

**RANDOM CAPILLARY BLOOD GLUCOSE CUT POINTS
FOR DIABETES AND PRE-DIABETES DERIVED FROM COMMUNITY
BASED OPPORTUNISTIC SCREENING IN INDIA**

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Aim: To determine random capillary blood glucose (RCBG) cut points which discriminate diabetic and pre-diabetic subjects from normal individuals.

Methods: RCBG was done in 1,333 individuals randomly chosen from 63,305 who had participated in an opportunistic screening program. OGTT was also done by venous plasma glucose on autoanalyser. RCBG cut points which discriminate diabetes, impaired glucose tolerance and impaired fasting glucose were determined using Receiver Operating Characteristic (ROC) curves.

Results: Using the $2\text{HrPG} \geq 200\text{mg/dl}$ (11.1mmol/L) criterion, the RCBG cut point of 140mg/dl (7.7mmol/l) gave the highest sensitivity and specificity. For the $2\text{HrPG} \geq 200\text{mg/dl}$ (11.1mmol/L) values and $\text{FPG} \geq 126\text{mg/dl}$ (7.0mmol/L) criterion, either $2\text{HrPG} \geq 200\text{mg/dl}$ (11.1mmol/L) or $\text{FPG} \geq 126\text{mg/dl}$ (7.0mmol/L) criterion, and the $\text{FPG} \geq 126\text{mg/dl}$ (7.0mmol/L) criterion, RCBG cut point was 143 mg/dl (7.9mmol/L). Respective RCBG cut points for IGT, IFG(WHO) and IFG(ADA) criteria were 119mg/dl (6.6mmol/L), 118mg/dl (6.6mmol/L) and 113mg/dl (6.3mmol/L).

Conclusion: In Asian Indians, those with $\text{RCBG} > 110\text{ mg/dl}$ on screening, can be recommended to undergo definitive testing.

Approximately 50 to 70% of people with diabetes remain undiagnosed in both developed (1) and developing countries (2) and these individuals often present with complications of diabetes (3). It is established that good control of diabetes can prevent complications. Undiagnosed diabetes and pre-diabetes therefore need to be detected and treated early through community based screening (4).

Definitions of diabetes are usually based on fasting or postprandial glucose. However, the random capillary blood glucose (RCBG) is the most convenient way to reach out to large numbers of people. A few studies in western countries (5,6), have tried to correlate random capillary blood glucose values(RCBG) with 2HrPG or FPG, (the basis for the WHO(World Health Organization) and ADA(American Diabetes Association) definitions) but none from India which has the largest number of people with diabetes globally (7). There is also no data on RCBG cut points for pre-diabetic states such as IFG and IGT. This is particularly relevant since IFG now has two definitions ADA $\geq 100\text{mg/dl}$ (5.6mmol/L) (8) and WHO $\geq 110\text{mg/dl}$ (6.1mmol/L) (9).

The aim of this study, carried out in a community setting in south India, was to derive RCBG cut points which discriminate diabetic from non-diabetic and pre-diabetic from non-prediabetic individuals.

METHODS

Between September 2004 and September 2007, 774 opportunistic screening camps for diabetes covering 103,878 people were conducted in various parts of Chennai (formerly Madras) city with a population of 5 million people in southern India as part of the Prevention Awareness Counselling And Evaluation (PACE) Diabetes Project. Of these, 76,645 (73.8%). individuals underwent an RCBG test using One Touch Ultra

(Lifescan Johnson&Johnson, Milpitas, USA). The detailed methodology of this project is described elsewhere (10).

Individuals with self reported diabetes (n=13,340) were excluded. Of the remaining 63,305 subjects, 1500 individuals were randomly selected and invited to attend Dr.Mohan's Diabetes Specialities Centre, a tertiary referral centre for diabetes care to undergo an oral glucose tolerance test (OGTT) within the next 2 to 3 days. A total of 1,333 individuals responded to the invitation (88.9% response rate). A fasting sample was drawn for venous plasma glucose (FPG) estimation, 75 g oral glucose was given and a second sample drawn at 120 minutes(2HrPG).

Statistical analysis: Statistical analysis was performed using SPSS PC Windows version 10.0 (Chicago, IL). Receiver Operating Characteristic (ROC) Curves were plotted using sensitivity and 1-specificity for different cut off values of RCBG. Using the ROC technique, comparison of sensitivity with the specificity was made over the entire range of RCBG cut points and Area Under the Curve (AUC's) were plotted. By interpolation from the AUC, the point which was closest to the upper left corner which maximized the sensitivity and specificity was selected and this identified the highest number of subjects with or without a condition (11). In this manner, RCBG cut points were determined for diabetes, IGT and IFG using ADA (8) and WHO (9) criteria. (See Figure A1 in the online appendix available at <http://care.diabetesjournals.org>.)

RESULTS

The mean age of the study group was 45.5 ± 10.7 years; 45.2% were males; and mean body mass index (BMI) was 24.8 ± 4.0 kg/m^2 . 27.2%(n=363) had RCBG < 100mg/dl (5.6mmol/L), 65.9%(n=878) had RCBG in the range of 100 to 200mg/dl (5.6 to 11.1mmol/L) and 6.9%(n=92) had RCBG over 200mg/dl (11.1mmol/L).

Using the 2HrPG \geq 200mg/dl (11.1mmol/L) criterion, the RCBG cut point of 140mg/dl (7.7mmol/l) gave the highest sensitivity and specificity (Table 1). Using the 2HrPG \geq 200mg/dl (11.1mmol/L) values *and* FPG \geq 126/dl (7.0mmol/L) criterion, *either* 2HrPG \geq 200mg/dl (11.1mmol/L) *or* FPG \geq 126 mg/dl (7.0mmol/L) criterion, or for FPG \geq 126 mg/dl (7.0mmol/L) criterion, the RCBG cut point was 143 mg/dl (7.9mmol/L).

For IGT, the RCBG cut point was 119 mg/dl (6.6mmol/L). Using the IFG (WHO) criterion of FPG \geq 110 (6.1mmol/L) *and* <126 mg/dl (7.0mmol/L), the RCBG cut point was 118 mg/dl (6.6mmol/L), while for the IFG (ADA) criterion of FPG \geq 100 mg/dl (5.6mmol/L) *and* <126 mg/dl (7.0mmol/L), the RCBG cut point was 113 mg/dl (6.3mmol/L).

DISCUSSION

The most commonly used tests for screening for type 2 diabetes, are fasting and 2HrPG (9, 10). Measurement of random capillary glucose has the advantage that it can be undertaken at any time of the day, does not require a venipuncture and can even be carried out by lay people. In studies from N.America, RCBG cut points ranging from 99 mg/dl to 140 mg/dl have been reported to identify diabetes (5, 12-14).

Our study presents the first data from India, and shows that in Asian Indians, RCBG cut points of 140 and 143 mg/dl (7.8 and 7.9mmol/L) maximized the sensitivity and specificity for diabetes. Moreover, this study provides the first data to our knowledge, on RCPG cut points for IGT-119 mg/dl (6.6mmol/l), for two definitions of IFG (WHO-118mg/dL and ADA-113mg/dL) and for abnormal glucose tolerance (141mg/dL) and abnormal glucose regulation (121mg/dL).

The strengths of this study are, that it is based on large numbers of subjects, was done in a 'real life' community based setting and, is the first to our knowledge, to report on

cut points for IGT and IFG according to the WHO and ADA criteria.

Based on our study, we propose that in opportunistic screening studies in Asian Indians, all those with RCBG values>110 mg/dl (6.1mmol/L) can be taken up for more definitive tests for diabetes and pre-diabetes. This could not only help limit the numbers of people who need to come on a fasting state for screening but also reduce the costs of screening as only 60% of those screened would have RCBG>110mg/dl.

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Table 1: RCBG cut points with respect to Diabetes, IGT and IFG in Asian Indians

CONDITION	CRITERIA	Mean RCBG (mg/dl)	RCBG cut points	Sens	Spec	PPV	AUC	Overall Accuracy %
DIABETES	2HrPG \geq 200mg/dl or FPG \geq 126mg/dl n = 238 (17.9%)	187.3 \pm 67.0	143	78.6	83.9	51.5	0.872	82.9
DIABETES	2Hr \geq 200mg/dl n = 185 (13.9%)	198.6 \pm 69.1	140	86.5	80.7	42.0	0.900	81.5
DIABETES	FPG \geq 126mg/dl n = 194 (14.6%)	193.3 \pm 70.2	143	80.4	81.7	42.9	0.873	81.5
DIABETES	2Hr \geq 200mg/dl and FPG \geq 126mg/dl n = 141 (10.6%)	210.5 \pm 71.8	143	89.4	80.2	34.8	0.919	81.2
IGT	2Hr \geq 140mg/dl and <200mg/dl n = 375 (28.1%)	168.4 \pm 62.6	119	64.7	65.5	27.2	0.715	65.4
IFG (WHO)	FBS \geq 110mg/dl and <126mg/dl n = 385 (28.9%)	165.0 \pm 63.1	118	62.8	62.9	25.4	0.683	62.9
IFG (ADA)	FBS \geq 100mg/dl and <126mg/dl n = 633 (47.5%)	146.9 \pm 57.1	113	58.3	58.6	46.9	0.619	58.5
Abnormal Glucose Tolerance	IGT and Diabetes n = 220 (16.5%)	191.8 \pm 67.1	141	82.3	82.4	48.0	0.888	82.4
Abnormal Glucose Regulation	IFG (WHO) or IGT or Diabetes n = 497 (37.3%)	157.5 \pm 59.3	121	70.2	69.9	58.1	0.777	70.0
Abnormal Glucose Regulation	IFG (ADA) or IGT or Diabetes n = 698 (52.4%)	145.4 \pm 55.5	116	66.5	65.5	68.0	0.714	66.0

Abbreviations: RCBG: Random capillary blood glucose; AUC: Area under curve; ROC: Receiver Operating Characteristic curve; Sens: Sensitivity; Spec: Specificity; PPV: Positive predictive value; IFG: Impaired fasting glucose; IGT: Impaired glucose tolerance; WHO: World Health Organisation, ADA: American Diabetes Association.