



Prevalence and risk factors for Diabetic Retinopathy: A population based assessment from Theni District, South India

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Title page

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Prevalence and risk factors for Diabetic Retinopathy: A population based assessment from Theni District, South India

ABSTRACT

Aims: To estimate the prevalence of Diabetic Retinopathy (DR) and the possible risk factors associated with DR, in a population of South India.

Methods: A cross sectional sample of subjects aged 30 years and older was selected using a cluster sampling technique from Theni district of Tamilnadu state. Eligible subjects were identified through a door to door survey and fasting blood glucose estimation. History of diabetes was elicited, and height, weight, and blood pressure were measured for all subjects. Ocular examinations including visual acuity and anterior and posterior segment examinations were performed at preselected sites within clusters.

Results: Among the 25,969 persons screened for Diabetes Mellitus (DM), 2802 (10.8%) (95%CI: 9.3%, 12.2%) were detected to have DM. Diabetic retinopathy was detected in 298 (1.2%) of 25,969 subjects. The age-gender adjusted prevalence of DR is 0.05% (95%CI: 0.04%, 0.06%) for rural and 1.03% (95%CI: 0.89%, 1.12%) for urban areas. The overall age-gender-cluster adjusted prevalence of DR was 0.74% (95% CI: 0.66%, 0.83%). Diabetic retinopathy was present in 12.2% (95% CI: 10.4%, 14.1%) of the DM population.

Conclusion: Adequate training of ophthalmologists in treating diabetic retinopathy and improvement in eye care infrastructure is needed to tackle this major public health problem in India.

INTRODUCTION

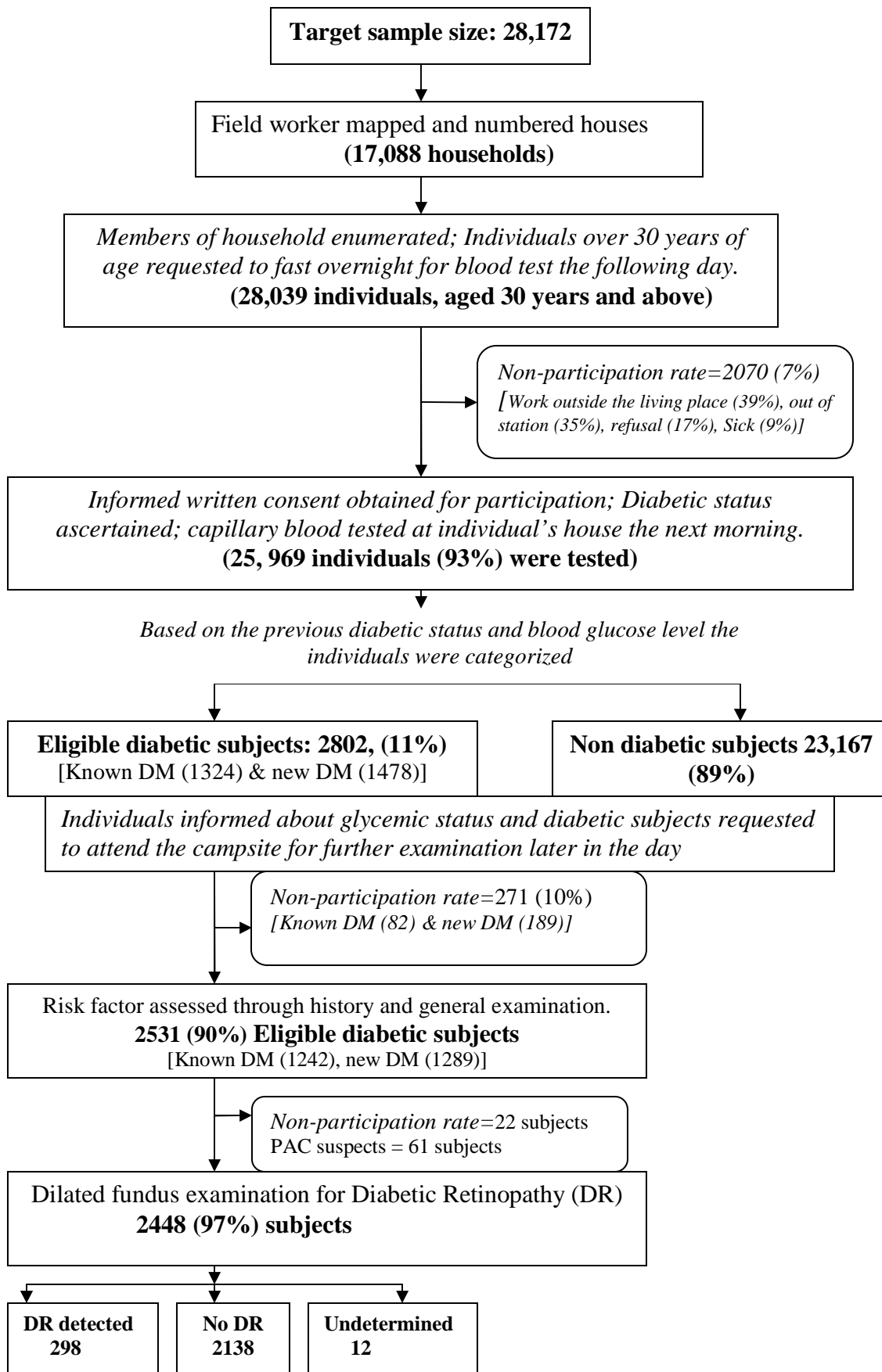
It is estimated that 79.4 million people in India will have diabetes by the year 2030.¹ The rapid increase in the number of persons with diabetes is expected to lead to an increase in the number of persons with complications from diabetes. There are few studies that have reported the magnitude and distribution of diabetic retinopathy (DR), in India.²⁻⁵ Accurate estimates of the magnitude and distribution of diabetes and complications from diabetes are essential to plan for appropriate healthcare infrastructure development in India. This study aimed at estimating the population prevalence of DR and the possible risk factors associated with DR.

METHODS AND MATERIALS

A population based cross-sectional study was done from August 2005 to March 2006 at the district of Theni in Tamil Nadu, south India (a geographical area of 3,244 square kilometers) covering individuals aged 30 years and older and resident of the district. Theni district is a semi-rural agrarian district in the southern part of Tamilnadu. It has five sub-districts, which includes, Theni, Andipatti, Bodinayakanur, Uthamapalayam, Periyakulam. We chose this district for the study since it has a semi-rural structure (55% rural) and infrastructure for retinal examinations through our base hospital are available in the district. Assuming a prevalence of 1% for DR (based on previous studies that reported prevalence of DR from 0.5 - 1.8% in India²⁻⁵), a relative precision of 15% with 95% confidence, a design effect of 1.5 and a drop-out rate of 10%, the sample size for the study was estimated at 28,172 individuals. Twenty four rural and 29 urban clusters (based on the proportion of individuals aged 30 years and above estimated at 35 - 40% of the total population⁶) were randomly selected from a sample frame that included all villages of the district. All full time residents of the sampled clusters irrespective of gender who had completed 30 years of age as on the day of enumeration were considered eligible for inclusion in the study. Persons living and partaking of the kitchen in that household for at least the past 6 months were considered as full time residents.

Trained field staff, through a door-to-door survey, identified eligible subjects for the study. Subjects were enrolled into the study after explaining about the study and obtaining informed consent. Trained field staff administered a standardized set of questionnaires that included socio-demographic details, diabetes screening form, risk factor assessment form that collected details of physical activity, smoking and dietary habits and clinical examination forms (measurement on blood pressure, anthropometry, visual acuity, cardiovascular disease (CVS)), to all enrolled subjects. The diabetes screening form includes the personal details of the subject, the details of whether a person was a known diabetic (determined by subject's previous medical history) and if they were diabetic, the duration of diabetes and details of the current medication they were using. These details were collected by the field worker and cross-checked by the field coordinator. Regarding diet, the data collected focused on whether the subject is a vegetarian or a non-vegetarian. Regarding smoking, the data collected focused on if the subject was a current smoker or not. We defined a person as having cardiovascular disease based on the medical history and medical records, and prescriptions.

The study protocol was approved by the Institutional Review Board and the research adhered to the tenets of the Declaration of Helsinki. A schematic representation of the study design is shown in the following flowchart.



Enrolled subjects were explained about the process of fasting for blood glucose estimation. Fasting blood glucose was estimated on capillary blood samples using a glucometer (MediSence Optimum, Abbott Laboratories, Bedford MA 01730, USA) and test strips (Optimum Point-of-Care Blood Glucose Test Strips). Individuals were categorized as ‘eligible subjects with diabetes’ if the fasting blood glucose level was ≥ 126 mg/dl.⁷ Previously diagnosed (based on medical history and prescriptions) persons with diabetes (Known Diabetes Mellitus, KDM) were categorized as ‘eligible subjects with diabetes’ irrespective of the fasting blood sugar levels.

A standard measuring tape was used to measure the height of subjects up to one decimal place. A standard platform weighing scale was used to measure weight (Kg) to the nearest one decimal place correcting for the zero-error. Body mass indices (BMI) were derived and individuals were categorized as underweight (<18.5 kg/m²), normal (18.5-24.9 kg/m²), overweight (25.0 – 29.9 kg/m²) and obese (≥ 30 kg/m²).⁸

A trained nurse measured blood pressure on the left arm of each individual using a Sphygmomanometer (Diamond Co industrial Electronics and Allied products, Pune , India) by a standardized technique.⁹ Hypertension was defined as a systolic blood pressure of >140 mmHg and/or diastolic pressure of >90 mmHg.

Trained ophthalmic nurses used E logMAR charts to measure presenting distance visual acuity. Fellowship trained retina specialists evaluated the anterior segment of enrolled subjects using a portable hand held slit lamp (Heine HSL 100). Subjects suspected to have narrow angles (by van Hericks method) had their dilatation deferred and were referred to the base hospital for gonioscopy and further evaluation.

Pupillary dilatation was achieved by instilling a combination of tropicamide (0.8%) and phenylephrine hydrochloride (5%) (TROPICAMET PLUS Sterile eye drops, Sun pharmaceuticals, India). The study ophthalmologists used both direct and indirect ophthalmoscopy to look for signs of DR including the presence of even one micro aneurysm within the arcades; dot or blot haemorrhages, hard exudates, cotton-wool spots, intra-retinal microvascular anomalies (IRMA), venous beading, neo-vascularization of the disc (NVD) or elsewhere (NVE), vitreous haemorrhages with or without fibro-vascular proliferation, and evidence of tractional retinal detachment. DR was classified for each eye as no retinopathy (level 1), mild-moderated non-proliferative DR (NPDR, levels 1.5-3), severe NPDR (levels 4-5) and proliferative DR (PDR, levels 6-7) based on the modified classification method as described by Klein et al.¹⁰ The level of retinopathy in the worst eye was used to classify the retinopathy status of each person. Persons for whom retinal status could not be assessed due to media opacities or other reasons were referred to the base hospital for further examination.

The study questionnaire collected details on activity habits (hrs/day) of diabetic subjects. Activity levels at work and in household duties were considered per day and the scores were multiplied by the number of days per week engaged in similar activity. The score varied from 1 to 70 and classified as sedentary, light, moderate and strenuous.¹¹

Study supervisors checked the forms for completeness and internal consistency using a predetermined list of random numbers.

Statistical Analyses

Between groups, comparison for continuous and categorical variables were done using independent t-test and Pearson Chi-Square test respectively. Cluster adjusted logistic regression analysis was carried out to find the factors associated with DM and DR. Factors that had a p-value <0.25 in univariate logistic regression analysis were included in a multivariate model. P<0.05 was considered statistically significant in the multivariate model. All analyses were carried out using STATA version 8. (StataCorp LP, College Station, Texas, USA). All analyses took account of the cluster design through the use of survey commands in STATA.

RESULTS:

The study covered 28,039 persons (99.5%) of the estimated sample size (n=28,172), and included 15,362 (54.8%) urban and 12,677 (45.2%) rural residents. The distribution did not differ significantly by gender (males = 13,887(49.5%), females = 14,152(50.5%). The mean age \pm SD was 47.0 \pm 12.7 years. Screening for DM was done on 25,969 (92.6%) of 28,039 enrolled subjects. The information on non-participation rate is provided in the flowchart 1. The participation rate was similar in both urban and rural areas (92.4% vs 93.0%, P<0.06) but was significantly different between males and females (89.8% vs 95.4%, P<0.000).

Diabetes mellitus was detected in 2802 (10.8%) of 25,969 people. This included 1324 (5.1%) individuals previously diagnosed with diabetes mellitus (KDM) and 1478 (5.7%) individuals newly detected with diabetes by the study. Table1 shows the prevalence of diabetes mellitus and diabetic retinopathy and 95% CI by gender and urban/rural population. Diabetic retinopathy was present in 12.2% (95% CI: 10.4%, 14.1%) of the DM population.

Table 2 shows the distribution of socio-demographic characteristics and the risk factor analysis of DM. A cluster adjusted analysis of the association between socio-demographic characteristics and DM status showed that the prevalence of DM was more among people aged above 45 years (adjusted OR: 2.3, 95% CI: 2.1, 2.6), urban population (adjusted OR: 1.4, 95% CI: 1.1, 1.8), female gender (adjusted OR: 1.4, 95% CI: 1.2, 1.5), Muslim (adjusted OR: 2.1, 95% CI: 1.2, 3.7), business people (adjusted OR: 1.8, 95% CI: 1.4, 2.3) and graduates (adjusted OR: 2.0, 95% CI: 1.5, 2.6). The age-gender adjusted prevalence of DM was 5.6% (95% CI: 5.3%, 5.9%) for rural clusters and 8.7% (95% CI: 8.4%, 9.1%) for urban clusters. The overall age-gender adjusted prevalence of DM was 6.98% (95% CI: 6.73%, 7.23%).

Table1:Prevalence of Diabetes Mellitus And Diabetic Retinopathy

	Prevalence	95% CI
DM (n=25,969)		
Overall	10.8	9.4, 12.3
Female	12.0	10.4, 13.9
Male	9.5	8.2, 10.9

Urban	12.7	10.7, 15.1
Rural	8.5	7.3, 9.8
DR (n=25969)		
General Population		
Overall	1.15	0.96, 1.37
Male	1.25	1.04, 1.52
Female	1.05	0.84, 1.31
Urban	1.47	1.23, 1.77
Rural	0.76	0.57, 1.00
DR among DM (n=2436)		
Overall	12.2	10.5, 14.2
Male	15.4	13.0, 18.1
Female	10.0	8.3, 12.1
Urban	13.4	11.2, 16.0
Rural	10.2	7.9, 13.1

DM-Diabetes Mellitus

DR-Diabetic retinopathy

CI-Confidence interval

Table 2: Factors associated with Diabetes Mellitus

variables	n	DM (%)	Multivariate adjusted OR	95% CI	P-value
Age (in year)					
≤ 45	14181	7.5	1.0		
>45	11788	14.7	2.3	2.1, 2.6	0.000
Place of residence					
Urban	14187	12.7	1.4	1.1, 1.8	0.003
Rural	11782	8.5	1.0		
Gender					
Male	12444	9.5	1.0		
Female	13525	12.0	1.4	1.2, 1.5	0.000
Education					
Illiterate	10104	9.1	1.0		
Informal	1896	9.7	1.4	1.1, 1.8	0.004
Primary	5355	10.7	1.5	1.3, 1.8	0.000
Secondary-high	7416	12.9	1.8	1.5, 2.2	0.000
Graduate +	1198	13.6	2.0	1.5, 2.6	0.000
Religion					
Hindu	24471	10.5	1.2	0.7, 1.9	0.610
Muslim	675	23.6	2.1	1.2, 3.7	0.012
Christian	791	8.9	1.0		

Occupation

Coolie	9529	6.7	1.0		
Agriculture	4501	8.9	1.3	1.1, 1.6	0.002
Employed	1335	12.7	1.5	1.2, 1.8	0.000
Business	1271	14.4	1.8	1.4, 2.3	0.000
Others	9333	15.1	1.8	1.6, 2.0	0.000

DM-Diabetes Mellitus; OR-Odds Ratio; CI-Confidence Interval

Note: the risk factor assessment was done only on the eligible diabetic subjects; hence the parameters such as BMI, physical activity score, and other clinical parameters were not included in this model.

Risk factor assessment was done for 2,531 (90.3%) of the 2,802 eligible diabetic subjects. Clinical examination was performed on 2,509 (99.1%) of 2,531 subjects and dilated fundus examination of at least one eye was performed on 2448 subjects, as 61 subjects were PAC suspects who could not be dilated. Retinal status of both eyes could not be determined in 12 patients due to dense cataracts.

Diabetic retinopathy was detected in 298 (1.2%) of 25,969 subjects. The age-gender adjusted prevalence of DR is 0.05% (95%CI: 0.04%, 0.06%) for rural and 1.03% (95%CI: 0.89%, 1.12%) for urban areas. The overall age-gender adjusted prevalence of DR was 0.74% (95% CI: 0.66%, 0.83%). Higher rates of DR was found among older age, male, urban, graduates, KDM, duration of DM>5 years, sedentary-light physical activity vegetarians and normal BMI category. Mean blood glucose level (217.7±79.8 vs 178.2±66.0, P<0.001) and mean systolic blood pressure (SBP) (138.0±21.3 vs 130.4±18.5, P<0.001) were significantly high among DR subjects. The risk factors for DR are presented in Table 3.

Table 3: Factors associated with Diabetic Retinopathy

Variables	n	DR (%)	Multivariate adjusted		P-value
			OR	95 % CI	
Age (in year)					
≤ 50	1253	8.1	1.0		
>50	1183	16.6	1.5	1.1, 1.9	0.009
Place of residence					
Urban	1563	13.4	1.4	1.1, 2.0	0.036
Rural	873	10.2	1.0		
Gender					
Male	1015	15.4	1.1	0.8, 1.4	0.623
Female	1421	10.0	1.0		
Education					
Illiterate	797	10.4	1.0		
Informal	161	9.9	0.9	0.5, 1.9	0.962
Primary	507	9.3	0.8	0.5, 1.4	0.432
Secondary-high	837	15.2	1.4	0.9, 2.1	0.101
Graduate +	134	18.7	1.5	0.8, 2.6	0.196

Religion						
Hindu	2241	12.1				
Muslim	125	14.4	---	----	---	
Christian	68	11.8				
Occupation						
Coolie	560	10.0				
Agriculture	357	12.6	---	----	---	
Employed	136	16.9				
Business	156	14.1				
Others	1227	12.4				
Smoking status						
Smokers	483	13.7				
Non-smokers	2953	7.9	---	----	---	
Diabetic status						
Known diabetes	1201	21.7	7.6	5.3, 10.7	0.000	
New diabetes	1235	3.1	1.0			
Physical Activity						
Sedentary-light	497	15.3	1.1	0.8, 1.4	0.689	
Mod - strenuous	1939	11.5	1.0			
Type of diet						
Vegetarian	218	19.7	1.3	0.9, 1.9	0.190	
Non-vegetarian	2218	11.5	1.0			
BMI						
Normal	1201	14.8	1.0			
Underweight	179	11.7	1.1	0.6, 1.9	0.763	
Overweight-obese	957	10.3	0.5	0.4, 0.7	0.000	
CVS Disease						
Yes	123	13.0				
No	2313	12.2	---	----	---	
SBP (mmHg)	138.0	± 21.3	1.02	1.01, 1.3	0.000	
DBP (mmHg)	83.1	± 10.0	1.0	0.9, 1.1	0.582	

Results are presented in Mean ± SD for continuous variables; DR-Diabetic Retinopathy; Mod-Moderate; SBP-Systolic Blood Pressure; DBP-Diastolic Blood Pressure; BMI-Body Mass Index; CVS-Cardiovascular disease

Note: Variables that had a p-value > 0.25 in the univariate logistic regression analyses were not included in the multivariate model.

Since there was a significant difference observed between KDM and NDM subjects (21.7% vs 3.1%, $P < 0.000$), a subset analysis was constructed to identify independent factors associated with DR among KDM (Table 4). Among the 1,242 KDM subjects, the information on duration of DM (mean duration 5.1 ± 5.0 years) was available only for 1,186 subjects. The classifications of duration of DM ≤ 5 & > 5 years and blood glucose level ≤ 160 & > 160 were derived based on the median. Prediction was done using

the duration of DM>5 years, SBP>140 and blood glucose level>160. Multivariate logistic regression model was used to estimate the quantitative effect of each significant risk factor with DR and to provide each of them their relative weight (β coefficient).

The probability of developing DR will be estimated from the equation,

$$\text{Prob(DR)} = \frac{e^Z}{(1 + e^Z)}, \text{ where } Z = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_n X_n$$

β_0 – constant (-2.5);

β_1 = 1.31 - duration of DM>5 years (1=yes, 0=no);

β_2 = 0.74 - blood glucose level>160 (1=yes, 0=no);

β_3 = 0.84 SBP>140 (1=yes, 0=no).

$Z = -2.5 + (1.31*1) + (0.74*1) + (0.84*1) = 0.39$

$\text{Prob(DR)} = 0.6$

i.e., the probability of developing DR for a person with duration of diabetes > 5 years, fasting blood glucose level > 160 and systolic blood pressure > 140 was estimated at 60%. Keeping the blood glucose level (>160) and duration (>5 years) constant, the probability of DR was 49% when SBP was > 120 and 68% when SBP was >160. Keeping the blood glucose (>160) and SBP (>140) constant, the probability of DR was 74% when duration was >10 years.

Table 4: Factors associated with DR among KDM subjects

Variables	DR		Multivariate adjusted (n=1186*)		P-value
	n	%	OR	95% CI	
Duration of DM					
(years)					
≤5	117	14.3	1.0		
>5	142	38.7	3.7	2.7, 5.1	0.000
SBP (mmHg)					
≤140	166	18.2	1.0		
>140	93	33.7	2.3	1.7, 3.2	0.000
Glucose Level (mm/dl)					
≤160	70	14.9	1.0		
>160	189	26.3	2.1	1.6, 2.8	0.000

*DM-Diabetes Mellitus, KDM-Known Diabetes Mellitus, SBP-Systolic Blood Pressure ; * Duration of diabetes mellitus was available only for 1186 known DM subjects*

The grading of DR was done on 298 subjects who had any retinopathy in at least one eye. Of the 596 eyes of 298 subjects, DR was present in 514 (86.2%) eyes (mild-moderate NPDR, 80.0%; severe NPDR, 11.1%; PDR, 8.9%). One hundred and sixty three (54.7%) subjects had mild-moderate NPDR, 16 (5.4%) had severe NPDR and 14

(4.7%) had PDR in both their eyes. The remaining 105 subjects had different levels of retinopathy in both eyes.

The visual acuity results are shown in the Table 5. About 90.5% of mild/moderate NPDR subjects had a visual acuity of $\geq 6/18$ as compared to 68.9% of subjects with PDR. Only 8.7% of subjects with mild/moderate NPDR had a visual acuity in the range of 6/18-3/60 whereas 26.7% of PDR subjects had visual acuity in that range. Three subjects with mild/moderate NPDR had visual acuity $< 3/60$, due to significant cataract. One subject who had DR but the grade could not be determined due to cataract, had a visual acuity of 6/60.

Table 5: Visual acuity status of DR affected eyes (252 right eyes and 262 left eyes)

DR grades	Visual Acuity			Total
	$\geq 6/18$	6/18-3/60	$< 3/60$	
Mild/Moderate NPDR	372 (90.5)	36 (8.8)	3 (0.7)	411 (100.0)
Severe NPDR	51 (89.5)	6 (10.5)	0 (0.0)	57 (100.0)
PDR	31 (68.9)	12 (26.7)	2 (4.4)	45 (100.0)
Undetermined	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
Total	454 (88.3)	55 (10.7)	0 (0.0)	514 (100.0)

DR-Diabetic retinopathy

NPDR-Non-proliferative diabetic retinopathy

PDR- Proliferative diabetic retinopathy

DISCUSSION

The age-gender-cluster adjusted prevalence of DR was 0.74% (95% CI: 0.66%, 0.83%) in our study. The prevalence of DR in diabetic population was 12.2% which was higher than a previous study conducted in Andhra Pradesh (7.8%)² and was lower than the Chennai based study (17.6%)³. These differences may be due to differences in the characteristics of the populations studied. The prevalence of DR among KDM subjects in our study (21.7%) is comparable to other population based studies done in India^{2,3} but lower than the 32.4% reported in Blue Mountains Eye Study,¹² 36.8% in Beaver Dam Eye Study,¹³ and 52% in Melton Study.¹⁴ The prevalence of DR was 3.1% among newly detected diabetic subjects, which is slightly lower than the 5.1% reported in a recent study.² Studies from other countries have reported a higher prevalence of DR (20-35%) among persons detected newly with diabetes.^{15,16} Gene environment interactions may possibly have a role in the different risk for diabetic retinopathy among different populations.

The urban- rural difference and the association of higher systolic blood pressure, duration of diabetes and poor glycaemic control with DR is consistent with previous reports.¹⁷⁻²¹ The association of overweight – obese diabetic subjects and DR has been reported previously²², but is contrary to the findings of the Hoorn Study.²³ A previous study²⁴ had reported that diabetic subjects have a tendency towards weight loss after the diagnosis of diabetes and this may be the reason for lower BMI being associated with increased prevalence of retinopathy (longer duration of diabetes may lead to more weight loss).

The population based design, large sample size and coverage, and evaluation by trained retina specialists are strengths of the study. The prevalence of DR reported from our study is an underestimate since we could not ascertain the status of DR in PAC suspects at the field level. It is possible that we may have missed mild DR since we did not use photographs for grading.²⁵ Even though the association of smoking with DR was not statistically significant in our study, the other forms of tobacco use were not assessed, so the full effect of tobacco on DM and DR could not be investigated.

The population structure of Theni district is 55% rural and 45% urban compared to 72.2% rural and 27.8% urban for the whole of India. However if we extrapolate our results to India, approximately 5.8 million people may have any diabetic retinopathy in India by 2030. This extrapolation has to be viewed with caution as our study population is not representative of the population of India; however, it indicates the need for a large number of ophthalmologists trained to provide medical and surgical retina services. Currently, few centers provide fellowship training in vitreo-retinal diseases in India and medical or surgical retina training is not part of the regular ophthalmology residency training. Eye care infrastructure will have to develop at a rapid pace to deliver appropriate services to such a large population with diabetes and complications from diabetes.

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