Original Article

Diabetic retinopathy and its risk factors in patients with type 2 diabetes attending rural primary healthcare facilities in Tamil Nadu

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ABSTRACT

Background. India has a high burden of diabetic retinopathy ranging from 12.2% to 20.4% among patients with type 2 diabetes mellitus (T2DM). A T2DM management programme was initiated in the public sector in Tamil Nadu. We estimated the prevalence of diabetic retinopathy and its associated risk factors.

Methods. We did a cross-sectional survey among patients with T2DM attending two primary health centres for treatment and follow-up in Kancheepuram, Tamil Nadu in January–March 2013. We did a questionnaire-based survey, and measured blood pressure and biochemical parameters (serum creatinine, plasma glucose, etc.) of the patients. We examined their eyes by direct and indirect ophthalmoscopy and defined diabetic retinopathy using a modified classification by Klein *et al*. We calculated the proportion and 95% CI for the prevalence and adjusted odds ratio (AOR) for risk factors associated with diabetic retinopathy.

Results. Among the 270 patients, the mean (SD) age was 54.5 (10) years. The median duration of T2DM was 48 months. The prevalence of diabetic retinopathy was 29.6%. Overall, 65.9% of patients had hypertension, 14.4% had nephropathy (eGFR <60 mg/dl) and 67.4% had neuropathy. Among patients with comorbid conditions, 60%, 48%, 32%, and 3% were already diagnosed to have hypertension, neuropathy, retinopathy, and nephropathy, respectively. The risk factors for diabetic retinopathy were hypertension (AOR 3.2, 95% CI 1.7–6.3), duration of T2DM ≥ 5 years (AOR 6.5, 95% CI 3.6–11.7), poor glycaemic control (AOR 2.4, 95% CI 1.4–4.4), and nephropathy (AOR 2.3, 95% CI 1.1–4.6).

Conclusions. There was a high burden of undetected retinopathy and other comorbid conditions among patients with T2DM. Early detection of comorbid conditions and glycaemic control can be improved by training care-providers and educating patients.

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INTRODUCTION

In the year 2000, India was estimated to have 31.7 million people with diabetes and by 2030 this number is likely to increase to 79.4 million.[1] In a national multicentric study, the prevalence of type 2 diabetes mellitus (T2DM) in various Indian states ranged from 5.3% in Jharkhand to 10.4% in Tamil Nadu.[2] Diabetic retinopathy is one of the important complications of T2DM and it contributed 4.8% to the burden of blindness in 2002.[3] The prevalence of diabetic retinopathy among people with diabetes ranged from 12.2% to 20.4% in three large studies in Tamil Nadu.[4–6]

Seven-field stereoscopic colour fundus (SSF) photography is the 'gold standard' test for retinal screening; however, with proper training, ophthalmoscopy can be used.[7] Non-communicable disease programmes in low-resource settings that focus on management of T2DM could provide periodic screening for diabetic retinopathy with direct fundoscopy in the absence of advanced diagnostic facilities.[8,9]

Tamil Nadu, one of the southern states in India, has a network of public sector primary healthcare facilities that provide T2DM screening and management through the Tamil Nadu Health Systems Project funded by the World Bank.[10] The programme protocols include opportunistic screening for T2DM among adults above 30 years of age in public sector healthcare facilities and free regular drug treatment.[2] The programme is in its early stages of implementation and preliminary assessment suggested lack of data regarding the prevalence and management of diabetic retinopathy among patients with T2DM seeking treatment at primary healthcare facilities. We, therefore, estimated the prevalence of retinopathy among people with diabetes attending primary healthcare facilities in Kancheepuram district, Tamil Nadu and determined its associated risk factors.

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METHODS

Study design and population

Primary health centres (PHCs) in Kancheepuram district have an ongoing diabetes screening and management programme. We identified two PHCs with the highest number of people with diabetes visiting them every month for follow-up and drugs. We did a cross-sectional survey at these two PHCs between January and March 2013 and enrolled consecutive patients with T2DM who came to the PHCs.

Sample size and sampling strategy

The sample size was 270 persons with diabetes based on the assumption of 17.5% prevalence of retinopathy, 95% confidence level and 4% absolute precision using open Epi software.[5] At both PHCs, persons with diabetes were recruited consecutively starting from the first person with diabetes reporting on the day of the survey.

Data collection and clinical examination

We used a structured questionnaire to collect data regarding sociodemographic details, behavioural risk factors, history of other diseases and history of eye examination. We reviewed the clinical records and prescription for drugs and diagnostic tests. We measured the height and weight of all the patients. Blood pressure was measured in the right arm after the patient had been sitting for at least 5 minutes using an electronic automatic blood pressure apparatus (Omron). The average of the two readings taken 5 minutes apart was recorded.

An ophthalmologist did a comprehensive eye examination that included visual acuity, intraocular pressure and dilated fundus examination. We did direct and indirect ophthalmoscopy using a 20-dioptre lens.

Biochemical measurements

We collected 5 ml of blood after an overnight 12-hour fast for plasma glucose, lipid profile and creatinine. We collected a urine sample and used a dipstick for assessing proteinuria. Biochemical parameters were estimated using Roche diagnostics kits (Roche Diagnostics, Mannheim, Germany) in an auto-analyser (Biochemical Systems International, Arezzo, Italy). The glucose oxidase–peroxidase method and cholesterol oxidase–cholesterol peroxidase methods were used for measuring plasma glucose and serum cholesterol, respectively.

Operational definitions

Diabetic retinopathy was categorized using a modified classification based on retinopathy levels by Klein *et al*.[11] Retinopathy was classified as non-proliferative diabetic retinopathy (NPDR), severe NPDR and proliferative diabetic retinopathy (PDR). NPDR included levels 1–3, severe NPDR included levels 4 and 5, and PDR included levels 6 and 7. Sight-threatening retinopathy was defined as severe NPDR, PDR or clinically significant macular oedema.[11]

Hypertension was defined as systolic blood pressure (SBP) ≤140 mmHg or diastolic blood pressure (DBP) ≤90 mmHg as per the WHO criteria or history of previously known disease or treatment with antihypertensive drugs.[12]

Hypercholesterolaemia was defined as total cholesterol level ≤200 mg/dl according to the USA-adult treatment panel (ATP) III guidelines.[13]

Elevated triglyceride (TG) was defined as >150 mg/dl (1.7 mmol/L), or receiving specific treatment for this lipid abnormality.[14]

Reduced high-density lipoprotein cholesterol (HDL-C) was defined as <40 mg/dl (1.03 mmol/L) in men and <50 mg/dl (1.29 mmol/L) in women, or receiving specific treatment for this lipid abnormality.[14]

Body mass index (BMI). Patients were classified using the WHO classification and the one recently recommended for Asians.[15,16]

Chronic kidney disease was defined as a persistently low estimated glomerular filtration rate (eGFR) of <60 ml/minute/1.73 m^2 computed using the MDRD (Modification of Diet in Renal Disease) formula.[17]

Monofilament testing. Inability to perceive the 10 *g* of force a 5.07 monofilament applies is associated with clinically significant large-fibre neuropathy. The filament was placed perpendicular to the skin, and pressure was applied until the filament buckled. The filament was held in place for approximately 1 second and then released.[18,19]

Glycaemic control was defined as fasting plasma glucose <130 mg/dl or post-prandial plasma glucose <180 mg/dl.[20]

Statistical analysis

We calculated the prevalence of diabetic retinopathy and various other comorbid conditions with 95% CI. We also analysed the various risk factors for diabetic retinopathy. We computed unadjusted and adjusted ORs with 95% CI using the logistic regression method. We adjusted each of the risk factors for age in separate models and used Epi-Info version 3.5.3 for data entry and analysis.

Protection of human subjects

We obtained approval from the Institutional Ethics Committee of the National Institute of Epidemiology, Chennai, Tamil Nadu as well as written informed consent from all the participants. We referred patients with retinopathy worse than mild NPDR for further examination to the district hospital. Patients with no or minimal retinopathy were advised to follow-up with their ophthalmologists at yearly intervals.

RESULTS

Characteristics of the study population and the health facility

We screened a total of 305 persons but excluded 25 persons because of lack of medical records confirming the diagnosis of T2DM and 10 persons due to shallow anterior chamber or un-dilating pupil. Thus, we studied 270 (88.5%) patients. The mean age of the included patients was 54.5 (10) years and 219 (81.1%) of them were women. The median duration of T2DM was 48 months. The mean time taken to reach the health facility by patients was 1.5 hours and the average cost for travel to and from the health facility was ₹70 (approximately US$ 1). One-fourth of the patients required assistance to reach the health facility and only half of them considered the outpatient time to be convenient. The mean waiting time at the health facility to complete the check-up, routine laboratory tests and collect their drugs was 3 hours. Only one-third were satisfied with their interaction at the health facility.

There was lack of glycaemic control among 59.6% patients. The drugs used for the treatment were either a combination of sulphonylureas and metformin (54.4%) or only metformin (42.6%; Table I). A quarter of the patients (70, 25.9%) were advised by the health staff about the dosing schedule of the drugs. Among 270 patients, 123 (45.6 %) did not take any medications for 5 or more days in the previous month. The main reasons were inability to visit the facility due to ill health (35%), inability to visit the facility

TABLE I. Sociodemographic characteristics and management of people with diabetes attending rural primary healthcare facilities (*n*=270)

Characteristic	*n*	(%)
Age (in years)		
<45	44	(16.3)
45–54	79	(29.3)
≥55	147	(54.4)
Gender		
Men	60	(22.2)
Wemen	210	(77.8)
Marital status		
Married	224	(83)
Unmarried/widow/widower	46	(17)
Education		
Never attended school	49	(18.1)
1–5 years of schooling	125	(46.3)
6–12 years of schooling	77	(28.5)
Diploma/degree	19	(7)
Occupation		
Homemaker	99	(36.7)
Unskilled and agricultural labour	87	(32.2)
Skilled labour	28	(10.4)
Private/self-employed	40	(14.8)
Retired	19	(7)
Family history of diabetes	118	(43.7)
Behavioural risk factors		
Current tobacco users	79	(29.3)
Current alcohol users	54	(20)
Diabetes control		
Fasting plasma glucose (≥130 mg/dl)	52	(19.3)
Post-prandial plasma glucose (≥180 mg/dl)	158	(58.5)
Fasting plasma glucose (≥130 mg/dl) or post-prandial plasma glucose (≥180 mg/dl)	161	(59.6)
Treatment		
Sulphonylureas only	2	(0.7)
Metformin only	115	(42.6)
Sulphonylureas and metformin	147	(54.4)
Insulin, sulphonylureas and metformin	6	(2.2)
Compliance: Missed drugs for >5 days in the previous month	123	(45.6)

due to other reasons (32.5%) and fear of side-effects of the drugs (12%). Only 33% of patients adopted one or more changes in the diet (reduced salt, reduced fried foods, increased fruit/vegetable intake). The nurse (34.8%) or medical practitioner (20%) counselled patients regarding these changes.

Comorbid conditions and treatment

BMI >23 kg/m^2 and hypertension were present in 51.5% and 65.9%, respectively, and 107/178 (60.1%) patients were on treatment for hypertension. The antihypertensive drugs prescribed included enalapril (64.5%), atenolol (19.6%) and calcium channel blockers (15.9%). Among those on antihypertensive drugs, 47% (50/107) had blood pressure levels <140/90 mmHg. Various lipid abnormalities were present in 39.6% to 66.3% of the patients studied. The estimated glomerular filtration rate was <60 mg/dl among 39 (14.4%) persons with diabetes and 67.4% had neuropathy using monofilament testing (Table II). Among patients with various comorbid conditions, 60%, 48%, 7%, and 3% were already diagnosed on routine screening for hypertension, neuropathy, lipid abnormalities and nephropathy, respectively (Fig. 1). Over half the patients (55%) knew about the possibility of foot problems, neuropathy and eye problems. The awareness for other complications was lower, being around 40% for kidney problems, heart problems and infection, and only 17% for sudden death.

TABLE II. Prevalence of retinopathy and other comorbid conditions among patients with diabetes attending rural primary healthcare facilities (*n*=270)

Characteristic	*n* (%)	95% CI
Retinopathy	80 (29.6)	24.2–35.1
Classification of diabetic retinopathy (n=80)		
Mild non-proliferative	44 (55)	44.1–65.9
Moderate non-proliferative	15 (18.8)	10.2–27.3
Severe non-proliferative	4 (5)	0.2–9.8
Proliferative	6 (7.5)	1.7–13.3
Clinically significant macular oedema	11 (13.8)	6.2–21.3
Body mass index (kg/m^2):		
a. *Asian classification*		
23.0–27.49 (increased risk)	102 (37.8)	32.0–43.9
≥27.50 (high-risk)	37 (13.7)	9.6–17.8
b. *WHO classification*		
25.00–29.99 (overweight)	64 (23.7)	18.8–28.8
≥30 (obese)	22 (8.1)	4.9–11.4
Hypertension		
Systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg or history of hypertension	178 (65.9)	60.3–71.6
Patients on drug treatment	107 (39.6)	33.8–45.4
Lipid profile		
Total cholesterol ≥200 mg/dl	107 (39.6)	33.8–45.5
Triglycerides ≥150 mg /dl	155 (57.4)	51.5–63.3
Total cholesterol ≥200 mg/dl or serum triglyceride ≥150 mg/dl	175 (64.8)	59.1–70.5
High-density lipoprotein cholesterol <40 mg/dl for men or <50 mg/dl for women	179 (66.3)	60.7–71.9
Proteinuria 3+	1 (0.4)	0.0–2.1
Estimated glomerular filtration rate (ml/minute/1.73 m^2)		
30–59	33 (12.2)	8.6–16.1
15–29	5 (1.9)	0.2–3.5
<15	1 (0.4)	0.0–1.1
Neuropathy (monofilament test) >5 sensations out of 10	182 (67.4)	61.8–73.0

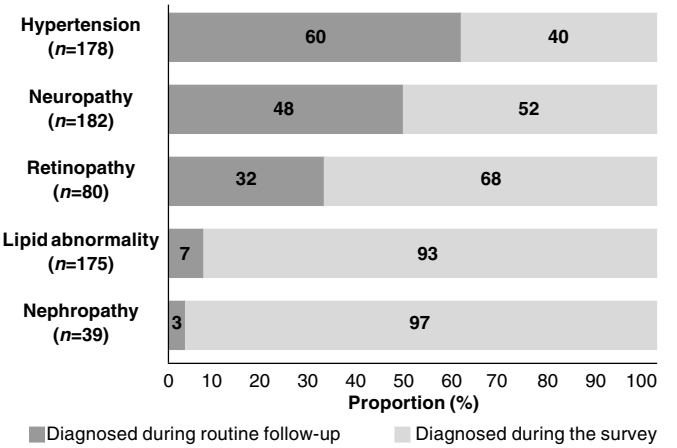

FIG 1. Proportion of people with diabetes with various undetected comorbid conditions (*n*=270)

TABLE III. Factors associated with diabetic retinopathy among patients with diabetes attending rural primary healthcare facilities in 2013 (n=270)

Factor	Retinopathy (n=80)	No retinopathy (n=190)	Unadjusted OR (95% CI)	Age-adjusted OR (95% CI)
Age (≥55 years)	58 (72.5)	89 (46.8)	3 (1.7–5.3)	–
Duration of diabetes >5 years	51 (63.8)	36 (18.9)	7.5 (4.2–13.5)	6.5 (3.6–11.7)
Hypertension	67 (83.8)	111 (58.4)	3.7 (1.9–7.1)	3.2 (1.7–6.3)
Fasting (≥130 mg/dl) or post-prandial plasma glucose (≥180 mg/dl)	59 (74)	102 (53.7)	2.4 (1.4–4.3)	2.4 (1.4–4.4)
Estimated glomerular filtration rate (<60 mg/dl)	19 (23.8)	20 (10.5)	2.6 (1.3– 4.3)	2.3 (1.1–4.6)

Eye screening and diabetic retinopathy

All the patients had undergone an eye check-up at least once in their lifetime. Among them, 94 (34.8%) patients were examined in medical college hospitals, 61 (22.6%) in private hospitals, 63 (23.3%) in block PHCs, 47 (17.4%) in camps and 5 (1.9%) in the district hospital. Nearly 67% of patients were examined by ophthalmologists and the rest were examined by an optometrist. Overall, 120 (44.4%) patients had undergone cataract surgery, of which 41 (34.2%) developed complications following the surgery. In addition, 5 (1.9%) patients had received treatment for glaucoma.

The prevalence of diabetic retinopathy was 29.6% (95% CI 24.2–35.1) and was higher among those >55 years (39.5%) of age. Nearly 60 (74%) of 80 patients had NPDR of varying severity. In addition, 13.8% had clinically significant macular oedema and 6 (7.5%) had PDR (Table II). Overall, 21 (7.8%) patients had sight-threatening retinopathy.

Only 26 (32%) patients were diagnosed to have diabetic retinopathy during the follow-up at the health facility. Among them, 15 had sight-threatening retinopathy requiring intervention. Only 10 of 15 had undergone laser treatment of which 6 were treated at a private health facility and the rest at a tertiary government facility.

Risk factors

The risk factors associated with diabetic retinopathy were hypertension (AOR 3.2, 95% CI 1.7–6.3), T2DM for more than 5 years (AOR 6.5, 95% CI 3.6–11.7) and lack of glycaemic control (AOR 2.4, 95% CI 1.4–4.4) independently as well as after adjustment for age. In addition, eGFR <60 mg/dl (AOR 2.3, 95% CI 1.1–4.6) was also associated with diabetic retinopathy (Table III).

DISCUSSION

We observed a high prevalence of undetected diabetic retinopathy among people with diabetes taking treatment at rural primary care settings; their major modifiable risk factors being lack of glycaemic control and hypertension. There was high prevalence of other undetected comorbid conditions such as hypertension, nephropathy, neuropathy and lipid abnormalities.

A high prevalence of diabetic retinopathy among patients seeking treatment in rural primary care settings reinforces the need for retinopathy screening in the chronic disease programmes in the public sector. The prevalence was higher in our study as compared to three large studies from Tamil Nadu probably due to differences in the study design, study population and diagnostic method. Our study was done in a programme setting in the public sector in contrast to the other studies that used camp- or community-based approach to screen for T2DM and retinopathy among people with diabetes.[4–6] The prevalence was comparable to studies among people with diabetes who self-reported.[21,22]

We used direct and indirect ophthalmoscopy due to lack of facilities for retinal photography in the public sector at primary and secondary level facilities. A systematic review of various available screening methods concluded that mydriatic retinal photography is the most effective method; however, ophthalmoscopy can be used for opportunistic case detection. Ophthalmoscopy had a specificity of >91% for sight-threatening retinopathy even though the sensitivity was lower.[23] We did opportunistic screening among people with diabetes attending the clinic for routine follow-up where direct or indirect ophthalmoscopy might be the most suitable and feasible method. This method was also recommended in another large study from Tamil Nadu, which attempted to develop a screening programme for sight-threatening diabetic retinopathy.[4] The Government of India has a national programme that primarily focuses on screening and treatment of cataract and glaucoma.[24] However, in view of the increasing burden of diabetic retinopathy, the programme should be extended to provide similar services for people with T2DM.

The key modifiable risk factors in our study were hypertension and glycaemic control. Hypertension was one of the major modifiable risk factors in our study; this is consistent with the evidence of other studies from India and China.[25,26] There were a large number of people with undetected hypertension and even among diagnosed patients the control was poor. The UK Prospective Diabetes Study (UKPDS) showed that blood pressure control was associated with a reduction in the incidence of diabetic retinopathy in a large cohort.[27] We also encountered a high prevalence of undetected nephropathy. The association of nephropathy with retinopathy observed in our study was consistent with the biological evidence of histological changes in the glomeruli and increased protein excretion by the time advanced retinopathy occurs among people with diabetes.[28] Tight blood pressure control might be the single most effective intervention in delaying progression of both retinopathy as well as nephropathy.

We observed poor glycaemic control despite availability of free drugs; it was also one of the risk factors for diabetic retinopathy. This might be due to a combination of poor compliance by patients and provider-related issues. Clinical inertia that refers to inadequate dosage and titration of drugs by the doctor has been identified as one of the reasons for poor glycaemic control. This might have contributed to poor glycaemic control as has been observed in other studies among people with diabetes in India.[29] Evidence from various large studies has shown that intensive glycaemic control delays the onset and progression of diabetic retinopathy.[30] Poor detection of various other comorbid conditions due to lack of routine screening among people with T2DM has been observed in studies from India.[29]

The limitation of our study was that the patients were selected from PHCs and a large proportion of them were women. Therefore, the results cannot be extrapolated to people with diabetes in other parts of India. The prevalence might have been underestimated, as we did not take photographs of the fundus due to limited resources.

In summary, there is a high burden of undetected diabetic retinopathy, hypertension and nephropathy among people with diabetes attending a public sector facility. A programme that addresses early detection of comorbid conditions and glycaemic control with a combination of provider training and patient education interventions could reduce this burden.

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