

# Glycaemic status and prevalence of comorbid conditions among people with diabetes in Kerala

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## ABSTRACT

**Background.** We aimed to assess the glycaemic status and prevalence of comorbid conditions such as obesity, hypertension and dyslipidaemia in people with diabetes in a southern Indian community.

**Methods.** A cross-sectional community survey of adults > 18 years of age was done in central Kerala. Among the 3069 subjects surveyed, 276 were known to have diabetes. Of these, 169 who had type 2 diabetes underwent a detailed physical examination and anthropometric measurements, and determination of levels of fasting blood glucose, glycosylated haemoglobin, fasting lipid, serum creatinine and urine protein. Data of 164 subjects who had glycosylated haemoglobin levels were included for final analysis.

**Results.** The mean (SD) duration of diabetes was 5.5 (5.04) years and the mean age was 56.9 (11.4) years. Among the patients, 28 (17.2%) were receiving no treatment for diabetes, 24 (14.7%) were on diet control and 111 (68%) on pharmacotherapy. Only 6 patients were on insulin. The mean fasting blood glucose was 153 (63) mg/dl and the mean glycosylated haemoglobin level was 8.1 (2.34)%. In 60% of patients, the glycosylated haemoglobin level was above the recommended target of 7%. Obesity (31%), hypertension (51%), low-density lipoprotein cholesterol > 100 mg/dl (90%) and serum triglyceride levels > 150 mg/dl (38%) were present in the study population. Only 29% of patients were on antihypertensive treatment and 5% on lipid-lowering agents.

**Conclusion.** In this population, only 40% of people with diabetes had adequate glycaemic control. The use of insulin was infrequent. Comorbid conditions were common and inadequately treated. This indicates a lack of proper diabetic care in this community, which could lead to an increase in the burden of cardiovascular disease in the future.

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## INTRODUCTION

In people with diabetes, achieving and maintaining euglycaemia is a major therapeutic objective in the prevention of target organ

damage and other diabetes-associated complications.<sup>1–4</sup> Evidence suggests that aggressive management of cardiovascular risk factors such as dyslipidaemia and blood pressure in such patients is beneficial.<sup>5,6</sup> Hence, treatment regimens that consist of diet therapy, exercise, oral hypoglycaemic agents, insulin, lipid-lowering agents and antihypertensives are the mainstay for the management of people with diabetes.

Though the American Diabetes Association (ADA) has laid down guidelines for desired glycosylated haemoglobin (HbA<sub>1c</sub>), lipid and blood pressure levels, these are often not achieved in primary care settings where most patients receive care. Most studies from India and abroad which assessed the glycaemic status of people with diabetes were done in outpatient clinic settings. These studies may not be representative of the glycaemic status of people with diabetes in the community. Our cross-sectional survey was done as a part of a population study to assess the status of glycaemic control among people with diabetes in a community in Kerala.

## METHODS

### *Sample selection and study design*

The Amrita Diabetes and Endocrine Population Survey (ADEPS 2002–05) was done in south central Kerala in 3 randomly selected areas of Ernakulam District to obtain a representative sample. The detailed methodology is described in a previous paper.<sup>7</sup>

Briefly, field workers visited the 3 survey areas and obtained data from all residents >18 years of age in selected house clusters. The field workers conducted a 15-minute verbal interview to collect details of demographic and socioeconomic status (SES), medical history, details of lifestyle and dietary pattern. The economic status was assessed indirectly using a scoring system that included the type of house, household possessions, etc. The SES was categorized into poor, middle or high income groups. A total of 931 houses were included from all the selected areas. The surveyed population was invited to participate in the second phase of the study, which was conducted in their own locality. This included physical evaluation such as height, weight, waist circumference and blood pressure level. Peripheral vascular disease was assessed by examining the dorsalis pedis and posterior tibial pulses, which were graded as present or absent. A fasting venous blood sample was collected and transported to the laboratory for biochemical investigations such as HbA<sub>1c</sub>, lipid profile, serum creatinine, etc. A urine sample was collected for urine protein testing. Informed consent was obtained from all those who participated in the second phase of the study.

### *Measurements*

The blood pressure (BP) was recorded in the sitting position in the

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non-dominant arm to the nearest 2 mmHg using a standard adult mercury sphygmomanometer. Two readings were taken 5 minutes apart and the mean of the two readings was recorded. The first and the fifth Korotkoff sounds were used to define the systolic BP and diastolic BP, respectively. Variations in BP measurements were minimized by ensuring a 10-minute rest period before the BP was recorded.

Anthropometric measurements included height and weight using a standard calibrated height and weight machine. The body mass index (BMI) was calculated using the standard formula.

Waist circumference (WC) was measured midway between the rib cage and the superior border of the iliac crest with a non-stretchable tape. These measurements were taken twice and the mean value for each measurement was used in all analyses. The patient's neck region was examined by the study physician for acanthosis nigricans—a condition characterized by black velvety discoloration of the flexor regions of the neck or axilla due to papillomatosis and hyperkeratosis of the skin and was graded as present or absent.<sup>9</sup>

HbA<sub>1c</sub> was measured by immunoturbidometry. The lipid profile was measured by an autoanalyser. Total cholesterol was measured by the cholesterol oxidase–peroxidase method and triglycerides by the glycerol oxidase–peroxidase method. Low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol were measured directly. Very low-density lipoprotein (VLDL) was then calculated using the formula: VLDL=Total cholesterol–(HDL+LDL). Serum creatinine was measured by the Jaffe method and urine microalbumin was measured by immunoturbidometry and urine protein assessed by the Uristix method.

#### Definition and diagnostic criteria

Subjects were considered to have diabetes if they reported being diagnosed by a physician or if they were on hypoglycaemic agents irrespective of their blood glucose values. Hypertension was diagnosed if the subjects had a systolic BP  $\geq 140$  mmHg and/or diastolic BP  $\geq 90$  mmHg or at any level of BP if they were taking antihypertensive medications. Hypertension was classified based on the Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.<sup>10</sup> BMI (in kg/m<sup>2</sup>) for men and women was categorized according to the Asian criteria: <20 (underweight); 20–23 (normal); 23.1–25 (overweight); 25.1–30 (obese); and >30 (morbidly obese).<sup>8</sup> The upper limit of normal for WC was taken as 85 cm for men and 80 cm for women as per Asian standards.<sup>8</sup> Dyslipidaemia was defined as serum total cholesterol >200 mg/dl and/or serum LDL-cholesterol >100 mg/dl and/or serum triglycerides >150 mg/dl.

#### Statistical analysis

SPSS for Windows (Version 11) was used for data management and statistical analysis. To assess factors influencing glycaemic control in the community, mean HbA<sub>1c</sub> values were compared across multiple variables, namely age, sex, duration of diabetes, obesity, blood pressure, lipid profile, education level and SES. Univariate analysis was done using a *t*-test or ANOVA to assess the differences in mean HbA<sub>1c</sub>.

#### RESULTS

Among the 3069 people surveyed, 276 (9%) were reported to have diabetes (129 men and 147 women). Of these, 171 (62%) participated in the second phase of the study and underwent a physical examination and blood tests. Type 2 diabetes mellitus

was present in 169 (85 men and 84 women) and 1 each had type 1 diabetes and fibrocalculus pancreatic diabetes. The latter two patients were excluded from further analysis. The HbA<sub>1c</sub> levels were measured in 164 (of the 169) patients, who were included for final analysis. The mean (SD) age of these 164 patients was 56.9 (11.4) years and the mean (SD) duration of diabetes was 5.5 (5.04) years; 12.8% had had diabetes for >10 years; 22.1% were economically poor; 25.8% belonged to the high income and 52.1% to the middle income group. One hundred twenty-nine patients (78.7%) were educated till high school or less and the remaining had studied beyond high school.

Twenty-eight patients (17.2%) were not receiving any treatment, 24 (14.7%) were on diet control and 111 (68.1%) were on oral hypoglycaemic agents with or without insulin. Six patients (3.6%)

TABLE I. Univariate analysis of factors studied with the mean HbA<sub>1c</sub> levels

Factor	n (%)	Mean (SD) HbA <sub>1c</sub>	p value
<b>Gender</b>			
Men	84 (51.2)	8.4 (2.4)	0.104
Women	80 (48.8)	7.8 (2.2)	
<b>Age (years)</b>			
<45	28 (17.1)	7.8 (2.5)	0.595
46–55	48 (29.3)	8.2 (2.3)	
56–65	56 (34.1)	7.9 (2.1)	
>65	32 (19.5)	8.5 (2.7)	
<b>Socioeconomic group</b>			
Poor	36 (22.1)	7.8 (2.4)	0.03
Middle	85 (52.1)	8.5 (2.5)	
High	42 (25.8)	7.4 (1.8)	
<b>Educational level</b>			
High school or less	129 (78.7)	8.1 (2.4)	0.792
More than high school	35 (21.3)	8.0 (2.0)	
<b>Duration of diabetes (years)</b>			
<1	21 (12.8)	7.6 (2.0)	0.031
1–5	86 (52.4)	7.9 (2.3)	
6–10	36 (22.0)	8.1 (2.1)	
>10	21 (12.8)	9.5 (2.7)	
<b>Type of therapy</b>			
None	28 (17.2)	7.6 (2.6)	0.02
Diet only	24 (14.7)	7.2 (2.3)	
OHA with/without insulin	111 (68.1)	8.4 (2.2)	
<b>Body mass index (kg/m<sup>2</sup>)</b>			
<23	68 (41.5)	7.9 (2.5)	0.109
23–25	44 (26.8)	8.7 (2.2)	
>25	52 (31.7)	7.8 (2.2)	
<b>Systolic blood pressure (mmHg)</b>			
<130	52 (32.1)	8.3 (2.5)	0.445
$\geq 130$	110 (67.9)	8.0 (2.3)	
<b>Diastolic blood pressure (mmHg)</b>			
<80	36 (22.2)	8.1 (2.2)	0.952
$\geq 80$	126 (77.8)	8.1 (2.4)	
<b>Total cholesterol (mg/dl)</b>			
<200	53 (32.9)	8.1 (2.5)	0.698
>200	108 (67.1)	8.0 (2.2)	
<b>Triglyceride (mg/dl)</b>			
<150	94 (58.4)	8.0 (2.4)	0.855
$\geq 150$	67 (41.6)	8.1 (2.2)	
<b>LDL cholesterol (mg/dl)</b>			
<100	16 (9.9)	7.9 (3.1)	0.784
$\geq 100$	145 (90.1)	8.1 (2.2)	

were on insulin (5 on insulin and oral hypoglycaemic agents and 1 on only insulin). Glibenclamide was the most commonly prescribed oral hypoglycaemic agent. Thirty-one patients (26.7%) on pharmacotherapy were also taking a multivitamin or vitamin B complex supplement. Consumption of tobacco (smoked) was present in 23.6% of men with diabetes while 42.1% of men were past smokers. None of the women smoked.

Acanthosis nigricans was present in 30 patients (17.8%). It was significantly ( $p=0.033$ ) more common among those with diabetes for <5 years (23.2%) compared with those who had diabetes for >5 years (7%).

#### *Glycaemic control*

The mean (SD) fasting blood glucose was 153.0 (63.0) mg/dl; 76% had fasting blood glucose levels >110 mg/dl (recommended target level). The mean HbA<sub>1c</sub> level was 8.10 (2.34)%; 60% had HbA<sub>1c</sub> levels >7% and 26.4% had HbA<sub>1c</sub> levels >9%.

#### *Factors affecting glycaemic control*

Univariate analysis showed that the mean HbA<sub>1c</sub> level correlated significantly with the duration of diabetes ( $p=0.03$ ), family income ( $p=0.03$ ) and type of therapy ( $p=0.02$ ). The duration of diabetes and mean HbA<sub>1c</sub> level showed a positive correlation, with increasing duration of diabetes being associated with a higher mean HbA<sub>1c</sub> level. Though younger patients had lower mean HbA<sub>1c</sub>, this was not statistically significant ( $p=0.59$ ). Similarly, although women had lower levels of HbA<sub>1c</sub> than men, the difference was not significant ( $p=0.10$ ). Among the various socioeconomic variables, the high income and poor income groups had significantly lower HbA<sub>1c</sub> levels than the middle income group. Glycaemic control had no association with the level of education in our subjects ( $p=0.792$ ).

When the different treatment groups were compared, the mean HbA<sub>1c</sub> level was significantly ( $p=0.02$ ) higher among those on pharmacotherapy. Only 52% of those on pharmacotherapy had good glycaemic control (HbA<sub>1c</sub> <7%) whereas 66% of those on diet alone and 50% of those receiving no treatment had good diabetes control.

#### *Comorbid conditions*

**Obesity.** Using the Asian criteria of BMI, 31% of the patients were obese and 27% were overweight. Obesity was significantly ( $p<0.001$ ) higher among women (44%) compared with men (17.6%). The mean (SD) waist circumference for men and women was 83.98 (8.89) cm and 80.92 (11.11) cm, respectively.

**Hypertension.** The mean systolic BP and diastolic BP of the patients was 135 (20.9) and 82 (9.7) mmHg, respectively; 51% had BP levels higher than the recommended target of 130/85 mmHg. Only 29% of those with higher BP levels were on antihypertensive treatment.

**Dyslipidaemia.** The mean (SD) total serum cholesterol was 221.34 (39.77) mg/dl, mean LDL cholesterol was 145.9 (35.1) mg/dl and mean serum triglycerides was 144.5 (67.9) mg/dl; 90% of the patients had LDL cholesterol >100 mg/dl and 38% had serum triglyceride level >150 mg/dl. However, only 5% of the patients were on lipid-lowering agents.

**Complications of diabetes.** Evaluation for nephropathy showed that 40% had proteinuria, of which 18% had microalbuminuria and 22% had macroproteinuria. Serum creatinine >1.5 mg/dl was present in 3% of patients. Regarding macrovascular complications, a history of coronary artery disease was present in 16 patients (10%) and 1 had a history of stroke and 1 had a foot ulcer. Clinical

examination revealed that 18 patients (11%) had peripheral vascular disease as evidenced by the absence of palpable pulses in the dorsalis pedis and/or posterior tibial arteries.

#### DISCUSSION

This community-based, cross-sectional study provides evidence that control of glycaemia and other metabolic parameters was suboptimal in the population studied and did not meet the ADA guidelines. A majority of patients were on pharmacotherapy for glycaemic control and the number on insulin was very small. This is in contrast to the results of hospital-based studies where the proportion of patients being treated with insulin is around 22%.<sup>11</sup>

Glycaemic control was significantly associated with the duration of diabetes, type of treatment and family income. The longer the duration, the higher was the HbA<sub>1c</sub>, indicating the progressive nature of the disease. This finding is similar to that of other studies.<sup>11</sup> Though the nature of dietary counselling received by the patients was not assessed, many of them may not have received proper dietary counselling.

Patients treated with insulin and oral hypoglycaemic agents had significantly higher levels of HbA<sub>1c</sub> compared with those on diet alone. Similar observations have been made by other studies as well,<sup>12-14</sup> and perhaps reflects the common clinical practice of treating aggressively only those with poor glycaemic control. Despite the fact that 60% of patients had HbA<sub>1c</sub> levels >7%, insulin was being used in very few of our study population. This suggests the presence of cultural and psychological barriers in initiating insulin treatment among both patients as well as primary care providers, a finding well described in other parts of the world.<sup>15,16</sup> Our study also showed that the commonest oral hypoglycaemic agent prescribed was glibenclamide even though many other agents are available. Unfamiliarity with the use of new drugs on the part of the physician and the low cost of glibenclamide could be responsible for this practice.

Among the socioeconomic variables, only annual family income was significantly related to glycaemic control, suggesting that compliance with medical care depends largely on family income and not just on awareness. Though the higher income group had the lowest mean HbA<sub>1c</sub> levels, the poor income group had better diabetes control than the middle income group. This could be due to the fact that the poor income group may be less sedentary than the middle income group. The level of formal education had no correlation with diabetes control in our study. This highlights the fact that diabetes education is essential for all patients to make them aware of the importance of diabetic control irrespective of their educational status.

Acanthosis nigricans was less common among patients with a longer duration of diabetes probably due to lower insulin levels among them. However, we neither assessed insulin levels nor measures of insulin resistance.

Despite the lack of standard healthcare and limitations due to financial constraints in India, the glycaemic status of our patients was comparable with those in the USA.<sup>17</sup> However, the number of patients with poor control was much higher among our population.

Even though hypertension was common, only 29% were on antihypertensive therapy. Even those on treatment had suboptimal control. Similarly, while dyslipidaemia was very common with 90% having lipid levels above target values, only 5% were receiving treatment for the same. This lack of treatment for hypertension and hyperlipidaemia in this population, which is much against what is practised elsewhere in the world, again points to the lack of awareness among patients and perhaps

primary care providers. The high cost involved in the use of multiple antihypertensives and lipid-lowering drugs may be another contributory factor.

The high prevalence of modifiable risk factors such as smoking and obesity in our patients points to the need for increasing awareness and motivation among patients so that these risk factors could be reduced. One-fourth of the patients on pharmacotherapy were receiving vitamin supplements that have no established role in the management of diabetes suggesting incorrect prescribing practices among healthcare providers in this part of the world.

Though our study was not designed to assess factors that could have contributed to the low standard of diabetes care, the lack of awareness among patients and primary care physicians may be contributing factors. The high cost involved in the long term treatment of diabetes and related disorders might be the reason for this suboptimal care as shown by better diabetes control in the high income category.

One of the limitations of our study is its small sample size. However, it is fairly homogeneous and hence representative of our population. We did not assess the prevalence of peripheral neuropathy and retinopathy though these are important complications. The strength of our study is that it provides a cross-sectional view of the status of people with diabetes in the community. The observation that 17.2% of people with diabetes in this population were not on any treatment and that insulin was sparingly used despite many patients having high HbA<sub>1c</sub> levels gives us a community perspective of diabetes care. It also provides information that would not have come forth from hospital-based studies.

### Conclusion

Our study shows that glycaemic control in this population is suboptimal, even though it is similar to that in the western world. BP and lipid control were also suboptimal. The data partly reflect the ineffectiveness of our primary care providers in managing the burden of this metabolic disorder. The reason for poor diabetes care in the community could also be related to the lack of emphasis in our current medical curriculum on common problems such as diabetes mellitus, hypertension and dyslipidaemia. Strengthening our undergraduate and postgraduate medical education by emphasizing proper management of these common disorders may help correct this anomaly.

As more and more studies are proving the necessity for BP, lipid and glycaemic control to prevent long term micro- and macrovascular complications of the disease, these results should alert us to the possibility of a large burden of disease in our

community in the near future unless immediate and effective measures are instituted.

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