

Original Article

Risk factors related to the development of diabetes in men working in a North Indian industry

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ABSTRACT

Background. Epidemiological and lifestyle changes have been implicated in the high burden of diabetes in urban India. However, longitudinal data on the determinants for the development of diabetes in this population are not available. We investigated the determinants for the development of diabetes in workers in an Indian industrial organization.

Methods. Two cross-sectional surveys were done, using similar methodology (Survey 1 during 1995–98 [$n=2548$] and Survey 2 during 2002–03 [$n=2800$]) among all employees (age 20–59 years) of an industrial organization. A large majority of these were men (89.5% in Survey 1 and 92.8% in Survey 2). Men with no diabetes at baseline, who participated in both the surveys ($n=942$), constituted the study population. Development of new-onset diabetes was defined using history and fasting glucose concentrations ≥ 7 mmol/L.

Results. The mean (SD) age of the participants at baseline was 40 (2) years. Diabetes developed in 8% of the study population over 6.8 (1.7) years. Individuals who developed diabetes had significantly higher age, blood pressure, body mass index, waist circumference, fasting and post-prandial glucose, post-prandial insulin and fasting triglyceride levels at baseline. On multivariate regression analysis, only impaired glucose tolerance (OR 3.8, 95% CI: 2.1–6.8) and waist circumference (OR 1.09, 95% CI: 1.02–1.16) predicted the development of diabetes. Presence of the metabolic syndrome, as defined by the modified National Cholesterol Education Program Adult Treatment Panel (NCEP-ATP) III and WHO criteria, increased the odds (95% CI) of developing diabetes by 2.2 (1.3–3.6) and 4.5 (2.7–7.4) times, respectively.

Conclusion. Impaired glucose tolerance, high waist circumference and the metabolic syndrome are powerful predictors for the development of diabetes among urban Indian men.

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INTRODUCTION

The burden of diabetes is rapidly rising across the world, with developing countries having a higher burden compared with developed countries. This is particularly evident in India; it has the highest number of people with diabetes—approximately 23 million in 2000, which is projected to rise to 57 million by 2025.¹ Several cross-sectional studies have documented a high prevalence of diabetes among urban Indians, as well as a temporal rise in the prevalence of diabetes.^{2–5} These studies report several lifestyle- and urbanization-related determinants to be causative factors for diabetes. While cross-sectional studies demonstrate association, causality is better determined by prospective studies. To the best of our knowledge, no prospective data relating to determinants for the development of diabetes in urban Indians are available. We conducted a cross-sectional survey for risk factors of cardiovascular disease (CVD) during 1995–98 (Survey 1) among employees of a large urban-based industrial organization, and repeated it in the same organization using similar measurement tools during 2002–03 (Survey 2). This provided us the opportunity to study the determinants for the development of diagnosed diabetes and undiagnosed fasting hyperglycaemia in an urban cohort of Indian men who participated in both the surveys.

METHODS

Two independent cross-sectional surveys were done in a large industrial organization near Delhi (Survey 1 during 1995–98 and Survey 2 during 2002–03). The survey population consisted of permanent employees, aged 20–59 years, working in the organization. The detailed methodology employed for both the surveys has been described elsewhere.^{2,6} Survey 2 used similar study tools and methodology as Survey 1. The Institutional Review Board of the All India Institute of Medical Sciences, New Delhi approved the conduct of the study.

Briefly, both surveys consisted of an administered questionnaire, clinical examination and biochemical estimations. All the employees of the industrial organization were invited to

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participate in the surveys and informed consent was given by all the participating subjects. The questionnaire, which was administered by trained lay interviewers, sought information relating to demographic characteristics, presence of cardiovascular disease (CVD) or its risk factors and treatment status. Clinical examination, which was done by a physician, consisted of duplicate blood pressure measurements, height and weight measurements to calculate body mass index (BMI), and measurement of hip and waist circumference. Trained technicians collected fasting and post-glucose load blood samples for estimating the levels of glucose, insulin and lipids. All biochemical analyses were done using standard methods² and the laboratory that analysed the samples underwent regular accreditation by UK-NEQAS (National External Quality Assurance Programme) network.

Survey 2 differed from Survey 1 in some aspects. While in Survey 1, blood pressure was measured by standardized random zero sphygmomanometers, Survey 2 used standardized automated blood pressure monitors (Omron MX2, Japan). Survey 2 did not include the estimation of hip circumference. Also, in Survey 2, we did not measure the post-glucose load plasma glucose and insulin levels due to logistic constraints. All the other biochemical investigations were done using the same methods as in Survey 1.

This analysis is restricted to those who participated in both the surveys and who did not have diabetes (by history, fasting and post-glucose load plasma glucose estimations) by the American Diabetes Association (ADA) criteria in Survey 1 (Fig. 1).

Definitions

Development of diabetes was defined as a new history of receiving treatment for diabetes, or presence of *fasting hyperglycaemia* ≥ 7.0 mmol/L in Survey 2 among individuals with no diabetes at baseline in Survey 1. As post-glucose load plasma glucose was not measured in Survey 1, it did not form a part of the definition for diabetes.

Impaired fasting glucose (IFG) was defined using both old criteria (fasting plasma glucose ≥ 6.0 mmol/L in the absence of diabetes) and the new criteria (fasting plasma glucose ≥ 5.5 mmol/L in the absence of diabetes) advocated by the ADA.

Impaired glucose tolerance (IGT), as measured in Survey 1, was defined as post-glucose load plasma glucose ≥ 7.7 and < 11 mmol/L in the absence of diabetes.

Pre-hypertension and *hypertension* were defined using the Seventh Joint National Committee (JNC VII) criteria. We considered total cholesterol:High density lipoprotein cholesterol (TC:HDL) ratio ≥ 4.5 and fasting serum triglycerides ≥ 1.7 mmol/L to denote *abnormal lipid levels*.

Overweight and *abdominal obesity* were defined using different thresholds. The values considered for *overweight* were thresholds of 23 (proposed Asian cut-off⁷) and 25 kg/m² (National Cholesterol Education Program Adult Treatment Panel [NCEP-ATP] III cut-off), and obesity was defined as a BMI of ≥ 27.5 kg/m².⁷

Abdominal obesity in men was defined using three cut-offs: waist circumference > 85 cm, > 90 cm (as recommended by International Diabetic Federation for Indians) and > 94 cm (the NCEP-ATP III definition in genetically susceptible individuals).

Metabolic syndrome was defined using the NCEP-ATP III criteria⁸ modified for genetically susceptible populations (waist > 94 cm in men, other criteria remaining the same), and the modified WHO criteria (presence of insulin resistance as evident by diabetes/IFG/IGT along with any two of the following: Hypertension as per JNC VI; serum triglycerides ≥ 1.7 mmol/L or serum HDL < 0.9 mmol/L; BMI ≥ 30 kg/m² or waist-hip ratio > 0.90).⁹

Statistical analysis

Statistical analysis was done using SPSS version 9.0 (SPSS Inc., Chicago). Continuous variables were summarized as mean/median with standard deviation/interquartile range and categorical variables as proportions. Initially, in the univariate analysis, odds ratios were calculated for individual predictor variables for development of diabetes. Subsequently, variables that were significant ($p < 0.05$) or borderline significant ($p < 0.1$) were entered into multiple logistic regression by the entry method, to generate odds ratios for predicting the development of diabetes. Values are provided with rounding off to the first decimal place. The metabolic syndrome variable was excluded from multiple logistic regression models as it was found to strongly correlate with other variables in the model. We generated receiver operator characteristic (ROC) curves and estimated area under the curve (AUC) for likelihood of development of diabetes for several cut-offs of waist circumference and BMI. Minima on the ROC curve were calculated for multiple thresholds using the formula:
Minimum distance = $\sqrt{([1 - \text{sensitivity}]^2 + [1 - \text{specificity}]^2)}$

RESULTS

Baseline characteristics

Of the 2935 eligible individuals (11.7% women) in the organization, 2548 (86.8% of the total, 266 women and 2282 men) agreed to participate in Survey 1. As the number of eligible women who participated in Survey 2 was also small (10.4%), we considered results pertaining to the male population in this paper, as was done in the initial paper.²

Complete information about the risk factor status was available for 2122 men. Of these, 15% ($n = 318$) had diabetes (defined as receiving treatment for diabetes, or fasting or post-glucose load hyperglycaemia as defined earlier) and were excluded from this analysis. In Survey 2, of a total of 2600 men employees, 2300 underwent a detailed assessment for risk

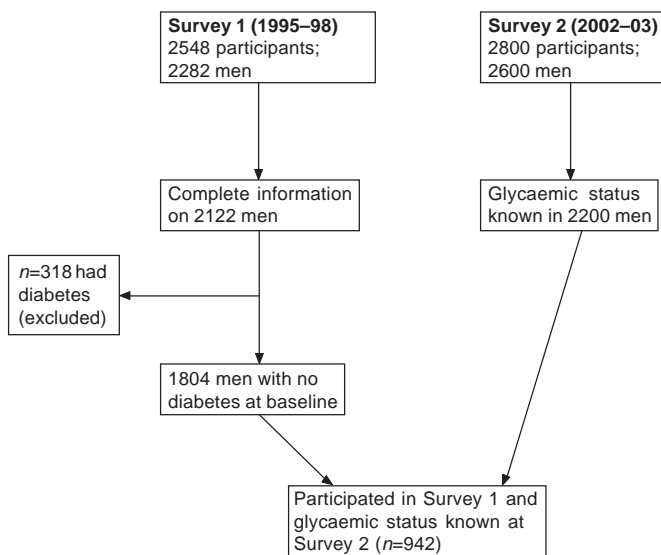


Fig 1. Design and sampling methodology of the study (Survey 1 done during 1995-98; Survey 2 done during 2002-03)

TABLE I. Baseline demographic and cardiovascular risk in the study population

Variable	Available for follow up (n=942)	Not available for follow up (n=862)
Men (%)	100	100
Mean (SD) age (in years)	40.0 (2.0)	42.3 (2.1)*
<35 years (%)	14.4	14.0
35–44 years (%)	67.2	66.6
≥45 years (%)	18.4	19.4
Education (%)		
Less than high school	11.8	12.4
High school	20.7	20.6
Graduate	15.8	15.2
Professional	51.7	51.6
Current smoking (%)	36.3	35.8
Pre-hypertension (%)	45.2	46.0
Hypertension (%)	26.1	25.8
Fasting plasma glucose (mmol/L)	5.1 (0.9)	5.0 (1.0)
Post-load plasma glucose (mmol/L)	6.1 (1.6)	6.2 (1.7)
Impaired fasting glucose using old criteria (%)	14.7	14.9
Impaired fasting glucose using new criteria (%)	34.7	35.1
Impaired glucose tolerance (%)	15.3	15.6
Fasting insulin [median] (IU/ml)	8.5 (13) [5.0]	8.6 (14) [5.0]
Post-load insulin [median] (IU/ml)	55.6 (76.6) [29.4]	55.9 (72.6) [29.0]
Family history of diabetes (%)	13.2	12.7
Lipids		
Total cholesterol (mmol/L)	4.7 (1.2)	4.8 (1.1)
HDL cholesterol (mmol/L)	0.95 (0.3)	0.9 (0.4)
Triglycerides (mmol/L)	1.6 (0.9)	1.7 (0.8)
Total cholesterol : HDL cholesterol ratio	5.3 (1.9)	5.7 (2.0)
Body mass index (kg/m ²)	23.4 (3.4)	23.0 (3.7)
Waist circumference (cm)	86.7 (9.9)	86.1 (11.6)

*p<0.05 Values are mean (SD) except where mentioned

factors. Of all the individuals with no diabetes in Survey 1 (n=1804), 942 men participated in Survey 2 and had estimations for their fasting glucose levels. The others had retired from service and were no longer available to participate in Survey 2. The baseline characteristics of individuals who were not available to participate in Survey 2, when compared with those who were part of Survey 2, were similar in nature except for age (Table I).

Baseline characteristics of subjects studied in Survey 2

The mean (SD) age of the subjects at baseline was 40 (5.1) years (range 23–54 years) and the majority were 35–44 years of age (67.2%). The time interval between the two surveys was a mean (SD) of 6.8 (1.7) years and the overall follow up was for 6416 person-years. The range of follow up was 1620–2880 days.

Development of diabetes

Of the 942 men, 77 (8.2%) had developed diabetes (defined as those requiring treatment [n=40] or undiagnosed fasting hyperglycaemia [n=37]). This would imply an annual incidence of new-onset diabetes of 12/1000 person-years in this relatively young male population. Further, 10.2% and 38.1% of subjects had IFG by the old and the new ADA criteria, respectively. If the older definition of IFG is considered, then of those with IFG in Survey 2, 17.7% had IFG at baseline and 12.5% had IGT at baseline. By the newer definition of IFG, 14% and 14.4% had IFG and IGT, respectively, at baseline. The metabolic characteristics, age and educational status of the subjects who developed diabetes were comparable with those who did not, as shown in Table II. Subjects who developed diabetes had significantly

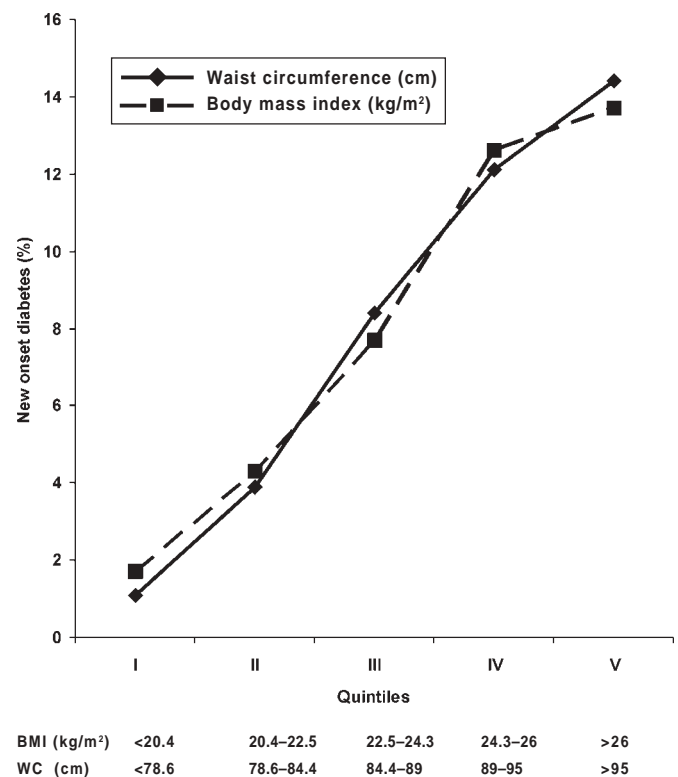


FIG 2. Incidence of diabetes across quintiles of body mass index, and waist circumference during Survey 1
BMI body mass index WC waist circumference

TABLE II. Differences in the baseline characteristics of individuals who developed diabetes compared with those who did not

Variable	Diabetes		p value
	Did not develop (n=865)	Developed (n=77)	
Age (years)	39.9 (5.2)	41.1 (5.0)	<0.05
Body mass index (kg/m ²)	23.3 (3.3)	25.7 (3.7)	<0.001
Waist circumference (cm)	86.1 (9.8)	93.8 (9.6)	<0.001
Systolic blood pressure (mmHg)	120.2 (12.7)	123.8 (10.3)	<0.05
<i>Plasma glucose (mmol/L)</i>			
Fasting	5.1 (0.9)	5.4 (0.8)	<0.05
Post-load	6.4 (1.5)	7.3 (1.8)	<0.001
<i>Plasma insulin (i.u./ml)</i>			
Mean/median (IQR)*			
Fasting	7.8/4.7 (4.6)	10.9/6.4 (6.3)	0.03
Post-load	52.2/27.7 (50.5)	93.3/64.8 (98.8)	<0.001
Serum triglycerides (mmol/L)	1.5 (0.9)	1.8 (1.0)	<0.05
Total cholesterol:HDL ratio	5.3 (1.9)	5.4 (1.6)	0.607
<i>Education (%)</i>			
Less than high school	11.8	10.4	0.440
High school	21.5	14.3	
Graduate	15.7	16.9	
Professional	51.0	48.4	
Current smoker (%)	36.5	32.5	0.28

IQR inter-quartile range * Independent *t* test used for comparison of means. Chi-square test used for comparison of prevalence rates
Values are mean (SD) except where mentioned

higher age, BMI, waist circumference, systolic blood pressure, fasting and post-glucose load glucose and insulin levels, and serum triglyceride levels. The incidence of diabetes increased almost linearly with increasing BMI and waist circumference (Fig. 2). Family history of diabetes, smoking status and educational status were not significantly different in those who developed diabetes compared with those who did not. Twelve per cent of individuals with waist circumference >85 cm and 14% of those with waist circumference >90 cm had developed diabetes by the time of Survey 2, compared to 2.8% and 4.6%, respectively, of those below these thresholds. Of all those who developed diabetes, approximately 85% and 63% had waist circumference >85 cm and >90 cm, respectively, at the time of Survey 1. Approximately one-fifth of all subjects with IGT at baseline developed diabetes or fasting hyperglycaemia ≥126 mg/dl. Further, 27.2% of those with both IGT and waist circumference >85 cm at baseline had developed diabetes at follow up. On the other hand, only 2.2% of subjects with none of these risk factors had developed diabetes at follow up. Eighty-nine per cent of subjects who developed diabetes had either IGT or a waist circumference of >85 cm at baseline. There was a trend towards a higher incidence of development of diabetes in the presence of baseline IFG by using the older criteria (12.3% v. 7.5%, p=0.06) and the new criteria (10.4% v. 7%, p=0.08).

Predictors of development of diabetes

Age, blood pressure, BMI, waist circumference, IGT and the metabolic syndrome by both the criteria at baseline were significant predictors for the development of diabetes (Table III). High TC:HDL ratio, hypertriglyceridaemia and IFG predicted the development of diabetes with borderline significance, while tobacco smoking, family history of diabetes and education status were not significant predictors for the development of new-onset diabetes.

On multivariable regression analysis, the only significant predictors for the development of diabetes were the presence of IGT and abdominal obesity at baseline. After adjusting for

other factors, the risk of developing diabetes increased by almost 9% for each centimetre increase in waist circumference (β -coefficient 0.08, OR 1.09, p<0.001). This result did not differ even after adjusting for the plausible interaction terms (such as those between waist, BMI, blood pressure, post-glucose load plasma glucose and age). The risk of developing diabetes started to increase in a linear fashion much before the waist circumference threshold of 94 cm, which is the cut-off suggested by the NCEP-ATP III guidelines for genetically susceptible individuals (Fig. 2). A significant increase in risk was observed from a waist circumference >84.4 cm. Similarly, raised BMI as a

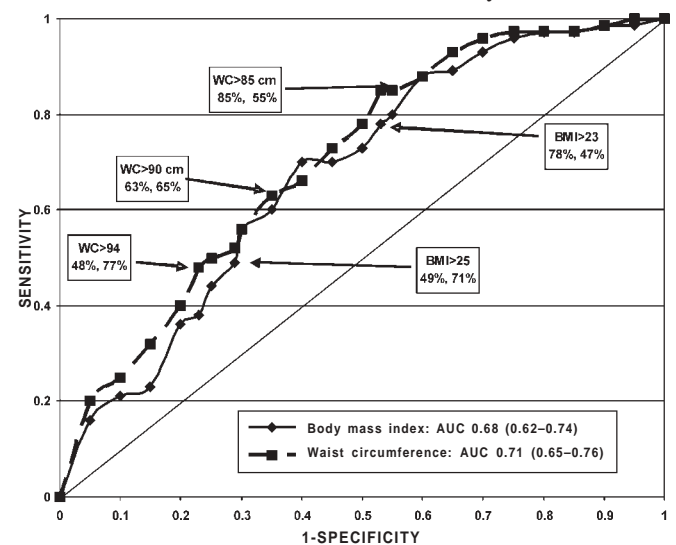


Fig 3. Receiver operator characteristic (ROC) curves and area under the curve (AUC) for waist circumference (cm) and body mass index (kg/m²) for development of diabetes. The box at right hand bottom refers to AUC with 95% confidence intervals shown in brackets. The boxes within the graph refer to the specific thresholds of body mass index and waist circumference and the sensitivity and specificity of that threshold in predicting the development of diabetes.

TABLE III. Univariate and multivariate odds of developing diabetes based on the presence of risk factors at baseline

Variable	Incidence of diabetes (%)	Univariate odds (95% CI)	Multivariate odds (95% CI)
<i>Age (in years)</i>			
<35	3.6	1.0	1.0
≥35	8.7	2.5 (1.0–6.4)	1.3 (0.5–3.6)
≥45	9.8	2.9 (1.0–8.0)	1.7 (0.6–5.0)
<i>Normal blood pressure</i>			
Normal	4.6	1.0	1.0
Pre-hypertension	8.0	1.8 (0.9–3.5)	1.1 (0.5–2.3)
Hypertension	11.8	2.8 (1.8–5.6)	1.3 (0.6–2.9)
<i>Fasting glucose (old criteria)</i>			
Normal	7.2	1.0	
Impaired	12.3	1.7 (1.0–3.7)	1.4 (0.7–2.7)
<i>Fasting glucose (new criteria)</i>			
Normal	6.9	1.0	
Impaired	10.4	1.5 (1.0–2.5)	
<i>Glucose tolerance</i>			
Normal	4.9	1.0	
Impaired	22.2	4.8 (2.9–7.8)	3.8 (2.1–6.8)
<i>Waist circumference >90 cm</i>			
Waist circumference >90 cm	14.0	3.4 (2.0–5.5)	
<i>Waist circumference (cm)</i>			
≤85	2.8	1.0	1.0
85.1–90	8.5	3.3 (1.5–7.2)	3.0 (1.1–8.3)
90.1–94	10.5	4.1 (1.8–9.6)	3.2 (0.9–11.3)
>94	15.9	6.6 (3.3–13.3)	6.2 (1.7–22.0)
<i>BMI (kg/m²)</i>			
<23	3.7	1.0	1.0
23–24.9	7.5	2.1 (1.0–4.3)	0.7 (0.3–1.9)
25–27.4	11.5	3.3 (1.7–6.3)	0.7 (0.2–2.3)
≥27.5	15.3	4.7 (2.2–9.9)	0.7 (0.2–2.5)
<i>Family history of diabetes</i>			
Family history of diabetes	9.6	1.2 (0.6–2.3)	
<i>Current smoking</i>			
Current smoking	7.3	0.8 (0.5–1.4)	
<i>Total cholesterol/HDL ratio ≥4.5</i>			
Total cholesterol/HDL ratio ≥4.5	9.5	1.6 (1.0–2.1)	1.4 (0.8–2.5)
<i>Triglycerides ≥150 mg/dl</i>			
Triglycerides ≥150 mg/dl	10.8	1.7 (1.0–2.7)	1.1 (0.7–2.3)
<i>Metabolic syndrome*</i>			
WHO modified definition	20.1	4.5 (2.7–7.4)	
ATP modified definition	12.7	2.2 (1.3–3.6)	
<i>Education</i>			
Less than high school	7.3	1.0	
High school	5.6	0.7 (0.3–1.9)	
Graduate	8.7	1.2 (0.5–3.0)	
Professional	9.3	1.3 (0.6–2.8)	

* not included in the multivariate model

continuous variable was strongly associated with the development of diabetes (β -coefficient 0.26, OR 1.3 [95% CI: 1.2–1.4], $p < 0.0001$). However, it strongly correlated with waist circumference (Pearson correlation 0.9, $p < 0.001$) and did not remain significant in the multivariable model after inclusion of waist circumference. Overall, both waist circumference and BMI were good at predicting the development of diabetes with AUC for ROCs being 0.71 (95% CI: 0.65–0.76) and 0.68 (95% CI: 0.62–0.74), respectively (Fig. 3). We identified the minima of the ROC curve for BMI and waist circumference at 24.2 kg/m² and 90 cm, respectively. After adjusting for other variables, IGT increased the odds of developing diabetes by about 4 times (OR 3.8, 95% CI: 2.1–6.8).

DISCUSSION

Our study demonstrates that levels of post-glucose load plasma glucose and waist circumference are important predictors for the development of diabetes in Indian men. Several other studies have investigated the determinants for the development of diabetes in communities worldwide, and have established the

efficacy of changes in lifestyle in the prevention of development of diabetes.^{10–14} To the best of our knowledge, there is no published data from the Indian subcontinent on the determinants of diabetes. The risk factors for the development of diabetes identified in our study are similar to those reported in other populations. However, the risk of developing diabetes increased at much lower thresholds of BMI and waist circumference as compared with western populations.

The presence of IGT is an important marker of abnormal glucose homeostasis with a high rate of progression to overt diabetes.¹⁵ We found a much higher rate of progression to diabetes among individuals with IGT than reported in Caucasian populations. This relationship was especially pronounced in those with the simultaneous presence of abdominal obesity. IGT at baseline itself was clustered with increased waist circumference, which explains some of the increased risk. The finding that IGT was a predictor and IFG was not, did not come as a surprise; the higher sensitivity of IGT over IFG for predicting progression to type 2 diabetes has also been reported in other populations.¹⁶ Though not all studies confirm this, compared to

subjects with IFG, subjects with IGT have been found to have greater insulin resistance¹⁷ and impaired insulin secretion.¹⁸

While both BMI and parameters of abdominal obesity such as waist circumference and waist-hip ratio are strongly associated with the risk of developing diabetes, their relative influence has been reported to vary depending on the population studied.^{19–22} We found the incremental value of waist circumference to be particularly evident at lower BMI levels, where within every category of BMI, the presence of waist circumference >90 cm led to an increase in the risk of development of diabetes. The minima that we obtained in our ROC curves for BMI and waist circumference were similar to those obtained by Zhu *et al.* in the Third NHANES survey in the USA.²³ However, their minima were at 26 kg/m² for BMI and 96 cm for waist circumference compared with 24.2 kg/m² and 90 cm, respectively, in our study population. This suggests that Asian Indians are at a considerably higher risk for diabetes at lower cut-offs of BMI and waist circumference. A similar elevated risk of diabetes at lower waist thresholds has been found by other Indian investigators in cross-sectional studies.²⁴ Thus, a simple measurement of waist circumference will identify a large number of individuals at risk for developing diabetes (waist circumference >90 cm alone predicted 63% of incident diabetes during the ensuing 6.8 years). Therefore, individuals with abdominal obesity, defined on the basis of high waist circumference, could be special targets for the prevention of diabetes.

India has been described as the diabetes capital of the world. Diabetes has been identified as one of the major reasons for the higher predilection for CVD among Asian Indians. Further, among individuals with diabetes, the results of treatment for CVD are poor.^{25,26} Therefore, to prevent the development of diabetes, identification of risk determinants for diabetes are of great importance. In this regard, our findings are consistent with several other studies from the West and emphasize the importance of abdominal obesity in the development of diabetes. Furthermore, this risk starts to rise at a much younger age and at much lower thresholds of markers of obesity. This has important implications for screening as well as formulating an informed health policy for prevention of diabetes in India.

Limitations

Our cohort of individuals is derived from 2 separate cross-sectional surveys conducted in the same organization—of people with no diabetes at baseline and those who were available for evaluation at the time of Survey 2. We were unable to include all those who had participated in Survey 1, as they had either retired or had left the organization by the time Survey 2 was begun. Of those who had not retired, the overall rate of refusal to participate in Survey 2 was low. Further, we did a sensitivity analysis by comparing the baseline characteristics of those who were not available to participate in Survey 2 with those who were part of this analysis. Except for age, which was expected to be different, there were no differences in other characteristics, attesting to the generalizability of the study results in this population. Our cohort consisted only of men, as the selected industrial organization has very few women employees. However, the results are likely to be similar for women, though thresholds of waist circumference or BMI associated with the development of diabetes may be different. We did not measure post-glucose load plasma glucose in Survey 2 due to logistic constraints and this may have led to underestimation of the incidence of diabetes. This study was conducted in a relatively

young population; hence, these results are not generalizable to the elderly age group, who may have an even higher risk for development of diabetes. We did not gather detailed information on the dietary and physical activity patterns in this population, and hence cannot comment on the specific role of these determinants in the development of diabetes.

Conclusion

Waist circumference and presence of IGT are strong predictors of future diabetes among urban Indian men. A waist circumference of >90 cm identifies a large number of men who are at risk for developing diabetes. Thus, individuals with IGT and increased waist circumference should be special targets for the prevention of diabetes.

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Clinical image



A 50-year-old man with a 9-year history of varicose veins and a non-healing venous ulcer had surgery for varicose veins and multiple attempts at skin grafting for the venous ulcer. A duplex ultrasound imaging showed a normal superficial venous system and a magnetic resonance venogram showed a 'double inferior vena cava (IVC)'.

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