






Prevalence and determinants of complications of type 2 diabetes in a community screening program in Kerala

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ABSTRACT

Introduction This study aims to estimate the prevalence and identify the determinants of peripheral neuropathy (PN), retinopathy and peripheral arterial disease (PAD) among persons with type two diabetes mellitus.

Methods A cross-sectional study with a two-stage cluster sampling was conducted in Kerala in 33 clusters among individuals with type 2 diabetes. The first 85–90 participants who visited the camp with a duration of diabetes of more than a year were enrolled in the study from 33 camps. Thus, a total of 3083 persons with diabetes were enrolled. Mixed effects logistic regression was used to find the factors associated with diabetic retinopathy (DR), PN and PAD.

Results The prevalence of PN, DR and PAD was found to be 48.5% (95% CI 46.74 to 50.26), 28.9% (95% CI 27.36 to 30.56) and 46.3% (95% CI 42.65 to 49.95) respectively. Increased risk of PN was observed among participants with age >60 years (aOR 1.71; 95% CI 1.41 to 2.03), diabetes duration >15 years (aOR 1.88; 95% CI 1.04 to 3.38), unsatisfactory glycosylated haemoglobin (HbA1c) (aOR 1.29, 95% CI 1.05 to 1.61) and unemployment (aOR 1.3, 95% CI 1.09 to 1.59). Women appeared to have a lower risk of 0.68 (95% CI 0.50 to 0.92) compared with men. PAD was higher among those from urban areas (aOR 1.56, 95% CI 1.08 to 2.27). The independent determinants of retinopathy were increasing duration of diabetes from 1.4 (95% CI 1.01 to 1.97) at 6–10 years to 3.58 (95% CI 2.48 to 5.15) more than 15 years and an unsatisfactory HbA1c had a two times (95% CI 1.50, 2.67) higher risk of retinopathy.

Conclusion There is a high prevalence of peripheral vascular disease, PN and retinopathy in Kerala. Retinopathy is more likely with longer duration of type two diabetes and high HbA1c levels. Older age and longer diabetes duration increase the risk of neuropathy, while PAD is more common in urban areas. This highlights the need to include regular screening through the public health system.

INTRODUCTION

There has been an unprecedented rise in the prevalence of type 2 diabetes (T2DM) across

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The prevalence of type two diabetes has increased dramatically in India, especially in the state of Kerala, which is undergoing an epidemiological transition. Previous studies have reported high rates of diabetic complications such as peripheral neuropathy, retinopathy and peripheral arterial disease in India. However, community-based data on the prevalence and determinants of these complications in Kerala are limited.

WHAT THIS STUDY ADDS

⇒ This community-based screening programme in Kerala provides robust data on the prevalence of key diabetic complications. This study found high rates of diabetic retinopathy (28.9%), peripheral neuropathy (48.5%) and peripheral arterial disease (46.3%) among people with type two diabetes. It also identified important risk factors such as age, duration of T2DM and glycosylated haemoglobin. Women appeared to be at lower risk of peripheral neuropathy.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings of this study underscore the urgent need to strengthen the screening efforts for diabetes-related complications in Kerala and similar high-burden settings in India. This study demonstrates the feasibility of conducting community-based screening programmes which could be scaled up and integrated into the public health system. Overall, this research provides critical evidence to guide policy decisions and healthcare planning to help mitigate the rising burden of type two diabetes and its complications in Kerala.

the world,¹ a trend mirrored in India as well. The prevalence has increased from 5.5% in 1990² to 11.4% in 2021, with particularly alarming rates observed in the state of Kerala.³ This is in the background of Asian Indians being more prone to developing diabetes at

a younger age, at a lower body mass index (BMI)⁴ and being more prone to complications related to diabetes at diagnosis, both micro and macrovascular.⁵ The high disability-adjusted life years due to diabetes result in a substantial financial burden. A recent study in Kerala has reported the total monthly per capita expenditure required for diabetes care to be 1793 Indian rupees.⁶

Good glycaemic control is essential for the prevention of target organ damage (TOD) in T2DM. However, studies around the world report a varying prevalence of good glycaemic control.^{7,8} In a nationwide survey in India, 31% of persons with T2DM were found to have good glycaemic control,⁹ whereas in Kerala it was considerably lesser at 21%.¹⁰ This, along with delayed diagnosis of T2DM, could potentially translate to a high risk of the development of TOD. TOD results from the micro and macrovascular complications due to diabetes. Macroangiopathy includes atherosclerosis of large and medium arteries (aorta, coronary, renal, basilar and peripheral arteries), whereas microangiopathy includes endothelial damage to vessels between primary arterioles and venules, vascular basement membrane thickening, microthrombosis, platelet and red blood cell adhesion aggregation, and microcirculatory disorders.¹¹ Microvascular complications include diabetic nephropathy, retinopathy, neuropathy and macrovascular complications include coronary artery disease, peripheral arterial disease (PAD) and stroke.¹²

Diabetic peripheral neuropathy (DPN) is a common microvascular complication globally.¹³ It affects one-third to two-thirds of the world's diabetic population, the global prevalence ranging from 6 to 51 per cent.¹⁴ Although DPN affects both the extremities, feet and legs are often involved prior to upper hands and arms.¹⁵ Also, being a more neglected area, PN involving the foot is often diagnosed late. A study in Tamil Nadu¹⁶ reported that 33% of people with T2DM had poor foot care practices, while in another study conducted in Chandigarh,¹⁷ approximately 80% of individuals were found not to adhere to good foot care practices. This is compounded by the unavailability of podiatric specialists in the country.

The other common microvascular complication is diabetic retinopathy (DR). It is a potentially blinding complication which occurs as a result of long-term hyperglycaemia and has a global prevalence of 35%.³ It is one of the leading causes of blindness among the working age population, leading to devastating personal and socioeconomic consequences, despite being potentially preventable and treatable.¹⁸ There is limited data on the prevalence of DR in developing countries, probably owing to the practical limitation for fundal examination at community level.

One of the common macrovascular complications associated with T2DM is PAD.¹⁹ Two-thirds of people with PN are likely to develop PAD in due course.¹⁹ It has been a major risk factor for lower extremity amputation (4%–5%). PAD is underdiagnosed and undertreated in persons with T2DM in India. The cumulative incidence

of PAD in people with diabetes has been estimated to be 15%, 10 years after the first diagnosis of diabetes and 45 per cent at 20 years.²⁰ In addition, people with T2DM and PAD have a higher death rate (22%) than those without PAD (4%).²¹ Due to these reasons, in addition to the microvascular complications, PAD among people with diabetes was also addressed in this study. Screening for PAD is done with the help of a non-invasive technique called ankle-brachial pressure index (ABI) which measures the ratio of systolic blood pressure in the arms and legs. It has a sensitivity of 95% and specificity of 100%.²²

All complications are closely related to morbidity and mortality in people with T2DM, increasing risk of amputations, blindness, ulcers and cardiovascular disease. Understanding the extent of the problem is important for states such as Kerala which are in an advanced stage of epidemiologic transition with a high prevalence of diabetes. The study demonstrates the feasibility of conducting community-based screenings by coordinating efforts among local self-governments (LSGs), the National Health Mission, tertiary care centres and non-governmental organisations, using point-of-care devices. While screening facilities are available at public and private tertiary care centres, many individuals are unable to access these services due to various barriers.

Hence, this study aims to identify the prevalence and determinants of PN, PAD and retinopathy in a state in an advanced stage of epidemiologic transition.

METHODS

A community-based cross-sectional study was carried out in Ernakulam district in Kerala, India, to obtain a snapshot of the prevalence and determinants of T2DM complications. The district, which is an administrative division in the state, has the highest population density and is the commercial capital of the state. Persons with T2DM of at least 1 year duration from various parts of Ernakulam were considered for the study.

A two-stage cluster sampling with population proportionate to size sampling (PPS) was carried out. In the first stage, 33 clusters, which are LSG areas, were drawn by probability proportional to their size. The population of all the LSG areas was listed, and the corresponding LSG was selected. The sampling interval was added 33 times to get the 33 LSG areas, which were the clusters.

Next, from the list of persons with T2DM provided by the primary health centre (PHC) in consultation with field workers of the cluster, we selected every third/fourth person. Thus, about 110 persons were provided with a referral card and referred, considering a non-response rate of 20%. The referral card was provided to ensure that the selected individuals could access the specialised services offered at the medical camp without any hindrances. It served as a formal document enabling smooth coordination and tracking of patients referred

from the PHCs to the camp, ensuring they received the necessary care.

The first 85–90 participants who visited the camp and provided written informed consent were enrolled in the study. In total, 3083 individuals with diabetes participated. The exclusion criteria were those who could not respond to the questions with coherence or those who were cognitively impaired, pregnant women and above 80 years. To ensure an efficient screening process, we implemented a first-come-first-served approach. Each camp screened around 50–65 patients (refer to online supplemental figures 1 and 2) for all complications carried out in this study. About 33 camps were conducted from November 2020 to March 2021 by a multidisciplinary team of community medicine physicians, ophthalmologists, doctors with training in podiatry, nurses, laboratory technicians, optometrists and medical social workers. The laboratory technicians were trained in the assessment of glycosylated haemoglobin (HbA1c) using the point of care device. MD residents were trained and retrained to use the Doppler and biothesiometer and measure ABPI. MS residents and optometrists carried out the retinal examination. Training was imparted to frontline health workers to measure height and weight accurately and to ask the questions in the questionnaire. The camps for screening diabetes-related complications were conducted in local self-administration areas selected by PPS, using halls provided by the local self-administration (Panchayat). The logistics of organising the camps were managed by Service Club volunteers. Trained frontline health workers, along with the primary healthcare team, facilitated patient mobilisation, assisted with registration and conducted anthropometric measurements.

Considering results from previous studies where the prevalence of DR was 21.7%,²³ DPN as 31.1%²⁴ and PAD as 26.7%,²⁵ the sample size was calculated with a relative precision of 10% to be 1443, 891 and 1098 using the formula $4pq/d^2$ where p is the prevalence, q is 1-p and d is the relative precision. In order to account for cluster variations, a design effect of 1.5 was used to arrive at a sample size of 2165, 1337, 1647 for DR, DPN and PAD respectively. We sampled 2160 patients for retinopathy, 1831 for neuropathy and 1696 for PAD.

Blood pressure (BP) was measured with the OMRON HEM 7124 automatic blood pressure monitor (Shimogyo-ku, Kyoto, Japan) by measuring upper arm BP using standard measures.²⁶ The independent variables collected included sociodemographic details, anthropometric measurements, such as weight and height using standard measurements, self-reported comorbidity, personal habits, such as tobacco and alcohol, known complications of diabetes, duration of illness, family history of diabetes and HbA1c. HbA1c was measured with a point-of-care device HbA1c HemoCue auto analyser after validation with the laboratory values.²⁷ The targets for glycated haemoglobin were as follows: <7% (<53 mmol/mol) as ideal, ≥7 to <8% (≥53 to <64 mmol/mol) satisfactory and ≥8 (≥64 mmol/mol) unsatisfactory.²⁸ BMI was calculated

from the weight in kilogram (kg) and height in metre (m) measurement, and the Asian standards were used for categorisation: 18.5–22.9 for normal, 23–27.5 for overweight and >27.5 for obese.²⁹

Standard methods for assessing DPN were used, such as measuring vibration perception threshold (VPT) using a biothesiometer, while PAD was evaluated using Doppler at the camp level with successful outcomes. After measuring PN, the patient continued to be in the lying posture, and the ankle-brachial pressure index was measured to detect PAD. First brachial BP was measured using a sphygmomanometer and handheld Doppler. The BP cuff was placed on the arm, with the limb at the level of the heart. The ultrasound gel was applied in the antecubital fossa over the patient's brachial pulse. The transducer of the handheld Doppler was placed over the antecubital fossa on the gel, and the transducer was positioned to maximise the intensity of the signal. The cuff was then inflated to about 10 mm Hg above the expected systolic BP of the patient such that the Doppler signal disappeared. The cuff was then deflated, and when the Doppler signal re-appeared, the pressure of the cuff was recorded as brachial systolic pressure. Similarly, to measure ankle pressure, the cuff was placed immediately proximal to the malleoli. The ultrasound gel was applied on the skin overlying the dorsalis pedis (DP) artery in the foot. Then, using the same technique, the cuff was deflated until the Doppler signal re-appeared and measurement recorded. The ankle brachial pressure index (ABI) was calculated for each leg using the higher of the two brachial systolic pressure measurements. The VPT value was categorised as follows: <15 volts as normal (grade I), 16–20 volts as mild loss of sensation (grade II), 21–25 volts as moderate loss of sensation (grade III) and >25 volts as severe and abnormal (grade IV).²⁸ ABI was used to measure PAD, with readings interpreted as follows: >1.4 indicating calcification/vessel hardening, 0.9–1.4 considered normal, 0.8–0.9 classified as mild, 0.50–0.8 indicating moderate arterial disease and <0.50 considered severe arterial disease.³⁰ An ABI lower than 0.9 in at least one leg was indicative of PAD. Participants with an ABI >1.4 were excluded from the analysis as this ABI value might reflect severe arterial rigidity and spurious ankle pressures.

DR was assessed by mydriatic fundus photography and rechecked by indirect ophthalmoscopy. All patients underwent visual acuity examination with available glass correction and pinhole to see if there was any improvement with a further change of glasses. All patients were dilated with tropicamide eye drops and mydriatic retinal photography was performed. All patients also underwent retinal examination with indirect ophthalmoscopy by a trained ophthalmologist, and retinal findings and diagnosis were confirmed. Grading of DR was done on site and confirmed with viewing the retinal photographs by experts.³¹

For the purposes of this study, multiple morbidities were defined as the presence of more than one morbidity

in a person with diabetes, such as heart disease, thyroid disease and hyperlipidaemia.

Descriptive statistics were reported as mean and SD, number and percentages. The mixed effects logistic regression model is used to model binary outcome variables where the log odds of the outcomes are modelled as a linear combination of the risk factors when there are both fixed and random effects. Mixed effect logistic regression was used to find the factors associated with the presence of DR, diabetic PN and PAD, considering the clustering effect of total number of camps as a random effect, and age category, place of residence, duration of DM categories, BMI categories, sex, SES status, the presence of physical activity, working status and controlled status of HbA1c were treated as fixed factors. We considered the abovementioned variables as fixed factors in the mixed effects logistic regression model in order to evaluate their net effect, taking into account that they are time-invariant variables. Variables with a probability value of less than 0.10 were considered for multivariable analysis. Probability value less than 5% was considered statistically significant. Statistical analysis was performed using STATA 13.0.

Patient and public involvement

Health system and other functionaries were involved in planning the conduct, while the public were involved in the dissemination plans of the research.

Ethical approval information

Institutional ethical committee approval was obtained from the Institution Ethics Committee, Amrita Institute of Medical Sciences, vide IEC-AIMS-2020-COMM-186 dated November 9, 2020. Confidentiality and adequate data protection measures were undertaken with an anonymised list of patients.

RESULTS

The prevalence of complications of diabetic neuropathy, retinopathy and PAD was 48.5% (95% CI 46.74 to 50.26), 28.9% (95% CI 27.36 to 30.56) and 46.3% (95% CI 42.65 to 49.95), respectively (online supplemental table 1).

More than half of the study participants (53.9%) were above 60 years, and more than three-fourths (78.3%) were residents of rural areas. About 40.3% had T2DM for 6–10 years, and 73.1% were classified as overweight or obese according to Asian standards. HbA1c was unsatisfactory (>8) among 70.5%. More than a third (37%) of the study participants were men (online supplemental table 1).

The independent determinants of retinopathy were duration of T2DM and level of HbA1c. With an increasing duration of diabetes, the OR of developing retinopathy increased from 1.4 (95% CI 1.01 to 1.97) at 6–10 years to 3.58 (95% CI 2.48, 5.15) when the duration was more than 15 years suggesting that the longer a person has diabetes, the higher their risk of developing retinopathy.

An unsatisfactory HbA1c had a two times (95% CI 1.50 to 2.67) higher risk of retinopathy (table 1).

The determinants of PN among persons with diabetes were age more than 60 years. They were 1.71 times (95% CI 1.41 to 2.03) more prone to have PN. Similar to retinopathy, diabetes neuropathy also increased with duration. A diabetes duration of more than 15 years increased the risk of neuropathy 1.88-fold (95% CI 1.04 to 3.38). Women appeared to have a lower risk of 0.68 (95% CI 0.50 to 0.92) compared with men. Those with an unsatisfactory HbA1c had 1.29 times (95% CI 1.05 to 1.61) increased risk of neuropathy. The unemployed had higher rates 1.3 (95% CI 1.09 to 1.59) of PN, and there was a protective effect on employed cum retired persons 0.63 (95% CI 0.52 to 0.77) (table 2).

In the context of PAD, individuals from urban areas had a significantly higher prevalence of PAD (aOR 1.56, 95% CI 1.08 to 2.27). None of the other factors in the model were significant after multivariable logistic regression (table 3).

In order to estimate the cut-off levels of duration of diabetes and presence of PN, we drew an receiver operating characteristic (ROC) curve at the various levels of duration of diabetes. The associated criterion of the Youden index was >14 which indicated that the sensitivity and specificity were highest at >14 years and were significant. However, sensitivity was only 47% and specificity 63% (figure 1).

For retinopathy and duration of diabetes, the associated criterion was >9 years, and the sensitivity and specificity were 71.98 and 51.81 at this duration. Our study shows that screening at >9 years of diabetes could differentiate between those with and without retinopathy ($p<0.001$) (figure 2). For PAD, the optimum cut-off of duration of diabetes was 10 years though not significant.

DISCUSSION

The prevalence of complications of diabetic neuropathy, retinopathy and PAD was about a half, more than a fourth and more than a half, that is, 48.5% (95% CI 46.74 to 50.26), 28.9% (95% CI 27.36 to 30.56) and 46.3% (95% CI 42.65 to 49.95), respectively, among persons with T2DM. Duration of diabetes for more than 6 years and unsatisfactory HbA1c were found to be independent determinants of DR. The factors associated with increased risk of PN were age more than 60 years, duration of diabetes more than 15 years, unemployment and an unsatisfactory HbA1c. Women appeared to have a lower risk of 0.68 (0.50, 0.92) compared with men. For PAD, those from rural areas had a significantly lesser rate of PAD absence 0.68 (95% CI 0.53 to 0.87).

The PN in this study was high at 48.5%. More than a decade ago, results from a neighbouring state had reported PN to be around 28% among those with known disease and about 20% in individuals with newly diagnosed T2DM.³² However, a community-based study in Goa in the same period revealed a high prevalence of

Table 1 Factors associated with diabetic retinopathy

	Retinopathy present n=622	Retinopathy absent n=1538	Unadjusted OR 95% CI	Adjusted OR 95% CI
Age (in years)				
≤60	282 (27.9)	728 (72.1)	1	1
>60	339 (29.7)	801 (70.3)	1.22 (1.01, 1.47)	1.05 (0.82, 1.32)
Place of residence				
Urban	69 (15.4)	378 (84.6)	0.38 (0.24, 0.59)	0.40 (0.24, 0.66)
Rural	553 (32.3)	1160 (67.7)	1	1
Duration of DM (in years)				
1–5	58 (15.5)	317 (84.5)	1	1
6–10	203 (23.0)	678 (77.0)	1.65 (1.25, 2.18)	1.40 (1.01, 1.97)
11–15	180 (38.6)	286 (61.4)	3.72 (2.63, 5.25)	3.22 (2.11, 4.85)
>15	180 (42.3)	246 (57.7)	4.42 (3.28, 6.05)	3.58 (2.48, 5.15)
BMI kg/m ²				
<23	187 (32.9)	383 (67.1)	0.78 (0.62, 0.99)	0.85 (0.67, 1.08)
≥23	425 (27.3)	1129 (72.7)	1	1
Sex				
Female	370 (26.9)	1006 (73.1)	0.77 (0.62, 0.95)	0.80 (0.61, 1.06)
Male	252 (32.1)	532 (67.9)	1	1
SES				
APL	295 (27.7)	771 (72.3)	1.05 (0.87, 1.30)	–
BPL	304 (29.8)	716 (70.2)	1	–
Physical activity				
Yes	279 (29.7)	897 (70.3)	1.68 (1.10, 2.55)	1.53 (0.96, 2.43)
No	45 (39.5)	69 (60.5)	1	1
HbA1C (%)				
Unsatisfactory	483 (34.1)	934 (65.9)	2.03 (1.54, 2.69)	2.01 (1.50, 2.67)
Ideal/satisfactory	114 (19.9)	460 (80.1)	1	1
Occupation				
Unemployed	171 (36.9)	292 (63.1)	1.44 (1.13, 1.87)	1.36 (0.99, 1.89)
Employed/retired	240 (28.7)	201 (24.8)	0.97 (0.75, 1.23)	0.82 (0.65, 1.06)
Home maker	201 (24.8)	609 (75.2)	1	1
Hypertension				
Yes	287 (26.7)	680 (70.3)	1.08 (0.89, 1.30)	–
No	335 (28.1)	858 (71.9)	1	–

Reported as number (%)

APL, above poverty line; BMI, body mass index; DM, diabetes mellitus; SES, socioeconomic status.

60%,³³ though the prevalence of diabetes in the same period in both the states is almost similar at 10%.^{34 35}

The higher prevalence in Goa may be related to the more subjective mode of assessment based on bilateral absence of ankle jerks and/or bilateral distal sensory loss or any other severe neurological deficit and not on biothesiometry. However, studies conducted in health facilities at both primary and tertiary levels in various South Indian regions indicate a heightened prevalence of DPN, with rates reported at 39.3%³⁶ and 35.2%.³⁷ Across the

world, varying levels of neuropathy have been reported at 21.3% in a hospital-based study in Taiwan³⁸ and 53.6% in Ethiopia.³⁹ The higher prevalence observed in this study may be attributed to the advanced stage of epidemiologic and demographic transition in the state, as well as the selection process, which involved recruiting participants from the list provided by the primary healthcare team, potentially leading to an overrepresentation of those with greater need.

Table 2 Factors associated with diabetic neuropathy

	Neuropathy present n=987	Neuropathy absent n=844	Unadjusted OR 95% CI	Adjusted OR 95% CI
Age (in years)				
≤60	349 (46.0)	409 (54.0)	1	1
>60	628 (59.2)	433 (40.8)	1.80 (1.47, 2.18)	1.71 (1.41, 2.03)
Place of residence				
Urban	195 (54.5)	163 (45.5)	1.02 (0.46, 2.22)	–
Rural	792 (53.8)	681 (46.2)	1	–
Duration of DM (in years)				
1–5	48 (41.7)	67 (58.3)	1	1
6–10	292 (49.1)	303 (50.9)	1.36 (0.94, 1.97)	1.21 (0.71, 2.07)
11–15	307 (54.3)	258 (45.7)	1.61 (1.09, 2.41)	1.46 (0.85, 2.53)
>15	337 (61.1)	215 (38.9)	2.29 (1.49, 3.49)	1.88 (1.04, 3.38)
BMI kg/m ²				
<23	258 (54.3)	217 (45.7)	1.02 (0.82, 1.27)	–
≥23	708 (53.6)	612 (46.4)	1	–
Sex				
Female	595 (53.0)	527 (47.0)	0.88 (0.72, 1.08)	0.68 (0.50, 0.92)
Male	392 (55.3)	317 (44.7)	1	1
SES				
APL	520 (54.3)	438 (45.7)	0.96 (0.80, 1.15)	–
BPL	439 (53.2)	386 (46.8)	1	–
Physical activity				
Yes	578 (52.1)	531 (47.9)	1.28 (0.83, 2.01)	–
No	73 (54.9)	60 (45.1)	1	–
HbA1c (%)				
Unsatisfactory	704 (55.0)	575 (45.0)	1.13 (0.93, 1.39)	1.29 (1.05, 1.61)
Ideal/satisfactory	266 (45.0)	233 (55.0)	1	1
Occupation				
Unemployed	242 (60.5)	158 (39.5)	1.57 (1.34, 1.84)	1.30 (1.09, 1.59)
Employed/retired	347 (54.8)	286 (45.2)	0.71 (0.58, 0.87)	0.63 (0.52, 0.77)
Home maker	353 (49.4)	362 (50.6)	1	1
Hypertension				
Yes	482 (54.8)	397 (45.2)	1.07 (0.89, 1.29)	–
No	505 (53.1)	447 (46.9)	1	–

Reported as number (%)

APL, above poverty line; BMI, body mass index; BPL, below poverty line; DM, diabetes mellitus; SES, socioeconomic status.

The determinants of PN in this study were age greater than 60 years, duration of diabetes more than 15 years, unemployment and an unsatisfactory HbA1c >8% (64 mmol/mol). Many studies have identified longer diabetes duration, increasing age and high blood sugar or HbA1c levels as determinants.^{36 37} The mechanism of action of prolonged hyperglycaemia is that glucose covalently binds to plasma proteins via glycation, forming advanced glycation end products (AGEs). AGEs contribute to diabetic complications by disrupting protein function; causing

cross-linking with lipids and nucleic acids; and activating receptor-mediated signalling, exacerbating retinopathy, nephropathy and neuropathy.⁴⁰ Moderately and severely increased albuminuria and greater long-term glycaemic variability were associated with DPN in Taiwan.³⁷ Mean HbA1c and HbA1c variability predicted all-cause as well as cardiovascular-specific mortality. HbA1c and HbA1c variability have also been found to predict diabetic ketoacidosis/hyperosmolar hyperglycaemic state/diabetic coma, as well as neurological, ophthalmological and

Table 3 Factors associated with the presence of peripheral arterial disease

	PAD present n=684	PAD absent n=794	Unadjusted OR 95% CI	Adjusted OR 95% CI
Age (in years)				
≤60	269 (43.7)	346 (56.3)	1.20 (0.98, 1.48)	-
>60	413 (48.3)	413 (51.7)	1	-
Place of residence				
Urban	157 (53.6)	136 (46.4)	1.44 (1.12, 1.86)	1.56 (1.08, 2.27)
Rural	527 (44.5)	658 (55.5)	1	1
Duration of DM (in years)				
1–5	34 (38.6)	54 (61.4)	1	-
6–10	215 (47.1)	241 (52.9)	1.42 (0.88, 2.26)	-
11–15	224 (46.3)	260 (53.7)	1.36 (0.86, 2.17)	-
>15	209 (46.8)	238 (53.2)	1.39 (0.87, 2.22)	-
BMI kg/m ²				
<23	182 (46.1)	213 (53.9)	1.01 (0.80, 1.28)	-
≥23	491 (46.5)	566 (53.5)	1	-
Sex				
Female	418 (46.0)	491 (54.0)	0.97 (0.78, 1.19)	-
Male	266 (46.7)	303 (53.3)	1	-
SES				
APL	343 (44.7)	424 (55.3)	1.17 (0.95, 1.43)	-
BPL	327 (48.6)	346 (51.4)	1	-
Physical activity				
Yes	389 (44.3)	489 (55.7)	0.65 (0.44, 0.98)	0.68 (0.45, 1.03)
No	57 (54.8)	47 (45.2)	1	1
HbA1C (%)				
Unsatisfactory	493 (46.9)	558 (53.1)	0.99 (0.85, 1.17)	-
Ideal/satisfactory	175 (46.7)	200 (53.3)	1	-
Occupation				
Unemployed	159 (47.9)	173 (52.1)	1.04 (0.78, 1.36)	-
Employed/retired	252 (45.6)	283 (53.0)	0.94 (0.74, 1.19)	-
Home maker	251 (47.0)	301 (54.4)	1	-
Tobacco use				
Yes	42 (48.8)	44 (51.2)	1.11 (0.72, 1.72)	-
No	639 (46.1)	747 (53.9)	1	-
Hypertension				
Yes	342 (47.7)	375 (52.3)	1.12 (0.91, 1.37)	-
No	342 (44.9)	419 (55.1)	1	-

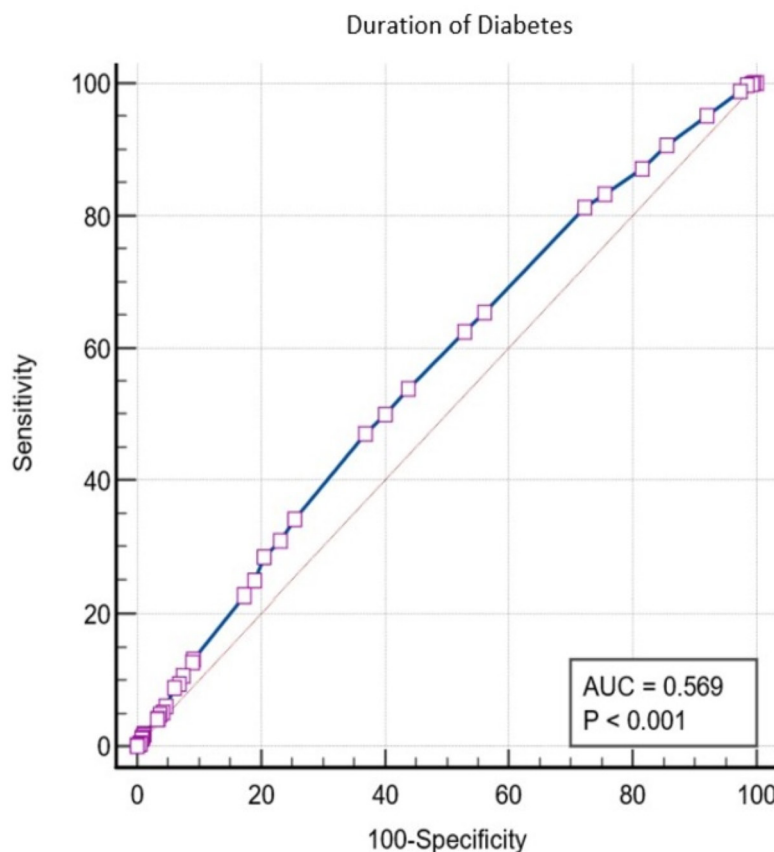
*118 readings had to be discarded as they were calcified, non-compressible, abnormal vessel thickening and hardening
Reported as number (%)

APL, above poverty line; BMI, body mass index; BPL, below poverty line; DM, diabetes mellitus; SES, socioeconomic status.

renal complications.⁴¹ Hyperglycaemia not only increases oxidative stress and inflammation⁴² but also contributes to the progression of PN, with two-thirds of affected individuals likely to develop PAD over time.¹⁸

PAD in this study was high at 46.3%. Other studies in coastal Karnataka found it to be low at 8.52%⁴³. Another study two decades before in Chennai showed a prevalence

of PAD of 6.3%. However, this was done among only 81 persons with diabetes, in a younger population above 20 years of age with a mean age of 46 years.⁴⁴ The higher levels observed in this study may be due to the fact that 54% of the study participants were older adults above the age of 60 with a mean age of 59.16. However, a more comparable community-based study done a decade



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.569
Standard Error	0.0134
95% Confidence interval	0.546 to 0.591
z statistic	5.135
Significance level P (Area=0.5)	<0.0001

Youden index

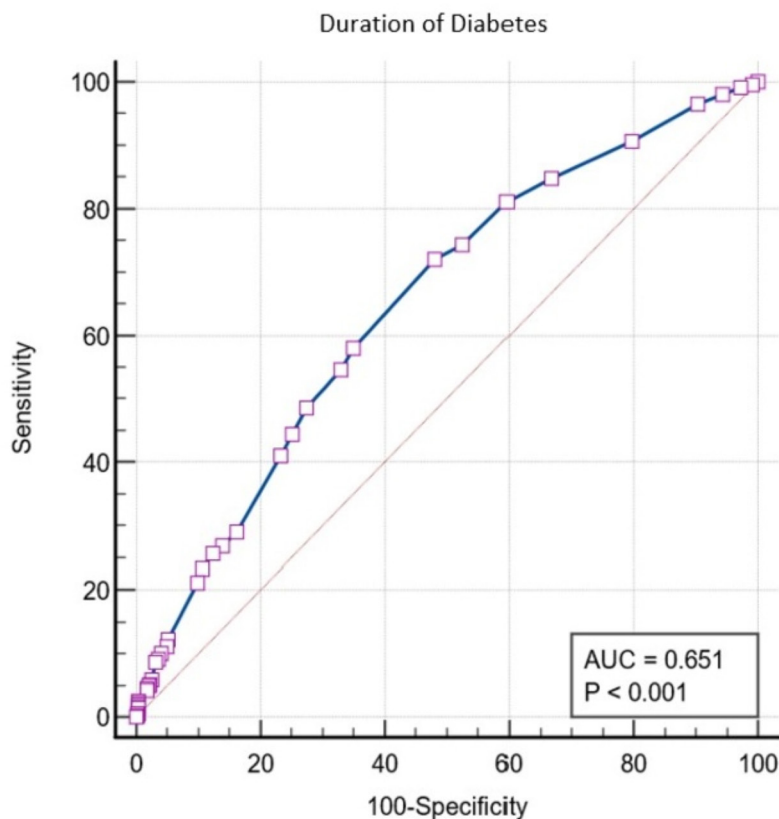
Youden index J	0.1011
Associated criterion	>14
Sensitivity	47.00
Specificity	63.11

Figure 1 Receiver operating characteristic (ROC) for the duration of diabetes and assessment of neuropathy.

earlier in Kerala among the elderly had reported an age-adjusted prevalence of 26.7%²⁵ and 36% in a hospital-based study in north India.³⁹ There was a significant association between PAD and duration of diabetes, waist circumference, hypertension and microvascular complications.⁴⁵ In a follow-up study in Chennai, older age, female gender and duration of diabetes were related to an increased incidence of PAD.⁴⁶ In this study, those residing in urban areas were found to be at higher risk of PAD. Correct diagnosis and supervision of patients with PAD is important for preventing the local progression of the disease and effective secondary prevention of future coronary and cerebrovascular events.⁴⁷ CAD and T2DM are related to a highly increased risk of long-term mortality even in intermittent claudication, and DM independently increases amputation risk. Cumulative incidence of all-cause death has been observed to be significantly higher in patients with abnormal and borderline ABI than in those with normal ABI.^{48 49}

In our study, the prevalence of retinopathy was 28.9%. This was similar to other studies in various parts of South India ranging from 18% to 26.8% among patients with self-reported diabetes in the early 2000s.^{50–52} A decade later, with non-mydratic retinal screening, a study across 10 states in India found a similar prevalence of DR at 15.5%.⁵² Non-proliferative DR (94.1%) was the most common form of retinopathy seen.

Our study identified increasing duration of T2DM above 6 years and an unsatisfactory HbA1c of more than eight as independent determinants of retinopathy. Duration of diabetes, as is known, has been cited as an independent risk factor in multiple studies. For every 5-year increase in the duration of diabetes, the risk for DR increased 1.89-fold (95% CI 1.679 to 2.135; $p < 0.0001$),⁵¹ and with a longer duration of diabetes of more than 10 years, 15 years increased the risk to six times.⁵² Our study also found an increasing risk after 5 years. Therefore, screening should commence at 5 years of an individual



Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.651
Standard Error	0.0128
95% Confidence interval	0.630 to 0.671
z statistic	11.734
Significance level P (Area=0.5)	<0.0001

Youden index

Youden index J	0.2379
Associated criterion	>9
Sensitivity	71.98
Specificity	51.81

Figure 2 Receiver operating characteristic (ROC) for the duration of diabetes and assessment of retinopathy.

living with T2DM. Whereas Rema *et al* found that every 2% elevation of HbA1c increased the risk for DR by 1.7,⁵¹ and poor glycaemic control with levels >200mg/dL has also been implicated. Use of insulin (OR, 3.52; 95% CI, 2.05 to 6.02) was also found to increase risk, which could also be a proxy for high glycaemic levels.⁵³ There is a need for a systematic DR screening programme which can contribute to DR no longer being a leading cause of certifiable blindness.^{47 54}

The duration of T2DM has been recognised as a pervasive risk factor for the onset of complications. Therefore, in assessing the point at which a significant proportion of complications becomes apparent, our findings reveal the following durations: 14 years for PN and 9 years for retinopathy. There is a significantly increasing risk observed after 5 years for retinopathy, with a non-significant trend in increase for neuropathy. Therefore, from a public health perspective, screening for these three complications could be considered after 5 years of duration of T2DM. This can help in increasing awareness

and delaying complications. A pilot programme for screening on retinopathy was found to be cost effective in Kerala.⁵⁵ Similar studies on other screening procedures are scarce. A study on the cost of diabetes care found it to be inordinately high with increased spending among the socioeconomically disadvantaged group.⁵⁶ This study demonstrates the feasibility of carrying out screening at the community level. There is a need for larger studies to integrate screening into the primary healthcare system.

While training and refresher courses were provided to study personnel, the involvement of personnel with varying skill sets may have inadvertently introduced inconsistencies, potentially leading to measurement errors. Additionally, selection bias is inherent due to the referral list being provided by the primary healthcare team based on the priority list, which may impact generalisability. However, systematic selection from the list is expected to have mitigated the bias to some extent. Despite these challenges, the study successfully conducted a comprehensive community-based assessment, demonstrating the

acceptability and feasibility of using point of care devices for measuring HbA1c, ABI and VPT using biothesiometer in resource-limited settings. In spite of the COVID pandemic, it was possible to carry out the study with the cooperation of the local self-government and PHC personnel.

This study also points to the role of service clubs as sponsors, and the public-private model adopted is one that could be scaled across the country. The role of the service clubs included arranging the training programmes, logistics of the screening venue, transport and the volunteers assisted in creating awareness on diabetes by distribution of leaflets. In a state and country where healthcare expenditure accounts for significant out-of-pocket expenditure in individuals with chronic disease, this is a model that can be replicated.

Duration of diabetes and HbA1c levels determine retinopathy and PN. Therefore, instituting screening measures and embedding them in the public health system will ensure sustainability. Longitudinal studies are necessary to track the progression of diabetic complications.

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Patient and public involvement Patients and/or the public were involved in the design, conduct or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involved human participants and was approved by the Institution Ethics Committee, Amrita Institute of Medical Sciences (IEC-AIMS-2020-COMM-186, 9 November 2020). Confidentiality and adequate data protection measures were undertaken with an anonymised list of patients.

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