3. Results

Two hundred and eleven participants underwent clinical and biochemical assessments, OGTT, and fundus photography in this study (Fig. 1). Six individuals who had normal glucose homeostasis and thirteen of them who were diagnosed with newly diagnosed diabetes and/or HbA1c values $\geq$ 6.5% were excluded from the analysis. Descriptive analysis of 192 participants (55% males) with prediabetes is presented in Table 2. The mean age of the individuals with prediabetes was 48 $\pm$ 13 years. One hundred and fourteen (59.4%) individuals had IGT, 65 (33.8%) had IFG and 13 (6.8%) individuals had both IFG and IGT.

Among the 192 individuals with prediabetes, twelve (6.3%) of them had DR. There were no statistically significant differences in the systemic parameters observed in the individuals with prediabetes, with and without DR (Table 2), although some parameters like mean age, systolic blood pressure, serum cholesterol and mean HbA1c were higher in individuals with DR when compared to those without DR. The prevalence of cataract was significantly greater among those with DR (p = 0.001).

Table 3 shows the distribution of varying grades of severity of DR among individuals with prediabetes. Mild non-proliferative DR (NPDR) was detected in 9 (4.7%) individuals and three (1.5%) had moderate NPDR. The DR lesions mainly observed included microaneurysms, the hallmark sign of diabetic retinopathy (DR). In addition to microaneurysms, dot and blot hemorrhages and cotton wool spots were also seen in a few of them. None of them had severe sight-threatening DR

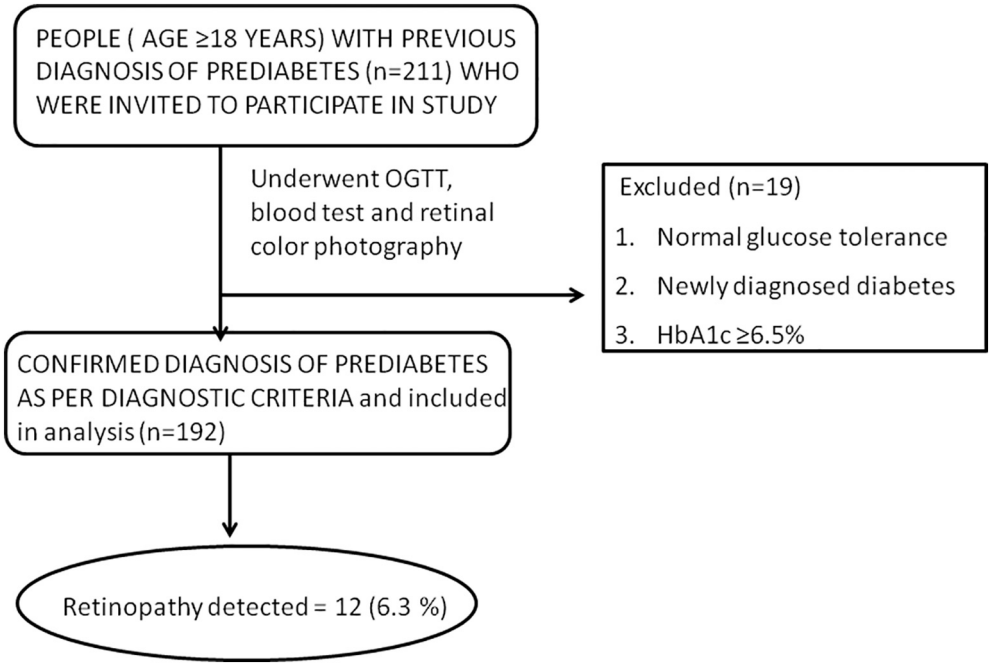

Fig. 1. Flow chart showing the recruitment of participants with prediabetes in the study.

Table 2
Baseline characteristics of people with pre-diabetes screened for diabetic retinopathy (DR).

Variables	Overall (n = 192)	Without retinopathy (n = 180)	With DR (n = 12)	p-Value
Age (years)	48 ± 13	48 ± 13	50 ± 11	0.621
Gender male n (%)	106 (55.2)	97 (53.9)	9 (75.0)	0.154
Height (cm)	162 ± 10	161 ± 10	165 ± 9	0.188
Weight (kg)	73 ± 17	73 ± 17	76 ± 15	0.575
Body mass index (kg/m^2)	28 ± 6	28 ± 6	28 ± 5	0.974
Waist (cm)	96 ± 11	96 ± 11	99 ± 11	0.384
Type of pre-diabetes				
Impaired Glucose Tolerance (IGT) n (%)	114 (59.4)	107 (59.4)	7 (58.3)	0.341
Impaired Fasting Glucose (IFG) n (%)	65 (33.8)	62 (34.4)	3 (25.0)	
IGT+ IFG n (%)	13 (6.8)	11 (6.1)	2 (16.7)	
Systolic blood pressure (mmHg)	124 ± 15	124 ± 14	130 ± 20	0.199
Diastolic blood pressure (mmHg)	78 ± 8	79 ± 8	77 ± 9	0.511
Fasting plasma glucose FPG (mg/dl)	104 ± 12	104 ± 12	108 ± 13	0.228
GTT_ 1 h plasma glucose (mg/dl)	183 ± 41	183 ± 41	175 ± 39	0.478
2 h post load plasma glucose (PPG) mg/dl	140 ± 34	140 ± 34	142 ± 27	0.826
Glycated hemoglobin HbA1c (%)	5.8 ± 0.42	5.8 ± 0.43	6.1 ± 0.30	0.071
Serum total cholesterol (mg/dl)	193 ± 39	193 ± 40	204 ± 24	0.429
Serum triglycerides (mg/dl)	137 ± 58	137 ± 60	139 ± 38	0.908
Serum LDL cholesterol (mg/dl)	122 ± 32	121 ± 32	133 ± 19	0.285
Serum HDL cholesterol (mg/dl)	44 ± 12	45 ± 13	40 ± 6.4	0.337
Cataract present n (%)	28 (14.6)	22 (12.2)	6 (50.0)	0.001
Other eye disorders (drusen, glaucoma, retinal vein occlusion) n %	5 (2.5)	3 (1.6)	2 (16.6)	0.329

Table 3
Varying grades of diabetic retinopathy (DR) in individuals with prediabetes.

Grades of severity of diabetic retinopathy (DR)	Individuals with prediabetes (n = 192)
No DR (normal) n (%)	180 (93.8)
Mild non-proliferative DR n (%)	9 (4.7)
Moderate non-proliferative DR n (%)	3 (1.5)
Severe non-proliferative DR n (%)	0 (0)
Proliferative DR n (%)	0 (0)

changes. DR was more commonly seen in people with IGT.

To assess the role of systemic risk factors associated with DR, we subdivided the study participants based on HbA1c into 2 groups; those with HbA1c $< 6\%$ and HbA1c $\geq 6\%$ (6–6.4%). Among the individuals with DR, 1/3rd had HbA1c $< 6\%$ and 2/3rd of them had HbA1c $\geq 6\%$ as shown in Fig. 2. The univariate regression analysis did not show any significant risk factors associated with DR. As the DR prevalence was low, risk ratio (RR) was used for assessment of systemic risk factors associated with DR in prediabetes. The Poisson multiple regression model was used to obtain the relative risk/risk ratio (RR). After adjusting for confounders like age, gender, BMI, hypercholesterolemia and hypertension, we found that HbA1c values $\geq 6\%$ (6–6.4%) was associated with 2 times higher relative risk of DR (Risk ratio 1.95 (95% CI 1.07–3.545, $p = 0.028$) in comparison to HbA1c $< 6\%$).

4. Discussion

Pre-diabetes is a state of intermediate hyperglycaemia with the plasma glucose levels below that diagnostic of diabetes. The most obvious sequel of prediabetes is the development of type 2 diabetes. Also according to the 'ticking clock hypothesis', the clock for macrovascular complications of diabetes starts ticking even at the stage of prediabetes.[13] In this study we have assessed the prevalence of DR, a microvascular complication of diabetes, in people with prediabetes. Studies done earlier elsewhere[5–7] as well as our current study have shown that typical DR lesions can be found even in people with prediabetes.

The prevalence of DR in prediabetes in the Asian Indians in our study was 6.3% is similar to DR prevalence in prediabetes in the AusDiab

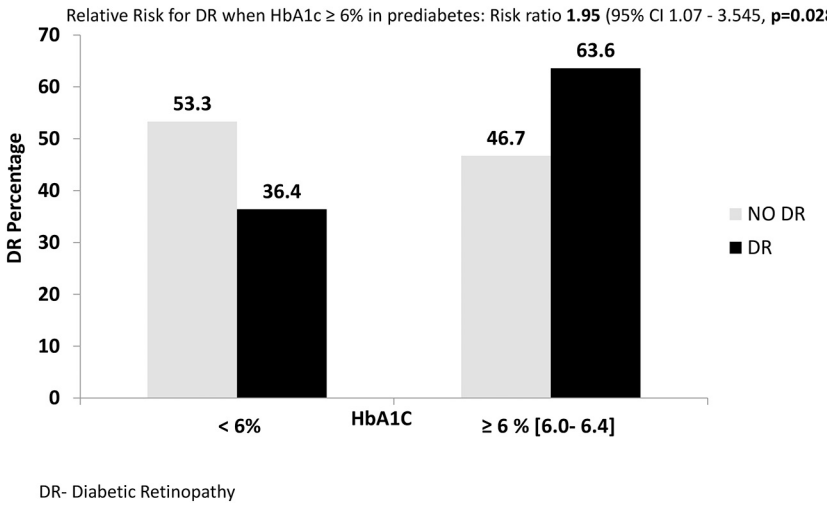

Fig. 2. Diabetic retinopathy (DR) based on glycated hemoglobin (HbA1c) in prediabetes.

study.[7] DR prevalence in pre diabetes reported in two studies in the western countries; the DPP conducted in the US[5] and the Gutenberg study done in Germany,[6] were similar (8%), slightly more than the prevalence of DR in our study . The prevalence of DR in prediabetes in a study done in China in 110 Chongqing pre-diabetes patients, reported a higher prevalence of 20.9% possibly because the study used fundus fluorescein angiography (FFA) for DR detection unlike our study and other studies that utilised fundus photography for documenting DR lesions.[14] Nagi et al. published a study in 1997, demonstrating DR in 12% of people with prediabetes in a study done in 68 Pima Indians with IGT.[15] In our study also we found that DR was more common in individuals with IGT than those with IFG. In the Shanghai diabetic complications study, prevalence of DR in prediabetes was lower at 2.5%.[16] However in that cohort, the prevalence of DR in known diabetes was also lower (9.4%).

It is now evident from various studies that retinal vascular changes such as microaneurysms, retinal arteriolar narrowing and retinal venous dilatation are also observed in prediabetes.[8] While microaneurysms constitute the first clinical sign and the hallmark sign of DR, intra-retinal hemorrhages like dot and blot hemorrhages, superficial hemorrhages, etc. can also be signs of other systemic vascular disorders like hypertension, blood dyscrasias or retinal vein occlusion. Retinal image analysis studies and measurement of caliber of the retinal vasculature in people with prediabetes by noninvasive methods or through the use of artificial intelligence algorithms can help to identify the individuals who are risk of development of diabetes or complications of diabetes like cardiovascular disease.[17]

Most importantly, this study shows that hyperglycemia is the strongest modifiable risk factor for DR before the glycemic threshold of diabetes is established, highlighting the need for optimal and early control of glycemia. This is in keeping with a recent environment-wide association study (EWAS) study on the National Health and Nutrition Examination Survey (NHANES) dataset.[18] Our study has also reinforced the importance of screening for DR right from the time of diagnosis of diabetes in people with type 2 diabetes and also among people with prediabetes, atleast in those who have HbA1c $\geq$ 6%. Robust control of HbA1c should be encouraged even before the diagnosis of diabetes is established.

Earlier epidemiological studies have shown the prevalence of DR in people with diabetes in India to be around 18%.[1] The lower prevalence of DR in India is reflected in the lower prevalence of DR in prediabetes among Indians seen in this study. With exponential increase in the diabetes in India, the prevalence of prediabetes as well as DR may rise over time in India.[9,19] Therefore, policy makers should focus on measures for prevention of diabetes.

The strengths of the study are that the study has been carried out in two tertiary care diabetes centres. To the best of our knowledge, this is possibly the first study from India on the prevalence of DR in Asian Indians with prediabetes. This is also possibly the first study globally that has utilised UWF fundus photography for documenting DR lesions in prediabetes as well as used HbA1c cut off points along with OGTT plasma glucose values. The UWF imaging enabled detection of DR lesions in the retinal periphery without dilatation.

This study is not without limitations. This is a clinic-based study and hence the findings with respect to prevalence of DR in prediabetes cannot be extrapolated to the population as referral bias could have influenced the results. It is a cross-sectional observational study, and causal inferences cannot therefore be drawn. We did not know the exact duration of prediabetes in the study participants to know if the duration of prediabetes had any role to play in the development of DR. The low prevalence of DR as well as the different sizes of the type of prediabetes groups in this cohort could have also possibly biased the results. However, such a study on the retinopathy in prediabetes with UWF fundus photography is possible only in the clinic scenario.

To conclude DR is present in about 6% of people with prediabetes, seen at two diabetes centres in south India. Lifestyle modification for better glycemic control in individuals with prediabetes is essential. Successful implementation of diabetes prevention programmes in India can also help in reducing the burden of diabetes and its complications on our healthcare systems.

CRediT authorship contribution statement

Conceived and designed the study: RR SS VM; Wrote the manuscript: RR; Data collection and Analysis: SK, GU, CS; Statistical Analysis: UV; Helped revising the manuscript for important intellectual content: VM, SS, SK, VV. Read and approved the final manuscript: RR, GU, SS, UV, CS, SK, VV, VM.

Declaration of competing interest

None.

Acknowledgement

We wish to thank Optos Plc, Scoland, (UK) for providing the Daytona Plus camera for performing ultrawide field fundus photography for this study.

This study, as a part of the ORNATE India project, was partly funded by the Global Challenges Research Fund (GCRF) UK Research and

Innovation (UKRI) (MR/P207881/1).

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