# Indian Diabetes Risk Score Helps to Distinguish Type 2 from Non-Type 2 Diabetes Mellitus (GDRC-3)

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### Abstract

#### Aim:

The aim of this study was to investigate whether the Indian Diabetes Risk Score (IDRS) could assist in classifying type 2 diabetes mellitus (T2DM) and non-T2DM among patients attending clinics in India.

#### Methods:

Patient records from 2006 through 2009 were taken from the clinical database of a tertiary care diabetes hospital in Chennai, Southern India. A total of 8747 patients with diabetes, diagnosed by a physician either as type 1 diabetes mellitus (T1DM), T2DM, or other types were included for analysis. The IDRS, based on age, abdominal obesity, family history of diabetes, and physical activity, was calculated for each patient at first visit to our clinic. Receiver operating characteristic (ROC) curves were generated to obtain optimal IDRS cut points for predicting T2DM and non-T2DM.

#### Results:

Of the 8747 patient records analyzed, 204 (2.3%) were classified as non-T2DM and 8543 (97.7%) as T2DM. In ROC analysis, an IDRS  $\geq 60$  [area under the curve (AUC), 0.894; sensitivity, 83.8%; specificity, 81.0%] was predictive of T2DM, while an IDRS <60 (AUC, 0.882; sensitivity, 79.9%; specificity, 83.8%) was predictive of non-T2DM.

#### Conclusions:

The IDRS, a simple, cost-effective risk score, can assist in classifying T2DM versus non-T2DM among clinic patients in India.

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Abbreviations: (A1C) glycated hemoglobin, (AUC) area under the curve, (BMI) body mass index, (CI) confidence interval, (CURES) Chennai Urban Rural Epidemiology Study, (FCPD) fibrocalculous pancreatic diabetes, (IDRS) Indian Diabetes Risk Score, (ROC) receiver operating characteristic, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus, (WHO) World Health Organization

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iabetes is no longer classified simply by insulin requirement, as was done previously, but rather by etiology, the two largest types being type 2 diabetes mellitus (T2DM) and type 1 diabetes mellitus (T1DM).<sup>1</sup> There are an estimated 51 million people with diabetes in India, and this number is projected to increase to 80 million by 2030.<sup>2</sup> Furthermore, with studies reporting that the increasing prevalence in obesity at younger ages may increase the risk of T1DM<sup>3</sup> and result in early age of onset of T2DM, the diagnosis of T2DM versus non-T2DM is becoming more complicated.4,5 Screening and accurate classification of diabetes, though difficult and expensive, are needed acutely; benefits include prevention of subsequent beta-cell failure via pharmacologic and lifestyle interventions in T2DM and prevention of complications from uncontrolled blood glucose in T1DM.<sup>4</sup> Unfortunately, greater than half of those with diabetes in the developing world remain undiagnosed,6 highlighting the need for simple, low-cost tools to aid in the classification of diabetes.7

One potential tool is the Indian Diabetes Risk Score (IDRS), which has been shown to be a cost-effective method of screening for undiagnosed diabetes in the community,<sup>8</sup> to predict incident diabetes,<sup>9</sup> to identify cardiometabolic risk in normoglycemic subjects,<sup>10</sup> to discriminate primary and secondary causes of diabetes,<sup>11</sup> as well as to be associated with complications of diabetes.<sup>12</sup> In this article, we demonstrate how the IDRS, when used in a clinic, can help classify diabetes and decrease costs related to classification of the type of diabetes.

### Methods

A total of 9755 patient records between 2006 to 2009 in which IDRS data were available were taken from the clinical database at Dr. Mohan's Diabetes Specialties Centre, a tertiary care diabetes center in Chennai (formerly Madras), Southern India's largest city. Those with gestational diabetes mellitus, impaired glucose tolerance and impaired fasting glucose, and normoglycemia (*n* =1008) were excluded from our analysis. All patients with diagnoses of T1DM and fibrocalculous pancreatic diabetes (FCPD) were classified as non-T2DM. Clinically, FCPD cases mimic T1DM cases,<sup>13,14</sup> and the American Diabetes Association classifies FCPD under "other specific types" of diseases of the exocrine pancreas;<sup>15</sup> hence we merged FCPD and T1DM cases to create the "non-T2DM" category. Patients classified as T2DM and non-T2DM were included in the final analysis (n = 8747).

Diabetes was diagnosed if a subject's fasting plasma glucose was  $\geq$ 126 mg/dl ( $\geq$ 7 mmol/liter) or if the 2 h postload glucose was  $\geq$ 200 mg/dl ( $\geq$ 11.1 mmol/liter). All biochemical assays were done using Hitachi 912 Autoanalyser (Roche Diagnostics GmbH, Mannheim, Germany) utilizing kits supplied by Roche Diagnostics GmbH (Mannheim, Germany).

Type 1 diabetes mellitus was defined as diabetes requiring insulin from onset, presence of ketosis or ketoacidosis, and poor beta-cell reserve as assessed by C-peptide assay.<sup>16</sup> Type 2 diabetes mellitus was defined as insidious onset of diabetes, absence of ketosis, good beta-cell reserve as assessed by C-peptide assay, and absence of pancreatic calculi.<sup>17</sup> Fibrocalculous pancreatic diabetes was identified by presence of pancreatic calculi on abdominal X ray, absence of alcoholism or other known causes of chronic pancreatitis, and evidence of diabetes.<sup>14</sup> The clinical and biochemical profiles of the patients, including age, body mass index (BMI), waist circumference, blood pressure, fasting blood glucose, lipid profile, and glycated hemoglobin (A1C), were obtained from the case records by an investigator who was blinded to the diagnosis.

The IDRS was calculated for each patient during his/her first visit to the clinic. The IDRS methodology has been reported earlier<sup>8</sup> and is briefly mentioned here. The IDRS is calculated from four simple parameters, namely, age, abdominal obesity, family history of diabetes, and physical activity. An IDRS of  $\geq 60$  was found to have optimum sensitivity and specificity for detecting undiagnosed diabetes in the community.

The risk score was derived from the Chennai Urban Rural Epidemiology Study (CURES), an epidemiological study on a representative population of Chennai.<sup>18</sup> Phase 1 of CURES recruited 26,001 individuals, of whom every 10th subject was requested to participate in phase 3 of screening for diabetes using World Health Organization (WHO) 2-hour venous plasma glucose criteria (i.e.,  $\geq$ 200 mg/dl). The response rate was 90.4% (2350/2600). The IDRS was developed based on results of multiple logistic regression analysis. Internal validation was performed on the same data. Beta coefficients were derived based on a multiple logistic regression analysis using undiagnosed diabetes as the dependent variable. The beta coefficients were

modified so as to obtain a maximum possible score of 100. Receiver operating characteristic (ROC) curves were constructed to identify the optimum value of IDRS for detecting diabetes by WHO consulting group criteria. The area under the curve (AUC) for ROC was 0.698 (95% confidence interval (CI), 0.663–0.733). An IDRS value  $\geq$ 60 had the optimum sensitivity (72.5%) and specificity (60.1%) for determining undiagnosed diabetes with a positive predictive value of 17.0%, negative predictive value of 95.1%, and accuracy of 61.3%.

The risk factors included in this score and their scoring pattern were as follows:

- 1. Age: This was categorized into three groups: age <35 years was coded as 0, 35–49 years as 1, and ≥50 years as 2.
- Abdominal obesity: Males—individuals with waist circumference ≥90–99 cm were coded as 1, those with ≥100 cm as 2, and the rest as 0. Females—individuals with waist circumference ≥80–89 cm as were coded as 1, those with ≥90 cm as 2, and the rest as 0.11.
- 3. Family history of diabetes: Individuals with no family history of diabetes were coded as 0, those having one parent with diabetes as 1, and those having both parents with diabetes as 2.
- 4. Physical activity: Individuals were coded as 0 if they did leisure time exercise and, in addition, had physically demanding work in their occupation, individuals who either did exercise or performed physically demanding work were graded as 1, and the rest as 2.

The information for these risk factors can be obtained based on four simple questions and one anthropometric measurement, namely, waist circumference. The four questions are as follows:

- 1. What is your age?
- 2. Do you have a family history of diabetes? If yes, does your father or mother or both have diabetes?
- 3. Do you exercise regularly?
- 4. How physically demanding is your work (occupation)?

## **Statistical Analysis**

Student's sample t-test was used to compare the two diabetes groups for continuous variables. Values are expressed as mean ± standard deviation or percentages as appropriate and a p value of <0.05 was considered significant. Due to skewed distribution, the descriptive data of serum triglycerides have been expressed as median and range. To determine if the IDRS can predict T2DM and non-T2DM in a clinic setting, a ROC curve was constructed using retrospective data from our electronic database. Sensitivity, specificity, positive and negative predictive values, and accuracy for predicting non-T2DM were calculated for different cut points. Chi-square test was used to compare proportions of patients with an IDRS less than and above 60 across the two diabetes groups. The cut point of 60 was selected based on our ROC analysis. All statistical analysis was performed using SPSS PC Windows version 15.0 (Chicago, IL).

### Results

A total of 8747 patient records were categorized using the aforementioned criteria as having non-T2DM (n = 204; 2.3%) or T2DM (n = 8543; 97.7%). The clinical, anthropometric, and biochemical profiles of each group are given in **Table 1**. Those with T2DM were older and had higher waist circumference and BMI than those with non-T2DM (p < .005). Similarly, blood pressure as well as the lipid profiles of the T2DM patients were higher compared to the non-T2DM group (p < .005). The non-T2DM group, however, had higher fasting blood sugars and A1C (p < .005) compared to the T2DM patients, indicating worse glucose control.

A ROC curve was obtained to determine the optimal cut point for identifying non-T2DM and T2DM cases. An IDRS of less than 60 was optimal for identifying non-T2DM and  $\geq$ 60 for identifying T2DM (AUC, 0.882; CI, 0.875–0.888; sensitivity, 79.9%; specificity, 83.8%) (Table 2 and Figure 1).

**Figure 2** shows the percentage distribution of IDRS for T2DM and non-T2DM patients. For T2DM cases, the peak was on the right-hand side of the graph, corresponding to higher IDRS values. The AUC, representing the total case number, was predominantly in the range of IDRS  $\geq$ 60 for T2DM cases. The opposite was true of non-T2DM cases, with a leftward peak corresponding to low IDRS values and the AUC predominantly in the IDRS <60 range. To look for a pattern in cases where the IDRS did not

accurately predict T2DM versus non-T2DM as we would expect based on our analyses, we examined the clinical, anthropometric, and biochemical profiles of patients with misleading IDRS values, i.e., non-T2DM cases with an

Table 1.   Clinical, Anthropometric, and Biochemical Profiles   of T2DM and Non-T2DM Subjects					
	Non-T2DM <sup>a</sup> (n = 204)	T2DM (n = 8543)	p for trend		
Age (years)	30.7 ± 16.1 51.9 ± 10.7		<0.001		
Waist circumference (cm)	rm) 73 ± 13 93 ± 11		<0.001		
IDRS	40 ± 17	68 ± 14	<0.001		
BMI (kg/m²)	19.6 ± 4	26.6 ± 4.5	<0.001		
Duration of diabetes (years)			0.060		
≤5 (%)	56.3	56.9			
6–9 (%)	19.1	27.5			
≥10 (%)	24.6	15.7			
Systolic blood pressure (mm Hg)	116 ± 21	133 ± 19	<0.001		
Diastolic blood pressure (mm Hg)	76 ± 10	83 ± 10	<0.001		
Fasting plasma glucose (mg/dl)	201 ± 97	175 ± 66	<0.001		
Serum cholesterol (mg/dl)	165 ± 42.8	184 ± 42.2	<0.001		
Serum triglycerides (mg/dl) Median (min-max)	84 (33–314)	144 (26–1943)	<0.001		
High density lipoprotein cholesterol (mg/dl)	1 48 ± 14 40 ± 10		<0.001		
A1C (%) 10.2 ± 2.7		8.8 ± 2	<0.001		
<sup>a</sup> Non-T2DM mainly includes T1DM and FCPD.					

Table 2.

Sensitivity, Specificity, and Predictive Values of IDRS in Identifying Non-T2DM in a Clinic Population

	Sensitivity	Specificity	Positive predictive value	Negative predictive value
<20	0.0	100.0	0	97.7
<30	17.6	99.8	66.7	98.1
<40	46.1	98.7	46.5	98.7
<50	62.3	95.4	24.5	99.1
<60	79.9	83.8	10.6	99.4
<70	88.7	61.3	5.2	99.6
<80	97.1	33.4	3.4	99.8
<90	99.0	10.5	2.6	99.8

IDRS  $\geq$ 60 and T2DM cases with an IDRS <60. Non-T2DM patients with higher IDRS values were older and had higher BMI than non-T2DM subjects with expected values (age, 51 versus 22.5 years, respectively; BMI, 23 versus 19 kg/m<sup>2</sup>, respectively; *p* = .000). Type 2 diabetes mellitus subjects with a lower IDRS were younger and had lower BMI than T2DM subjects with expected values (age, 45 versus 53 years, respectively; BMI, 24 versus 27 kg/m<sup>2</sup>, respectively; *p* = .000).



Figure 1. A ROC curve showing performance of IDRSs in identifying non-T2DM in a clinic population (AUC, 0.882; CI, 0.875–0.888).



Figure 2. Percentage distribution of T2DM and non-T2DM by IDRS.

### Discussion

An accurate classification of diabetes is necessary for optimal treatment. Currently, a clinician must combine a variety of data, including family history, age, weight, and symptoms plus laboratory testing to definitively classify a patient with diabetes. Accurate classification of those with T2DM allows for a clinician to advise lifestyle and pharmacological interventions to prevent subsequent beta-cell failure in the patient.<sup>4</sup> For those with T1DM, prompt classification is necessary to prevent more severe consequences surrounding uncontrolled blood glucose in the immediate post-diagnosis period and to allow a clinician to immediately start insulin and counsel regarding its proper use. In the Indian clinic setting, where follow-up rates for chronic disease are less than optimal, clinicians have only a few hours to correctly classify a diabetes patient, counsel them, and initiate treatment. Hence, a tool to simplify classification is needed.

There are numerous risk scores and other low-cost tools for screening diabetes in the general population and for assessing the risk of developing complications in those with diabetes.<sup>19–25</sup> However, tools that can aid in classification of diabetes in clinic populations are limited. This can be at least partly explained by ease of classifying T1DM by biochemical assay. However, in resource-limited settings such as India, classifying T1DM presents unique challenges because of the high costs of laboratory tests and travel to equipped health care facilities relative to median income. In such settings, a simple, accurate, low-cost predictor of T2DM versus non-T2DM would be substantially useful.

Studies have questioned the accuracy and value of established population risk scores, including the Framingham Risk Score, in a clinical setting, in spite of such scores performing well when used as an epidemiological tool.<sup>24,26</sup> Extensive literature search revealed only two risk scores that were applicable as clinical and epidemiological diabetes risk predictor tools.<sup>27,28</sup> The risk score from the Diabetes Prevention Trial-Type 1 study group was specifically suitable for the prediction of T1DM.27 Calculated from BMI, age, fasting C-peptide, and postchallenge glucose and C-peptide from 2-hour oral glucose tolerance tests, this score is not applicable in resource-limited settings because of the costs associated with the required laboratory tests. Another tool, the QDScore, is a risk prediction algorithm that does not require laboratory examination.28 It estimates a 10-year risk of diabetes and can be used

in both a clinical and field setting to predict the risk of diabetes. Similarly, the IDRS can be used in a clinic as an inexpensive, noninvasive tool to help a primary care physician or lay health care provider to distinguish non-T2DM from T2DM. Because the IDRS can be calculated by unskilled lay persons, it can be of particular use in rural and semi-urban clinics where paramedical staff or community health workers can be trained to calculate the IDRS and thereby identify those necessitating further evaluation for non-T2DM at referral centers.

From the economic standpoint of our clinic, the average cost range for confirming a diagnosis of T2DM is Rs. 300–500 (\$6.50–11.00) and for non-T2DM is Rs. 1500–3000 (\$33.00–65.00). Hence, for each case of T2DM that we incorrectly order non-T2DM tests for, we spend Rs. 1200–2500 (\$26.00–54.00) more than necessary. In our analysis, 17.7% of the study population had an IDRS <60, meaning that they underwent further testing, which subsequently identified 79.9% of all non-T2DM subjects in our study population. From this, we conclude that the IDRS can considerably reduce costs by providing guidance as to which patients to test for more expensive laboratory examinations while still identifying non-T2DM cases with high fidelity.

Limitations of our study include having a study population limited to those attending a single tertiary care diabetes center in a single city in southern India. Wider testing and evaluation is needed to further confirm the validity of our results in other clinical settings and other Indian populations. Additionally, due to logistical difficulties, we did not include all patients who attended our clinic during the time period mentioned, though we have taken adequate methodological and statistical measures to ensure that the population included in the analysis was similar to the population not included.

Lean patients with T2DM tend to be anomalous in their presentations.<sup>29</sup> As already mentioned, those with a misleading IDRS also tend to be atypical in their clinical profiles when compared to those with an expected IDRS. The IDRS is not necessarily a good predictor in these cases, highlighting that the IDRS can aid in diagnosis of diabetes but is not in itself diagnostic. Such anomalous cases deserve further investigation to confirm diagnosis. Moreover, because our center is a tertiary care center with many patients previously diagnosed by and referred from other physicians, it can be speculated that the modifiable risk factors of the IDRS (physical activity and waist circumference) have changed in our T2DM population since their initial diagnosis, meaning

that these cases would have actually had a higher IDRS at diagnosis of diabetes. Despite these, the correlation between high IDRS and T2DM and low IDRS and non-T2DM was remarkable.

In summary, we suggest that, in incident diabetes cases where the IDRS on presentation is  $\geq 60$ , a diagnosis of

T2DM is highly probable and costly examinations to classify non-T2DM could be avoided. Similarly, in cases where the IDRS is <60 at presentation, we encourage clinicians to think of the spectrum of non-T2DM cases, of which T1DM is the most common. As illustrated in **Figure 3**, we propose a simple algorithm to help clinicians utilize the IDRS as a diagnostic tool in clinics.



Figure 3. Schematic utility of the IDRS in Indian clinics

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