# Prevalence of diabetic retinopathy in India stratified by known and undiagnosed diabetes, urban-rural locations, and socioeconomic indices: results from the SMART India population-based cross-sectional screening study



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# Summary

Background National and subnational estimates of the prevalence of diabetic retinopathy and vision-threatening diabetic retinopathy (VTDR) are needed to inform the stepwise implementation of systematic retinal screening for people with diabetes in India to decrease the rate of blindness. We aimed to assess these national and subnational estimates and to stratify the prevalence of diabetic retinopathy and VTDR on the basis of people with known versus undiagnosed diabetes, urban versus rural residence, and epidemiological transition level (ETL) and Socio-demographic Index (SDI) categories of states.

Methods We did a multicentre cross-sectional screening study for diabetic retinopathy using a complex cluster sampling design in people aged 40 years or older in ten Indian states and one union territory between Dec 20, 2018, and March 20, 2020. We did non-mydriatic retinal screening and assessed risk factor burden for people with diabetes. We estimated nationally weighted prevalence of diabetic retinopathy and VTDR for individuals with known and undiagnosed diabetes by urban versus rural residence, and by state categorisation by ETL and SDI. We also assessed adjusted risk factors.

Findings From 42146 participants screened, 7910 (18·8%) were identified to have diabetes. Of these, 6133 (77·5%; 4350 with known diabetes and 1783 with undiagnosed diabetes) had gradable retinal images. 3411 (56%) participants were women and 2722 (44%) were men, and the median age was 56 years (IQR 49-65). The estimated national prevalence was  $12\cdot5\%$  (95% CI  $11\cdot0-14\cdot2$ ) for diabetic retinopathy and  $4\cdot0\%$  (3·4–4·8) for VTDR, with no significant differences between urban and rural residence for diabetic retinopathy. Compared with individuals with undiagnosed diabetes, we observed a higher prevalence of diabetic retinopathy (15·5% [13·4–17·8] vs 8·0% [6·3–10·1]) and VTDR (5·3% [4·5–6·3] vs 2·4% [1·6–3·6]) in individuals with known diabetes. The prevalence was significantly lower in low ETL–SDI states compared with high and middle ETL–SDI states for diabetic retinopathy (by 7·0%, 1·9–12·2, p=0·024) and VTDR (by 4·8%, 3·0–6·6, p<0·0001). Hyperglycaemia was the strongest modifiable risk factor.

Interpretation We estimate that, in absolute numbers, approximately 3 million people aged 40 years or older have VTDR in India, with a higher prevalence in those with known diabetes residing in high and middle ETI–SDI states.

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# Introduction

Eye health is integral to achieving the Sustainable Development Goals and universal health coverage.¹ Diabetic retinopathy is a microvascular complication of diabetes that can progress without symptoms to vision-threatening diabetic retinopathy (VTDR). If left untreated, VTDR can result in irreversible visual loss. Therefore, periodic retinal screening is recommended for all people with diabetes to enable prompt identification and treatment of VTDR. However, establishing national systematic screening and treatment pathways for diabetic retinopathy is challenging in low-income and middle-income countries, where available resources are

prioritised for other health needs.<sup>2</sup> A needs assessment based on the prevalence of diabetic retinopathy is required for each country to plan the prioritisation of screening programmes.

India is a diverse country with substantial variations in demography, socioeconomic transition, disease burden, and health outcomes across the states.<sup>3</sup> Hence, a national diabetic retinopathy screening and treatment pathway is not feasible. Subnational estimates of the prevalence of diabetic retinopathy and VTDR are required to facilitate stepwise and risk-based implementation of screening and treatment pathways for diabetic retinopathy in India.

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#### Research in context

#### Evidence before this study

We searched PubMed for studies in English published from Jan 1, 1990, to Jan 31, 2022, using the search terms "('prevalence of diabetic retinopathy' OR 'vision threatening diabetic retinopathy' OR 'sight threatening diabetic retinopathy') AND ('India')". The search yielded 11 papers that reported prevalence in certain areas in India. Regular retinal screening for vision-threatening diabetic retinopathy (VTDR) and timely treatment of this diabetes complication can reduce the rate of blindness in people with diabetes. National and subnational estimates of the prevalence of VTDR in India are not available to enable prioritisation, and prevalence data are limited to population-based studies, mainly from south India.

# Added value of this study

In this cross-sectional study in people aged 40 years or older across ten Indian states and one union territory, we estimated national and stratified prevalence estimates of this potentially blinding condition. Our study showed that the overall prevalence is 12.5% (95% CI 11.0-14.2) for diabetic retinopathy and 4.0% (3.4-4.8) for VTDR. People with known diabetes had a 15.5% prevalence of diabetic retinopathy, higher than the 8.0% prevalence in those undiagnosed. We also observed that

the states with low sociodemographic index and epidemiological transition levels had the lowest prevalence of diabetic retinopathy in individuals with known diabetes (11·2%), lower by 7% compared with their counterparts. We observed no significant difference in the distribution of diabetic retinopathy between urban and rural residence. Hyperglycaemia was the strongest modifiable risk factor. We estimate that about 3 million people aged 40 years or older in India today live with VTDR and are at risk of vision loss.

# Implications of all the available evidence

Because offering regular screening for an estimated 77 million people with diabetes in India to identify this group at high risk is an unattainable task, this study provides evidence for population-level risk stratification. The subnational and various stratified estimates of the prevalence of diabetic retinopathy in India provide a clear direction for policy makers to use available resources to plan the stepwise implementation of systematic screening and treatment programmes for diabetic retinopathy in India. Our findings also corroborate those of previous epidemiological studies done mainly in south India and provide new data on other regions in India.

India is home to approximately 77 million people with diabetes, and these numbers are predicted to increase to 125 million by 2045.⁴ Approximately one in five adults are now estimated to have diabetes in India.3-6 Most are diagnosed with type 2 diabetes during their working age, with some diagnosed only after developing complications. If screening and treatment pathways for diabetic retinopathy are not prioritised urgently, the rate of blindness due to VTDR is projected to increase in parallel with the exponential rise in the prevalence of diabetes in the country.<sup>4,6</sup> Traditionally, prioritisation for diabetic retinopathy screening is achieved by stratifying people by their risk factor burden.7 However, given the resources required to establish screening and treatment pathways for diabetic retinopathy, policy makers in India require population-level risk stratifications.

At a national level, one approach might be by state-level prioritisation on the basis of recognised indices of epidemiological and socioeconomic transitions.<sup>3,8</sup> The India State-Level Disease Burden Initiative Diabetes Collaborators—as part of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)—grouped the 36 Indian states and union territories into epidemiological transition levels (ETLs) in 2016.<sup>3,8</sup> Although diabetes is more prevalent in high ETL states, whether the prevalence of diabetic retinopathy follows the same pattern is unknown, because it has been shown that the disability-adjusted life-year (DALY) rates of some complications of diabetes, such as stroke, do not show a consistent pattern with high ETL states.<sup>8</sup> Another indicator is the

Socio-demographic Index (SDI), which is a composite measure of income per capita, average educational attainment over the age of 15 years, and total fertility rate under the age of 25 years for each state. Previous epidemiological studies that evaluated the prevalence of diabetic retinopathy, VTDR, and associated risk factors were mainly done in south India, in high ETL states (appendix p 2). Stratifying the distribution of diabetic retinopathy and VTDR on the basis of ETL and SDI will identify those states that need urgent screening and treatment pathways for diabetic retinopathy compared with other states. Additionally, the prevalence of diabetic retino pathy and VTDR stratified by urban and rural locationshas been estimated to inform the need for risk stratification to implement systematic screening and treatment pathways for diabetic retinopathy.5 Diabetes is twice more frequent in the urban population compared with their rural peers.5

In this study, we aimed to estimate the national and subnational prevalence of diabetic retinopathy and VTDR in India. To inform population-level prioritisation, we stratified the prevalence of diabetic retinopathy and VTDR on the basis of people with known versus undiagnosed diabetes, urban versus rural residence, and ETL and SDI categories of states.

# Methods

# Study design

The SMART India Study was a multicentre cross-sectional study designed to select at least one area from each of the

See Online for appendix

six regions in India, totalling ten Indian states and one union territory: one in north India, one in northeast India, two in east India, one in west India, two in central India, and four in south India; more areas were selected in south India because of its higher prevalence of diabetes.<sup>3,5</sup> These areas represent all three categories of ETL and SDI. The national representation is shown in the appendix (p 4). Each area was further stratified into urban and rural locations. The sampling was based on data from the 2011 census of India. As primary sampling units, we used a census enumeration block, usually consisting of 125-150 households with a population of 650-700. for urban areas and villages for rural areas. Bigger villages were subdivided to ensure that approximately 300 households could be covered. In each household, all family members aged 40 years or older in the household were invited to be screened for diabetes. People with diabetes were then screened for diabetic retinopathy and its risk factors at the same visit. Only individuals living in their current residence for at least 6 months were eligible to participate. If the selected individual refused or was unavailable, the adjacent household was selected from the same neighbourhood or village to ensure an adequate sample size within each selected area.

The SMART India Study complied with the Declaration of Helsinki. It was approved by the Indian Council of Medical Research—Health Ministry Screening Committee (HMSC/2018–0494, dated Dec 17, 2018) and institutional ethics committees of all the participating institutions. Written informed consent was obtained from each participant. The study details were explained to the patient in local vernacular; the translated local language consent form was either signed (for participants who were literate) or a thumb impression was obtained (for those who were illiterate). The study protocol has been published.

# Study participants

Individuals aged 40 years or older in each household were eligible for inclusion. Adult individuals for whom it might not be possible to do all the required tests (eg, who had mobility issues or consent issues), pregnant and breastfeeding women, anyone deemed too ill to be screened in the opinion of the field workers, and those who did not provide consent were excluded. Additionally, people with type 1 diabetes, gestational diabetes, and secondary diabetes were excluded. Hence, we only included individuals with presumed type 2 diabetes to estimate the prevalence of diabetic retinopathy and VTDR.

# Screening procedures

Trained fieldworkers administered a questionnaire in English or translated it to local languages to all study participants who consented. The collected data included demographic characteristics, anthropometric characteristics, socioeconomic status, quality of life measures, medical and ocular history, family history, and lifestyle factors. This questionnaire was followed by screening for

diabetes with random blood glucose (RBG) tests. Glycated haemoglobin (HbA<sub>1c</sub>) was also measured in participants with RBG of 8.9 mmol/L or higher and in a random sample of those with RBG lower than 8.9 mmol/L by use of point-of-care kits (appendix pp 5–6).

## ETL and SDI

The ETL is a ratio of all-age DALYs due to communicable, maternal, neonatal, and nutritional diseases versus those due to non-communicable diseases and injuries together. A high ETL state has a higher non-communicable diseases and injuries burden than that of lower ETL states. The SDI is expressed on a scale of 0–1, with 0 representing the lowest income per capita, lowest educational attainment, and highest fertility under the age of 25 years from 1980 to 2017, and it is categorised into low SDI ( $\leq$ 0·53), middle SDI (0.54–0.60), and high SDI (>0.60). The distribution of diabetic retinopathy and VTDR based on ETL and SDI states and any differences between urban and rural locations were estimated.

# Screening for diabetic retinopathy and associated risk factors

The sample selected for estimation of the prevalence of diabetic retinopathy and VTDR included the following: all people with known diabetes, defined as individuals who self-reported a previous diagnosis of diabetes irrespective of their medication history, RBG, or HbA $_{\rm lc}$  values; and all people with undiagnosed diabetes, defined as individuals with RBG of 11·1 mmol/L or higher or point-of-care HbA $_{\rm lc}$  of 48 mmol/mol or higher with no known history of diabetes.

Non-mydriatic fundus photographs of both eyes were captured with a handheld retinal camera (Visuscout 100, Zeiss, Oberkochen, Germany). At least two fundus images (one macula-centred and one disc-centred) of each eye were captured. A teleophthalmology system was set up whereby the images captured by each fieldworker were uploaded to a cloud-based, study-specific database and graded at the local clinical centre by an ophthalmologist or optometrist (primary grader), as well as transferred to four central reading centres in four tertiary centres, where grading was done by a second ophthalmologist (secondary grader). A senior retinal consultant arbitrated primary and secondary grading discrepancies at four tertiary centres. The International Clinical Disease Severity Scale was used to grade the severity of diabetic retinopathy.10 Diabetic macular oedema was determined as present or absent. For reporting prevalence, diabetic retinopathy was categorised as any diabetic retinopathy or VTDR, which included severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, and diabetic macular oedema. The diabetic retinopathy outcomes at a person level were based on the severity in the worse eye or the single eye that was photographed or gradable.

Details of risk factor assessment procedures and definitions used for analysis are shown in the appendix

(pp 5–6). Briefly, the parameters included age, gender, education, duration of diabetes in people with known diabetes, BMI, waist circumference and waist to hip ratio, systolic and diastolic blood pressure, and point-of-care blood lipid and urine albumin measurements.

# Quality assurance

We implemented a stringent quality assurance and quality control programme to ensure the validity and reliability of study data. All research staff received inperson training at each site on the standardised protocols and use of devices. Only trained staff collected data. All laboratory equipment was calibrated regularly. Additionally, 52 online monitoring calls were completed with additional training when required. Data quality monitoring, inbuilt checks in the database, and data queries were resolved throughout the study. Field staff were trained repeatedly to ensure the gradeability of images. Additionally, the teleophthalmology programme ensured that all retinal images were graded by at least two graders.

# **Outcome variables**

The primary outcome variables were diabetic retinopathy and VTDR status, primarily to estimate the nationally weighted prevalence of diabetic retinopathy and VTDR overall and stratified by known diabetes and undiagnosed diabetes. We also estimated the number of people with VTDR in India. Secondary purposes included assessing risk factors and providing an estimate of diabetic retinopathy and VTDR by age and gender, urban and rural location, and state-level categorisation by ETL and SDI.

# Statistical analysis

We determined the sample size by considering the number of participants expected to be found with VTDR,

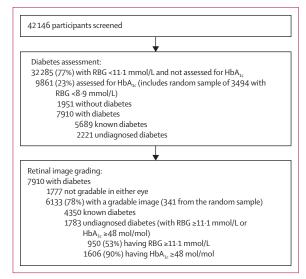


Figure: Flowchart for assessment of diabetic retinopathy HbA<sub>1</sub>,=glycated haemoglobin. RBG=random blood glucose.

as this outcome would have a smaller number of cases than diabetic retinopathy. More details on the sample size estimations are presented in the appendix (p 7).

Participants were sampled from ten selected states and one union territory. For each state, rural and urban areas were further defined to produce a total of 22 strata. Enumeration blocks were cluster sampled within each stratum, and participants and their families were invited into the study.

Participants with diabetes and gradable retinal images are referred to as the sample denominator for the analyses, which use weighting. As there were only three participants from rural New Delhi, its rural stratum was combined with the urban stratum, resulting in 21 analysis strata, with New Delhi representing the northern region. The sample denominator was weighted at the stratum level, in proportion to the relative population size of the strata within their region, to the national population of India with diabetes, estimated by multiplying the 2011 population census of India data with diabetes rates published in GBD (appendix pp 4, 7).  $^{2.3}$  A study has reported the prevalence of diabetes to be  $5\cdot2\%$  in rural areas and  $11\cdot2\%$  in urban areas, the ratio of which was used to provide urban and rural estimates of the diabetes population within each state.  $^5$ 

The analysis allowed for the weighting and clustering by enumeration block and household using the SPSS command for weighted and clustered analysis named complex sample analysis. We used the sample frequencies subcommand to estimate the weighted prevalence of diabetic retinopathy and VTDR and make assessments between groups, with 95% CIs and weighted Pearson  $\chi^2$  tests. We used the logistic regression subcommand to fit models to obtain weighted unadjusted and adjusted odds ratios of risk factors and their interactions, with 95% CIs and Wald test p values. For known diabetes, we adjusted for age, sex, rural or urban location, duration of diabetes, ETL-SDI combination, and education. As there were fewer individuals with diabetic retinopathy and VTDR among individuals with undiagnosed diabetes than those with a diagnosis, we adjusted for age, ETL-SDI combination, and education, on the basis of univariate significance or association with gradeability. Missing data rates were very low, and missing data were omitted from the corresponding analyses. More details can be found in the appendix (p 7).

# Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

# Results

Between Dec 20, 2018, and March 20, 2020, 35 209 households were approached for the study, and 35 147 (99  $\cdot$  8%) households and 42 146 individuals aged 40 years or older participated (appendix p 3). 7910 (18  $\cdot$  8%)

	Known diabetes (n=4350)	Undiagnosed diabetes* (n=1783)	All participants (n=6133)	
Age, years				
40-54	1668 (38%)	951 (53%)	2619 (43%)	
55-64	1459 (34%)	482 (27%)	1941 (32%)	
≥65	1223 (28%)	350 (20%)	1573 (26%)	
Gender				
Men	1876 (43%)	846 (47%)	2722 (44%)	
Women	2474 (57%)	937 (53%)	3411 (56%)	
Location				
Rural	1441 (33%)	865 (49%)	2306 (38%)	
Urban	2909 (67%)	918 (51%)†	3827 (62%)	
Duration of diabetes, y	ears			
<5	1955 (45%)	NA	NA	
5-9	1196 (27%)	NA	NA	
≥10	1199 (28%)	NA	NA	
Age at diagnosis, years				
<40	568 (13%)	NA	NA	
40 to <50	1446 (33%)	NA	NA	
50 to <60	1454 (33%)	NA	NA	
≥60	882 (20%)	NA	NA	
Education	, ,			
None	647 (15%)	385 (22%)	1032 (17%)	
Primary	1681 (39%)	681 (38%)	2362 (39%)	
Secondary	1427 (33%)	532 (30%)	1959 (32%)	
Graduate	595 (14%)	185 (10%)	780 (13%)	
Occupation				
Housewife	1733 (40%)	591 (33%)	2324 (38%)	
Not working due to health reasons	144 (3%)	32 (2%)	176 (3%)	
Not working due to vision	1 (<1%)	4 (<1%)	5 (<1%)	
Professional	102 (2%)	43 (2%)	145 (2%)	
Retired	556 (13%)	138 (8%)	694 (11%)	
Self employed	403 (9%)	185 (10%)	588 (10%)	
Skilled worker	597 (14%)	374 (21%)	971 (16%)	
Unemployed	209 (5%)	82 (5%)	291 (5%)	
Unskilled worker	605 (14%)	334 (19%)	939 (15%)	
BMI, kg/m²				
<18.5 (underweight)	107 (2%)	74 (4%)	181 (3%)	
18.5 to <25.0 (normal)	1836 (42%)	729 (41%)	2565 (42%)	
25.0 to <30.0 (overweight)	1725 (40%)	699 (39%)	2424 (40%)	
≥30·0 (obese)	682 (16%)	281 (16%)	963 (16%)	
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individuals were diagnosed with or were known to have diabetes, of whom 6133 (77·5%; 4350 with known diabetes and 1783 with undiagnosed diabetes) had gradable retinal images to confirm diabetic retinopathy status (figure). 3411 (56%) participants were women and 2722 (44%) were men, and the median age was 56 years (IQR 49-65). Participants with ungradable retinal images were older, from high ETL–SDI regions, and had lower education

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status (appendix p 8), and the models that are presented have been adjusted to account for these factors. In the study population, 3387 (55%) participants were overweight or obese, 2816 (46%) had concomitant systolic blood pressure of 140 mm Hg or higher, and 2122 (35%) had diastolic blood pressure of 90 mm Hg or higher (table 1).

The overall weighted prevalence in India (considering both known diabetes and undiagnosed diabetes) was 12·5% (95% CI 11·0–14·2) for diabetic retinopathy and 4·0% (3·4–4·8) for VTDR. This equates to approximately 3 million people living with VTDR in India. The weighted prevalence of diabetic retinopathy and VTDR by known and undiagnosed diabetes, urban and rural location, and ETL and SDI categories is shown in table 2. The prevalence of diabetic retinopathy and VTDR in

	Prevalence of diabetic retinopathy (95% CI)	p value	Prevalence of VTDR (95% CI)	p value
Overall prevalence in India				
Overall (n=6133)	12·5% (11·0 to 14·2)		4·0% (3·4 to 4·8)	
Known diabetes (n=4350)	15·5% (13·4 to 17·8)		5·3% (4·5 to 6·3)	
Undiagnosed diabetes (n=1783)	8.0% (6.3 to 10.1)		2·4% (1·6 to 3·6)	
Difference between known and	7·5% (4·6 to 10·4)	<0.0001	2.9% (1.6 to 4.2)	<0.000
undiagnosed diabetes	, 5 (( ) )		3 (	
Prevalence based on urban-rural locati	on			
Overall				
Urban	12·8% (11·2 to 14·5)		5.0% (4.1 to 6.1)	
Rural	12·4% (10·3 to 14·8)		3.5% (2.7 to 4.6)	
Difference between urban and rural	0·4% (-2·4 to 3·2)	0.77	1.5% (0.2 to 2.8)	0.032
Known diabetes	, , ,		3 (	
Urban	14·4% (12·4 to 16·6)		5·7% (4·7 to 6·9)	
Rural	16.7% (13.1 to 21.1)		4·9% (3·7 to 6·6)	
Difference between urban and rural	-2·3% (-6·9 to 2·2)	0.29	0.8% (-1.1 to 2.6)	0.42
Undiagnosed diabetes	25% (051022)	025	00%(111020)	0 72
Urban	9.6% (7.3 to 12.5)		3·3% (2·0 to 5·5)	
Rural	7·2% (5·0 to 10·2)		2·0% (1·1 to 3·6)	
Difference between urban and rural	2.4% (-1.2 to 6.1)			
Prevalence based on ETL	2.4% (-1.2 to 0.1)	0.19	1·3% (-0·7 to 3·4)	0.19
Known diabetes				
	16 (1 1 10 -)		0 (=	
High ETL	16.5% (14.9 to 18.3)		8-4% (7-2 to 9-7)	••
Middle ETL	18·9% (16·6 to 21·4)		6.8% (5.4 to 8.5)	
Low ETL	11·2% (7·2 to 17·0)		2·4% (1·4 to 4·2)	
Difference between low and middle-high ETL	7.0% (1.9 to 12.2)	0.024	4·8% (3·0 to 6·6)	<0.000
Undiagnosed diabetes				
High ETL	7.0% (5.3 to 9.2)		2·4% (1·5 to 4·0)	
Middle ETL	10·9% (8·4 to 14·1)		4·1% (2·6 to 6·4)	
Low ETL	5·0% (2·7 to 9·1)		0.6% (0.2 to 2.5)	
Difference between low and middle-high ETL	5·3% (1·4 to 9·2)	0.025	3·2% (1·4 to 5·0)	0.005
Prevalence based on SDI				
Known diabetes				
High SDI	17·1% (15·1 to 19·4)		7.6% (6.3 to 9.2)	
Middle SDI	20·2% (17·1 to 23·7)		6·5% (4·7 to 8·8)	
Low SDI	11·2% (7·2 to 17·0)		2·4% (1·4 to 4·2)	
Difference between low and middle-high SDI	7·0% (1·9 to 12·2)	0.024	4·8% (3·0 to 6·6)	<0.000
Undiagnosed diabetes				
High SDI	10·1% (7·8 to 13·1)		4·2% (2·7 to 6·5)	
Middle SDI	10·4% (6·9 to 15·4)		3·3% (1·5 to 7·2)	
Low SDI	5.0% (2.7 to 9.1)		0.6% (0.2 to 2.5)	
Difference between low and middle-high SDI	5·3% (1·4 to 9·2)	0.025	3·2% (1·4 to 5·0)	0.005
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Table 2: Prevalence of diabetic retinopathy and VTDR categorised by people with known and undiagnosed diabetes

individuals with known diabetes was twice that in the undiagnosed group, with no significant difference in rates between rural and urban residence for diabetic retinopathy (table 2). For both known and undiagnosed diabetes groups, high and middle ETL and SDI states had a higher prevalence of diabetic retinopathy and VTDR than low ETL and SDI states.

The age and gender distribution of people with diabetic retinopathy and VTDR in rural and urban locations is shown in table 3. The prevalence of diabetic retinopathy was similar across age groups, although we observed a tendency for VTDR prevalence to increase with age (p=0·064, test for trend), and for the men-to-women differential in diabetic retinopathy and VTDR to be larger in urban areas (p=0·039 for diabetic retinopathy and p=0·015 for VTDR, age-adjusted test for gender–location interaction).

We analysed the known risk factors for diabetic retinopathy and VTDR for individuals with known diabetes (table 4, appendix pp 9-10). The prevalence of both diabetic retinopathy and VTDR was higher in people with raised RBG and hypertension than in those with lower levels. Although high BMI was not a risk factor for diabetic retinopathy, a higher waist to hip ratio was associated with VTDR. Albuminuria was associated with VTDR, but dyslipidaemia was not associated with either diabetic retinopathy or VTDR. We observed a similar association of raised RBG (p=0.030 for diabetic retinopathy and p=0.039 for VTDR) and HbA<sub>1</sub> (although non-significant; p=0.065 for diabetic retinopathy and p=0.085 for VTDR) in individuals with undiagnosed diabetes. The prevalence of diabetic retinopathy and VTDR in individuals with undiagnosed diabetes was also higher in high and middle ETL and SDI states than in low ETL and SDI states, but no significant differences in rates between urban and rural residences were observed (appendix pp 11-14).

# Discussion

As the key finding of our study, we estimate that, on the basis of the overall 4% weighted prevalence of VTDR in people with diabetes aged 40 years or older, at least 3 million people are at risk or already have vision loss due to VTDR in India. This estimate calls attention to an urgent need to identify and treat VTDR in India. To achieve this, every person with diabetes should be offered regular retinal screening to identify and treat VTDR promptly. However, implementing such systematic programmes in the entire country is a mammoth task because of resource constraints and the continuing rise of people with diabetes. Our study provides useful indicators for policy makers to make strategic decisions on a stepwise implementation of the diabetic retinopathy screening programme nationally.

Firstly, we highlight the heterogeneity in the distribution of VTDR in India, with high and middle ETI-SDI states having three to four times higher prevalence of VTDR than their counterparts. Therefore, prioritisation of screening and treatment pathways for diabetic retinopathy in states with high ETL and SDI

	Rural area Urban area									
	Men	Women	Total	Men	Women	Total				
Any diabetic retine	ppathy									
Age 40-54 years	12-1% (7-7-18-2)	13.6% (9.9-18.4)	12.7% (9.7–16.6)	15.0% (11.5-19.4)	8.3% (6.2-11.1)	11-4% (9-3-13-8)				
Age 55-64 years	11.6% (6.3–20.5)	13.5% (9.2–19.3)	12.5% (8.7–17.5)	16-2% (11-7-22-2)	15.0% (11.3-19.6)	15.5% (12.5-19.1)				
Age ≥65 years	10.9% (7.2-16.3)	11.6% (7.2-18.3)	11-2% (8-2-15-2)	13.7% (9.9-18.5)	10.0% (6.5-15.1)	11.9% (9.0-15.6)				
Total	11.7% (8.6-15.6)	13.2% (10.7–16.2)	12-4% (10-3-14-8)	15.1% (12.7–17.8)	10.8% (9.0-12.9)	12.8% (11.2-14.5)				
Vision-threatening	diabetic retinopathy									
Age 40-54 years	1.7% (0.9-3.3)	4.9% (2.8-8.3)	3.1% (2.0-4.7)	5.2% (3.5-7.8)	2.5% (1.5-4.0)	3.7% (2.7-5.1)				
Age 55-64 years	3.3% (1.7-6.3)	4.6% (2.4-8.6)	3.9% (2.5-6.1)	3.8% (2.2-6.6)	7-4% (4-9-11-1)	5.8% (4.1-8.1)				
Age ≥65 years	2.3% (1.2-4.4)	6.0% (3.0-11.9)	3.9% (2.3-6.5)	6.6% (4.1–10.5)	6.6% (3.6-11.7)	6.6% (4.5-9.5)				
Total	2.3% (1.6-3.4)	5.0% (3.5-7.1)	3.5% (2.7-4.6)	5.2% (3.9-6.7)	4.9% (3.7-6.5)	5.0% (4.1-6.1)				
. , ,	95% CI). Prevalences by ag			· ·	groups, and rural or urb					

	Sample size (n=4350)	Any diabetic retinopathy (n=724)						Vision-threatening diabetic retinopathy (n=324)					
		Prevalence	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value	Prevalence	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value		
RBG, mmol/L	4323			<0.0001		<0.0001			0.0002		0.0002		
<8.9	1410	10.1%	1 (ref)		1 (ref)		2.7%	1 (ref)		1 (ref)			
8·9 to <11·1	825	10.4%	1.03 (0.69-1.53)		0.97 (0.66-1.44)		4.6%	1.76 (0.98-3.18)		1.83 (1.02-3.26)			
11·1 to <22·2	1839	19.9%	2.20 (1.55-3.13)		1.93 (1.38-2.69)		7.0%	2.71 (1.71-4.30)		2.67 (1.67-4.29)			
≥22.2	249	22.0%	2.50 (1.20-5.22)		2-32 (1-24-4-32)		7.3%	2.86 (1.48-5.55)		3.10 (1.64-5.83)			
HbA <sub>1c</sub> , mmol/mol	4350			<0.0001		<0.0001			<0.0001		0.0003		
<48	686	7.6%	1 (ref)		1 (ref)		2.0%	1 (ref)		1 (ref)			
<53	448	7.4%	0.97 (0.51-1.84)		1.01 (0.53-1.93)		2.3%	1.17 (0.35-3.94)		1.20 (0.36-4.03)			
<75	1510	16.3%	2.38 (1.50-3.77)		2.34 (1.47-3.72)		5.6%	2.90 (1.48-5.70)		2.81 (1.41-5.59)			
≥75	1706	21.4%	3.33 (2.11-5.27)		3.12 (1.99-4.89)		7.8%	4-20 (2-21-7-95)		3.84 (1.99-7.43)			
Systolic BP, mm Hg	4350			<0.0001		<0.0001			<0.0001		<0.0001		
<120	725	11.3%	1 (ref)		1 (ref)		4.2%	1 (ref)		1 (ref)			
120 to <140	1624	10.9%	0.96 (0.54-1.69)		0.89 (0.50-1.59)		3.0%	0.70 (0.41-1.21)		0.61 (0.36-1.05)			
140 to <160	1288	22.0%	2-22 (1-21-4-06)		2.05 (1.09-3.84)		6.4%	1.57 (0.90-2.72)		1.35 (0.78-2.34)			
≥160	713	19.0%	1.85 (1.02-3.34)		1.79 (0.95-3.36)		10.1%	2.58 (1.47-4.51)		2.26 (1.28-3.98)			
Diastolic BP, mm Hg	4350			0.034		0.030			0.50		0.17		
<80	1381	12.6%	1 (ref)		1 (ref)		5.2%	1 (ref)		1 (ref)			
80 to <90	1513	16.5%	1-37 (0-92-2-04)		1-42 (0-96-2-08)		5.0%	0.96 (0.61–1.52)		1.10 (0.71-1.69)			
90 to <100	1005	13.8%	1.12 (0.76-1.63)		1.26 (0.86-2.87)		5.0%	0.96 (0.56-1.63)		1.30 (0.78-2.16)			
≥100	451	24.6%	2-27 (1-25-4-09)		2.19 (1.25-3.85)		7.4%	1.46 (0.81-2.64)		1.85 (1.04-3.28)			
BP, mm Hg	4350			0.0027		0.0024			0.0007		0.0002		
<140/90	2011	11.9%	1 (ref)		1 (ref)		3.7%	1 (ref)		1 (ref)			
≥140/90	2339	18.5%	1.68 (1.20-2.35)		1.71 (1.21-2.43)		6.7%	1.88 (1.30-2.71)		1.94 (1.37-2.73)			
BMI, kg/m²	4350			0.20		0.53			0.0092		0.028		
<18.5	107	14.6%	0.84 (0.33-2.14)		1.00 (0.39-2.52)		7.3%	1.06 (0.27-4.07)		1.38 (0.33-5.75)			
18·5 to <25·0	1836	16.9%	1 (ref)		1 (ref)		7.0%	1 (ref)		1 (ref)			
25·0 to <30·0	1725	15.7%	0.91 (0.64-2.14)		0.99 (0.70-1.42)		4.2%	0.59 (0.40-0.88)		0.64 (0.43-0.96)			
≥30.0	682	11.2%	0.62 (0.40-0.96)		0.72 (0.46-1.13)		3.3%	0.45 (0.26-0.79)		0.44 (0.24-0.79)			

	Sample size (n=4350)	Any diabet	ic retinopathy (n=7	24)	4)			Vision-threatening diabetic retinopathy (n=324)				
		Prevalence	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value	Prevalence	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value	
(Continued from previous	page)											
Waist circumference, cm	4350			0.094		0.096			0.49		0.070	
<80 for women, <90 for men	850	18.7%	1 (ref)		1 (ref)		5.9%	1 (ref)		1 (ref)		
≥80 for women, ≥90 for men	3500	14-4%	0.73 (0.50–1.06)		0.69 (0.45-1.07)		5.1%	0.85 (0.54–1.34)		0.62 (0.37–1.04)		
Waist to hip ratio	4350			0.27		0.28			0.025		0.022	
<0.85 for women, <0.90 for men	431	12.8%	1 (ref)		1 (ref)		2.8%	1 (ref)		1 (ref)		
≥0.85 for women, ≥0.90 for men	3919	15.9%	1-29 (0-82-2-05)		1.29 (0.81–2.05)		5.7%	2·10 (1·10-4·02)		2.06 (1.11–3.83)		
Albuminuria	3839			0.093		0.18			<0.0001		<0.002	
Negative	1937	13.3%	1 (ref)		1 (ref)		2.7%	1 (ref)		1 (ref)		
Positive	1902	17-3%	1.36 (0.95-1.96)		1.24 (0.91-1.68)		8.5%	3.31 (2.22-4.95)		2.88 (1.89-4.38)		
Total cholesterol, mmol/L	4350			0.64		0.43			0.26		0.38	
<5.18	3248	15.0%	1 (ref)		1 (ref)		5.0%	1 (ref)		1 (ref)		
5.18-6.18	673	18-2%	1.26 (0.76-2.08)		1.30 (0.83-2.05)		6.1%	1.24 (0.80-1.94)		1.14 (0.72-1.78)		
≥6.18	429	16-4%	1.11 (0.69-1.79)		1.23 (0.75-2.04)		7.9%	1.64 (0.85-3.14)		1.62 (0.81-3.21)		
HDL cholesterol, mmol/L	4341			1.0		0.69			0.19		0.52	
<1.5	3154	15.5%	1 (ref)		1 (ref)		5.0%	1 (ref)		1 (ref)		
≥1.5	1187	15.4%	0.999 (0.73-1.37)		1.06 (0.79-1.43)		6.5%	1-32 (0-87-1-99)		1.15 (0.75-1.76)		
LDL cholesterol, mmol/L	4080			0.59		0.34			0.24		0.51	
<2.6	2332	15.2%	1 (ref)		1 (ref)		4.9%	1 (ref)		1 (ref)		
≥2.6	1748	16-4%	1.10 (0.78–1.55)		1.17 (0.85-1.62)		6.1%	1.26 (0.86-1.85)		1.14 (0.77-1.71)		
Triglycerides mmol/L	4342			0.38		0.24			0.99		0.61	
<1.7	2030	14.4%	1 (ref)		1 (ref)		5.3%	1 (ref)		1 (ref)		
≥1.7	2312	16.3%	1.15 (0.84-1.57)		1.19 (0.89-1.61)		5.3%	1.00 (0.69-1.45)		1.11 (0.75-1.63)		
Total cholesterol to HDL ratio	4086			0.28		0.27			0.44		0.38	
<4	1637	14.2%	1 (ref)		1 (ref)		4.9%	1 (ref)		1 (ref)		
≥4	2449	16-6%	1.21 (0.86-1.71)		1.21 (0.86-1.71)		5.7%	1.17 (0.79-1.74)		1.20 (0.80-1.79)		

Data are n, prevalence, or OR (95% CI). The p values come from weighted logistic regression Wald tests. Estimates of prevalence are weighted to the population. BP=blood pressure. ETL=epidemiological transition level. HbA<sub>12</sub>-eplycated haemoglobin. OR=odds ratio. RBG=random blood glucose. SDI=Socio-demographic Index.

Table 4: Modifiable risk factor burden before and after adjustment for age, gender, urban or rural location, ETL and SDI combination, duration of diabetes, and education for diabetic retinopathy and vision-threatening diabetic retinopathy in individuals with known diabetes

needs to be considered for a high-impact solution to reduce the burden of VTDR-related blindness. This requires additional resources to the investments and initiatives that are currently focused on improving health in the poorer states in India.<sup>11</sup>

Secondly, we found that the prevalence of diabetic retinopathy and VTDR was generally increased with age, irrespective of urban or rural residence, in keeping with the time taken to develop the complication. However, we recommend systematic screening programmes to include people aged 40 years or older to help identify some early-onset type 2 diabetes with VTDR. The impact of vision loss due to VTDR in the working-age group is substantial in terms of burden to families and society, primarily because 63% of people in India depend on

out-of-pocket expenses for their health care.<sup>12,13</sup> Vision loss due to late diagnosis of VTDR can lead to loss of productivity and increase in DALYs, and several families can spiral to below the poverty line.<sup>1</sup>

Thirdly, we showed that the prevalence of VTDR in people with known diabetes is approximately double that observed in those with undiagnosed diabetes. Nevertheless, 2.4% of people newly diagnosed with diabetes already have appreciable VTDR at diagnosis, indicating a delayed diagnosis of diabetes. Ideally, despite these findings, people with both known and undiagnosed diabetes should be screened regularly to minimise vision loss. Recent measures of HbA $_{\rm lc}$  or RBG might identify those at higher risk. However, policy makers might need to consider the cost-effectiveness of

diabetic retinopathy screening programmes to inform this decision.

Fourthly, the prevalence of diabetic retinopathy in urban and rural areas is similar. With very few trained retinal specialists in India, who are mostly concentrated in urban areas, people with VTDR in rural areas are more likely to lose vision due to VTDR unless steps are taken to provide them equal access to screening and treatment pathways for diabetic retinopathy similar to that of people living in urban areas.

Finally, the prevalence of diabetic retinopathy in India has always been reported to be lower than the global prevalence (appendix p 2), and our study validates these findings.<sup>6</sup> However, the prevalence of VTDR in India is not different from that in the rest of the world, further emphasising the need for a national policy to screen and treat VTDR to reduce the risk of blindness due to this condition.

The International Agency for Prevention of Blindness modelled data from the Global Vision Database and estimated that in 2020, 335 million people had moderate to severe visual loss or blindness in south Asia.14 The GBD study showed that, although the prevalence of blindness due to other common ocular conditions has started to decline globally, blindness due to diabetic retinopathy has continued to increase over the past three decades.<sup>15</sup> These reports, together with the findings from our study, emphasise the need for an urgent national policy on eye health that includes screening and treating VTDR promptly.<sup>1,15</sup> These findings call for considerable investments for raising the required trained workforce (including ophthalmologists), infrastructure development, subsidised treatment costs where required, and public-private partnerships. We suggest that programmes such as the National Programme for Control of Blindness and Visual Impairment and Ayushman Bharat consider diabetic retinopathy screening and treating VTDR as a national priority.16,17 With buy-in from the Government of Kerala, we have been successful in setting up a pilot screening and treatment programme for diabetic retinopathy spanning primary, secondary, and tertiary care in the Thiruvananthapuram district.18

In our study, we identified three modifiable risk factors for diabetic retinopathy and VTDR: hyperglycaemia, hypertension, and albuminuria. Optimally controlling these risk factors reduces the risk of development and progression of VTDR. However, regular monitoring and patient compliance are major hurdles, particularly in countries where the primary health-care system is underdeveloped. Of note, increased BMI was not associated with diabetic retinopathy and was inversely related to VTDR, in keeping with a metanalysis of previous studies.<sup>19</sup>

The strengths of our study include the very large sample size, with wider geographical coverage and population mix than previous studies in India (appendix p 2), the high proportion of gradable fundus pictures, the

use of standardised grading protocols, and the detailed assessment of risk factors. We also minimised bias by ensuring rigorous criteria for sampling and with analyses using validated categories and careful weighting and adjustments of outcome measures.

The general limitation of the inability to infer causality based on a cross-sectional study design applies to this study. The weights applied in the study based on estimated data from some states in India, absence of diabetic retinopathy data from ungradable images, and non-mydriatic imaging might have introduced unknown biases in the reported estimates. Our tests did not allow us to differentiate between type 1 and type 2 diabetes. Although the prevalence of type 1 diabetes is low in India, misclassification of type 1 diabetes for type 2 diabetes in our study sample cannot be excluded. However, the best possible estimates are presented on the basis of available data, and the estimations are unlikely to alter the conclusions.

In conclusion, the burden of VTDR in India is significant. Future policies should consider the heterogeneity of the VTDR burden to plan a stepwise implementation of screening and treatment pathways for diabetic retinopathy in India.

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# Contributors

SS, JCV, RRam, RRaj, VM, PKR, TD, KR, ATP, DM, and DC were part of the SMART India writing group. SS, RRam, RRaj, VM, KR, DM, PKR, ATP, and TD conceptualised the study. SS, VM, ATP, JCV, DM, RRam, and RRaj were responsible for the methods. SS, JCV, ATP, and RRaj did the formal analysis. SS, JCV, ATP, DC, RRam, RRaj, and TD wrote and prepared the original draft. SS, RRam, RRaj, VM, KR, TD, ATP, JCV, DM, and DC wrote, reviewed, and edited the manuscript. SS, RRam, RRaj, VM, KR, and TD handled funding acquisition. SS, ATP, and JCV

had access to and verified the raw data. All authors had final responsibility for the decision to submit for publication.

#### **Declaration of interests**

SS reports consultancy and payments for lectures from Bayer, Boehringer Ingelheim, Novartis, Oxurion, Roche, Allergan, and Apellis, outside the submitted work. ATP reports payment for a trial design lecture from Bayer and for membership of a trial data monitoring committee from Roche, outside the submitted work. All other authors declare no competing interests.

#### Data sharing

The curated anonymised dataset on deidentified participants is available to researchers on application to the Moorfields Eye Hospital Research Management Committee (moorfields.resadmin@nhs.net) for data access, after sufficient regulatory approval is obtained and data access agreement is signed. The study protocol is published, and the statistical analysis is provided in the appendix (p 7).

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