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Random Capillary Blood Glucose in the Diagnosis of Diabetes- A Bangladesh Study

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Abstract

Objective

To assess the effectiveness of random capillary blood glucose (RCBG) as a diagnostic tool for type 2 diabetes mellitus (T2DM) and determine optimal cut-off values for adults in Bangladesh.

Design

A cross-sectional study.

Setting

Sixteen diabetes centers were randomly selected from eight divisions across Bangladesh.

Participants

A total of 3,200 adults aged 18 years and older were recruited using systematic random sampling between May and September 2022.

Primary and Secondary Outcome Measures

The primary outcome was the diagnostic accuracy of RCBG compared to fasting plasma glucose (FPG), 2-hour plasma glucose (2hPG) after a 75-gram glucose load, and glycated hemoglobin (HbA1c). Secondary outcomes included sensitivity, specificity, area under the curve (AUC), and agreement with FPG, 2hPG, and HbA1c.

Results

RCBG demonstrated a strong positive correlation and high concordance with FPG, 2hPG, and HbA1c. A cut-off value of ≥8.7 mmol/L for RCBG showed improved diagnostic performance compared to the current cut-off of ≥11.1 mmol/L. The ≥8.7 mmol/L cut-off provided higher sensitivity, specificity, AUC, and better agreement with OGTT, 2hPG, and HbA1c. Importantly, hyperglycemic symptoms were not required to diagnose T2DM using RCBG. The number needed to treat to screen (NNTS) one case of T2DM for RCBG (≥8.7 mmol/l) was 2.74, which was lower than FPG (2.86), and the current cut-off of RCBG ≥11.1 mmol/L (4.68).

Conclusions

RCBG is an effective and low-cost diagnostic tool for T2DM in resource-limited settings in Bangladesh. The identified cut-off of ≥8.7 mmol/L enhances diagnostic accuracy and reflects the population's unimodal blood glucose distribution.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study found that a cut-off value of ≥8.7 mmol/L for RCBG is more effective in diagnosing T2DM in the adult Bangladeshi population compared to the current cut-off of ≥11.1 mmol/L. This demonstrates improved diagnostic accuracy.
- The findings suggest that RCBG can be a practical and accessible diagnostic tool in resource-limited settings, where more specific tests like FPG, 2hPG, and HbA1c may not be available.
- The study provides valuable insight by indicating that hyperglycaemic symptoms are not necessary for diagnosing T2DM using RCBG, simplifying the diagnostic process.
- The study's focus on a specific population may limit its generalizability to other regions or ethnic groups.
- This study did not assess individual metabolic differences, variations in food intake before the test, different time points or the inherent variability of capillary blood glucose measurements, which limits the explanation of glycaemic variance.
- This study's proposed lower RCBG cut-off value has not been evaluated for long-term outcomes, limiting our understanding of its broader clinical impact.

Introduction

Type 2 Diabetes (T2DM) is a major public health concern in Bangladesh, with around 13.1 million people suffering from the disease in 2021, as per the International Diabetes Federation (IDF).[1] Shockingly, 43% of these cases remain undiagnosed, leading to a rise in T2DM prevalence in both rural and urban communities. [2-4] The problem is compounded by the fact that T2DM often goes undetected, with 30-50% of people presenting with one or more complications at the time of diagnosis. [5-7] This leads to increased healthcare expenses, making early detection and identification of people at risk for T2DM crucial. [8-9] Fortunately, lifestyle and drug intervention programs have been shown to prevent and delay the progression of T2DM among high-risk individuals. [10-12]

There is no consensus on the most effective screening tool for diagnosing diabetes. The most widely used screening tests include FPG (fasting plasma glucose), OGTT (Oral glucose tolerance test), HbA1c (glycated hemoglobin), and RBG (random blood glucose). However, FPG and OGTT require patients to fast overnight for at least 8–14 hours, with the FPG results needing confirmation through a second test on another day. The OGTT is also expensive, labor-intensive, and time-consuming, while the accuracy of both FPG and OGTT can be compromised by patient compliance. [13-15] HbA1c is expensive and often not standardized in Bangladeshi laboratories. It is also influenced by several factors, including age, pregnancy, hemoglobinopathies, and ethnicity, making it unsuitable for large population screening programs. On the other hand, RCBG is less expensive, easy to use, and can be used by primary healthcare providers.

Studies in developed and developing countries have tried correlating RCBG with 2-h plasma glucose or FPG, but no such data exists for Bangladesh. Therefore, RCBG can be used at the primary care level to screen individuals at high risk of T2DM in rural Bangladesh, where healthcare facilities are inadequate. [16-19] This study aims to evaluate the effectiveness of RCBG in diagnosing diabetes and identifying the optimal cut-off values suitable for diagnosing T2DM in the adult Bangladeshi population.

Methods

Study design and study site

The study was conducted between May and September 2022 at 16 centers of the Diabetic Association of Bangladesh (BADAS) in order to identify T2DM. BADAS serves around twelve to fifteen thousand individuals daily through its 130 small, medium, and large centers and hospitals across the country, offering both outpatient and inpatient services. The centers were chosen randomly from within and outside the capital city of Bangladesh, Dhaka, covering all eight geographical divisions of the country. A systematic random sampling technique was employed to select study participants, with every second eligible patient recruited into the study.

Sampling procedure

The study calculated the required sample size based on the national prevalence rate of T2DM, which was 8.3% in the 2018 STEPS survey. [20] It was determined using the student's formula, $n = \frac{Z^2P(1-P)}{d^2}$, where n was the sample size, d was the allowable error, and Z was 1.96. However, considering a non-response rate of 10%, the final sample size was 3113. The research involved around 3,200 individuals who were 18 years of age or older, who agreed to participate and gave informed consent. The screening process excluded individuals who had known cases of T2DM, were taking medications that could alter OGTT, had any chronic diseases at the time of screening, were unwilling or unable to give informed consent, communicate with study staff, or were pregnant.

Data collection

Planning of the Study

Before the study began, an expert panel comprising an epidemiologist, diabetologist/endocrinologist, statistician, and biochemist was invited to a discussion meeting with the project team leader. The panel's comments and suggestions were considered while designing the study. Furthermore, one physician, one technician, and three volunteers were employed from each center to oversee the project work. Before the study's commencement, project workers were given two days of theoretical and practical training.

Potential participants were given sufficient time to read participant information sheets and ask questions to clear up any doubts they had before providing consent. Staff members who obtained consent had to ensure that potential participants fully understood the information provided before being included in the study. Those who were not believed to be fully informed were not included. After obtaining informed consent, each interested participant was requested to attend the study. The data collection techniques included a face-to-face interview (STEP 1), physical measurements (STEP 2), and body fluid (blood) collection (STEP 3) in line with the modified WHO STEPS questionnaire.

The process began by taking a blood sample to measure FPG and HbA1c levels. Subsequently, all participants consumed a 75-gram oral glucose solution and waited for 2 hours before a second blood sample was collected. During this 2-hour waiting period, participants were interviewed to collect socio-demographic information using a pre-formulated questionnaire. After the interview, the participants' anthropometric measurements, including height, weight, hip, and waist circumference (WC), were taken, and their blood pressure was recorded. After 2 hours, another blood sample was taken for an OGTT test using a glucose analyzer. During the doctor's visit on the same day (2.30 pm to 7.30 pm) or the next day (8.30 am to 2.30 pm), an RCBG (non-fasting) was measured using the portable glucometer (One Touch Ultra II, Lifescan, Milpitas, CA, USA) in fresh capillary whole blood obtained by finger prick in the left middle finger. It employs a glucose oxidase assay.

Measurements of anthropometrical parameters and blood pressure (BP)

The importance of accurate anthropometric measurements cannot be overstated, and the researchers in this study took great care to ensure their measurements were as precise as possible. They took measurements of height, weight, and waist and hip circumferences while the subjects wore light clothing and no shoes. Weight was recorded using electronic digital LCD weighing machines that were calibrated daily with a standard weight. Height was taken with the subjects standing erect against a straight measuring wall. Body mass index (BMI) was calculated from weight and height, and waist and hip circumferences were measured with a tape. The researchers then calculated the waist-to-hip ratio (WHR) from waist and hip circumference (cm).

To ensure the accuracy of BP readings, subjects were asked to rest for five minutes in a sitting position before measurements were taken. The researchers used regular cuffs for adults fitted with a standard sphygmomanometer to measure BP on the right arm. They recorded BP to the nearest two mmHg from the top of the mercury meniscus and recorded systolic pressure at the first appearance of sounds and diastolic pressure at phase V. The researchers' thorough approach to taking measurements and BP readings strengthens the validity of their study.

Blood glucose estimation

Initially, a sample of 5 ml of fasting venous blood was collected on arrival for FPG and HbA1c measurements. Another 2 ml of venous blood was taken two hours after a 75-gram glucose (2hPG) drink. The samples for the plasma glucose test was collected in a tube containing sodium fluoride and potassium oxalate (1:3) and were centrifuged immediately after collection. Plasma glucose was measured by the glucose oxidase method using Dimension RxL Max (Siemens AG, Erlangen, Germany). Quality control of the blood glucose measurement was checked by measuring the 2hPG values using the glucose oxidase methods in every 10th case. HbA1c was collected in ethylenediaminetetraacetic acid (EDTA) vials (2 mg/ml) and estimated on the same day by the Bio-Rad 10 system (Bio-Rad Laboratories, Hercules, CA, USA) functioning on high-performance liquid chromatography (HPLC)-based ion-exchange chromatography with a reference value of 4.0– 6.0%. The methodology aligns with the DCCT and National Glycohemoglobin Standardization Program (NGSP). The glucose meter used is plasma calibrated, and without hematocrit correction, it provides accurate results for a hematocrit range of 30-50%. The intra- and inter-assay coefficients of variation (CV) for the venous glucose ranged from 0.88 to 1.88%, while the mean CV for RCBG was 4.8%. All study participants were informed of their glucose status as soon as the results were available.

Definition of variables

Cut-off points for general obesity for both sexes were defined as a BMI ≥25 kg/m^2. Cut-off points for central obesity, including WC for men and women, were ≥90 cm and ≥80 cm, respectively. For WHR, the cut-off points for men and women were ≥0.90 and ≥0.80, respectively. [21, 22] T2DM was defined as FPG of ≥7.0 mmol/l and/or 2hPG of ≥11.1 mmol/l. [23] In addition, HbA1c of ≥6.5% and RCBG of ≥11.1 mmol/l with symptoms were also defined as T2DM. [23] Individuals were considered

to have HTN if their average systolic blood pressure was ≥140 mmHg, or diastolic blood pressure was ≥90 mmHg, or if they receive treatment for HTN. [24] Smoking habits were classified as either current or non/ex-smokers. Based on the monthly expenditure, the socio-economic condition was classified as low (<10000 Bangladeshi Taka [BDT, 1 USD = 110 BDT]), medium (10000-20000 BDT), and high (>20000 BDT). Education level was graded as illiterate (unable to read and write), undergraduate (having primary and higher secondary education), and graduate. Physical activity was graded on an ordinal scale of 1-3, corresponding to light, moderate, and heavy, according to the activity level based on occupation.

Statistical analysis

Means and percentages with 95% confidence intervals were given for continuous variables and categorical variables as needed. Differences between the groups of means and proportions were tested by independent sample *t*-test and Chi-square test, respectively. The pairwise association of RCBG with FPG, 2hPG, and HbA1c were assessed by Pearson's correlation coefficients (r) and simple linear regression analysis. In addition, the Bland and Altman method was used to determine mean difference (bias) and limits of agreement of RCBG with FPG, 2hPG, and HbA1c. The receiver operating characteristic (ROC) curve analysis was used to assess the discriminatory ability of the RCBG test for detecting diabetes, given the OGTT as the gold standard. Additionally, ROC curves were also applied to compare the performance of RCBG, FPG, and 2hPG, and HbA1c for diabetes. Optimal cut-off points were obtained based on the highest Youden index. The agreement for classification of diabetes using different cut-off points of RCBG, FPG, and 2hPG, and HbA1c were assessed by the kappa statistic. and values greater than 0.75 may be taken to represent excellent agreement beyond chance, values below 0.4 represent poor agreement beyond chance, and values between 0.4 and 0.75 may be taken to represent fair to good agreement beyond chance. Diagnostic test properties including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), with 95% CI and the number needed to screen (NNTS), which represents the number of people screened to accurately identify one case of undiagnosed disease without error, were also calculated for different cut-off points of RCBG, FPG, and 2hPG, and HbA1c. The statistical inference was based on 95% confidence intervals (CIs) and the significance level

was set at 0.05. PASW statistics 21 for Windows (SPSS, Chicago, IL USA), STATA and MedCalc were used.

Results

Table 1 shows the basic characteristics of the study participants by gender. Among the 3200 participants, 1680 were female (52.5%) and 1520 (47.5%) male aged 18-82. The mean age of participants was 44.4 years (male 45.9 vs female 42.9 years, p<0.001). About 11% of the respondents were less than 30 years, 23.9% were between 30-39 years, 29.9% were between 40-49 years, and 35% were at or above 50 years. A total of 53.4% (male vs. female: 54.6 vs 52.3%) of participants had a family history of T2DM.

The mean BMI and WC were 25.9 kg/m^2 (male vs. female: 25.3 vs 26.5 kg/m^2, p<0.001) and 92.4 cm (male vs. female: 92.4 vs. 92.4 cm), respectively. The rate of obesity was 57.1% (male vs. female: 52 vs. 61.6%, p<0.001) and the rate of abdominal obesity defined by high WC (male ≥90 cm & female ≥80 cm) was 73.3% (male vs. female: 58.6 vs. 86.5%, p<0.001). The mean level of SBP and DBP were 119.8 mmHg (male vs. female: 121.3 vs. 118.4 mmHg, p<0.001) and 78.6 mmHg (male vs female: 79.5 vs. 77.7 mmHg, <0.001), respectively. The rate of HTN was 29.8% (male vs. female: 30.5 vs. 29.2%).

About 63.1% of participants (male vs female: 61.3 vs. 64.7%, p=0.047) had typical symptoms of T2DM. The mean level of FPG, 2hPG, HbA1c, and RCBG were 7.9 mmol/l (male vs female: 8.0 vs. 7.9 mmol/l), 12.5 mmol/l (male vs female: 12.6 vs. 12.5 mmol/l), 7.4% (male vs female: 7.4 vs. 7.4%), and 10.6 mmol/l (male vs female: 10.6 vs. 10.6 mmol/l), respectively. The rate of T2DM based on OGTT, HbA1c (≥6.5%) and RCBG (≥11.1 mmol/l with typical symptoms) were 49.5% (male vs female: 49.6 vs. 49.5%), 48.9% (male vs female: 50 vs. 48%), and 33.2% (male vs female: 32.7 vs. 33.6%), respectively. About 96% participants (male vs female: 96.7 vs. 95.3%, p=0.042) had one NCD risk factor.

Table 2 shows the correlation (p values) between RCBG, FBG, 2hAG, and HbA1c. All four blood glucose tests are positively correlated. The correlation of RCBG with FPG, 2hPG, and HbA1c was 0.828 (p<0.001), 0.840 (p<0.001), and 0.826 (p<0.001), respectively. The strongest linear relationship was observed between RCBG and 2hPG.

Figure 1 shows the concordance between RCBG, FBG, 2hAG, and HbA1c. The mean difference between RCBG and FPG, 2hPG, and HbA1c was 2.7 mmol/l, -1.9 mmol/l, and 3.2 mmol/l, respectively. The standard deviation (1SD) ranged from -3.8 to 9.1 mmol/l, -9.1 to 5.2 mmol/l, and -4.4 to 10.8%, respectively. The mean difference (bias) between RCBG and FPG, 2hPG, and HbA1c was small, and the range of values was narrow, indicating that the measurements are in good agreement with each other.

The ROC curve of RCBG to diagnose T2DM is presented in **Figure 2A**, with an optimal cut-off level of 8.7 mmol/l. It demonstrated 79.7% sensitivity and 89.9% specificity.

Figure 2B present the AUC of ROC curves for FPG, 2hPG, HbA1c, and RCBG to diagnose T2DM. The AUC values for FPG, 2hPG, HbA1c, and RCBG were 0.968 (95% CI: 0.962, 0.973), 0.984 (95% CI: 0.980, 0.988), 0.936 (95% CI: 0.928, 0.945), and 0.905 (95% CI: 0.894, 0.916), respectively.

Moreover, the Youden Index for FPG, 2hPG, HbA1c, and RCBG to diagnose T2DM were 0.839, 0.917, 0.755, and 0.697, respectively (not shown).

Figure 3 shows the random capillary blood glucose (RCBG) levels among participants with or without symptoms, measured on the same day and the next day. In symptomatic participants, the mean RCBG was higher on the same day (11.5 mmol/L) compared to the next day (10.4 mmol/L), while asymptomatic participants showed relatively stable RCBG levels across both time points (10.8 mmol/L on the same day and 10.6 mmol/L the next day). The proportion of participants with RCBG ≥11.1 mmol/L and ≥8.7 mmol/L was slightly lower on the next day in both groups, with the highest percentage observed in those with RCBG ≥8.7 mmol/L and symptoms (49.6% on the same day).

Table 3 shows the comparison of diagnostic performance for T2DM among FPG, 2hPG, HbA1c, and RCBG using both proposed and current cut-off points revealed that 2hPG (≥11.1 mmol/l) had the highest sensitivity (91.7%) and specificity (100%), with the highest diagnostic accuracy (95.9%) and agreement (κ = 0.917). FPG (≥7 mmol/l) and HbA1c (≥6.5%) also performed well with sensitivities of 84% and 86.8%, and specificities of 100% and 88.6%, respectively. HbA1c (≥6.5%) had the highest diagnosis rate at 48.9% and the NNTS at 2.36, followed closely by 2hPG (≥11.1 mmol/l) with an NNTS of 2.40. RCBG (≥11.1 mmol/l) showed lower sensitivity (63.1%) but high specificity (97.8%), and its diagnostic performance improved slightly when combined with typical

symptoms. The use of RCBG (≥8.7 mmol/l) yielded better sensitivity (80.4%) and specificity (89.0%), with an NNTS of 2.74, which further improved with the addition of typical symptoms. Overall, 2hPG (≥11.1 mmol/l) was identified as the most effective test for diagnosing T2DM, followed by HbA1c (≥ 6.5%) and FPG (≥ 7 mmol/l), due to their high diagnostic performance and lower NNTS values.

Discussion

This study is the first to compare the effectiveness of RCBG to FPG, OGTT, and HbA1c in detecting undiagnosed T2DM in the Bangladeshi population.

More than 60% of Bangladesh's population lives in rural areas.[25] In primary healthcare facilities, there is a lack of expert training and standard laboratory procedures for FPG, OGTT, or HbA1c tests. As a result, the only option for diagnosis of T2DM in these areas is RCBG using a handheld glucometer. Furthermore, most urban and rural clinicians use RCBG to diagnose T2DM in daily practice.

The study found a high rate of undiagnosed T2DM, ranging from 33.2% to 49.5%, as defined by different diagnostic methods including FPG, 2hPG, OGTT (both FPG or 2hPG), HbA1c, and RCBG. This finding is consistent with the IDF's 45%. [1] As per the guidance provided by WHO and IDF, [26] early detections of the undiagnosed T2DM can be achieved in Bangladesh by conducting screening and confirmatory tests for high-risk individuals. Our study reinforces the notion that RCBG is a viable choice for the same.

First, there was a high positive correlation (0.826-0.840) between RCBG and FPG, 2hPG, and HbA1c. In addition, RCBG showed high concordance with minor discrepancies with the other three diagnostic measurements.

Second, to develop more efficient screening strategies for detecting undiagnosed T2DM, practical risk assessments that are both sensitive and specific are needed. [27] The present study indicates that RCBG is a viable option for mass screening in asymptomatic individuals and the detection of undiagnosed T2DM. RCBG showed good diagnostic performance with high sensitivity (80%) and specificity (90%). While the AUC and Youden Index values were lower than the other three measures, they were still high at 0.905 and 0.697, respectively. This makes RCBG a suitable option for detecting T2DM. The study also found that RCBG's PPV and NPV were equally high. This could

effectively rule out individuals with average blood glucose from patients with abnormal glucose metabolism.

Third, elevations in random glucose levels that are not indicative of T2DM are actually more strongly associated with undiagnosed T2DM compared to traditional T2DM risk factors. [28, 29] These elevations can act as an early indication of glycemic dysregulation. While glucose values that are random and greater than or equal to 11.1 mmol/l in the presence of typical symptoms of hyperglycemia are considered diagnostic for T2DM, there are no clear guidelines for interpreting values that are less than 11.1 mmol/l. [30] Some studies conducted in different regions of the world have suggested that RCBG cut-off points ranging from 5.5 to 7.9 mmol/L can be effective in identifying T2DM. [31-35] The current study determined that the optimal cut-off point of RCBG was 8.7 mmol/L, which is in line with these studies provided a highly discriminatory capacity for identifying undiagnosed T2DM.

The study found that the use of RCBG ≥8.7 mmol/l without typical symptoms was more effective for diagnosing undiagnosed T2DM than RCBG ≥8.7 mmol/l with typical symptoms. This approach had better sensitivity, specificity, and diagnostic accuracy than the latter. The study also proposed that the RCBG cut-off value of ≥8.7 mmol/l without typical symptoms showed better diagnostic performance than the currently used RCBG cut-off value of ≥11.1 mmol/l with typical symptoms. It had better sensitivity, NPV, diagnosis capability, and diagnostic accuracy.

In addition, the RCBG cut-off value of ≥8.7 mmol/l showed a good agreement with OGTT, 2hPG, and HbA1c cut-off values for diagnosing T2DM than the currently used RCBG cut-off value of ≥11.1 mmol/l. One article by Caroll E in JAMA highlighted the potential negative consequences of medical screening, mainly a false-positive result. [36] This can lead to overdiagnosis and overtreatment, harming patients physically and financially. Our study showed that a value of ≥8.7 mmol/l had a 50% lower rate of false-positive cases than a value of ≥11.1 mmol/l. This indicates that the former cut-off value may be more useful in clinical practice.

Lastly, the logistic regression analysis showed that the RCBG cut-off value of ≥8.7 mmol/l had a higher association with T2DM defined by OGTT than the RCBG cut-off value of ≥11.1 mmol/l. The odd ratio for RCBG ≥8.7 mmol/l was 8.91 (7.03, 11.29) and for RCBG ≥11.1 mmol/l was 5.52 (3.55, 8.61) (data are not shown). The findings suggest that RCBG ≥8.7 mmol/l is an effective diagnostic

marker for detecting T2DM than RCBG cut-off value of ≥11.1 mmol/l. However, the RCBG cut-off value of ≥8.7 mmol/l was found to be less effective than the currently used cut-off points of FPG (≥7 mol/l), 2hPG (≥11.1 mmol/l), and HbA1c (≥6.5%).

Fourth, it is common that T2DM can often go unnoticed in its early stages, and may continue to do so for several years, as it may not present any symptoms. However, if left untreated and undiagnosed, it can lead to serious health complications.[1] According to this study, the diagnostic performance of RCBG values without typical symptoms was found to be better than those with symptoms. This finding suggests that the presence of symptoms of hyperglycemia with RCBG is not essential in diagnosing T2DM. Therefore, this test can be used for screening in the community and diagnosing T2DM in a hospital setting, even in the absence of symptoms. This can significantly improve the prevention and care of T2DM in the Bangladeshi population.

Fifth, in this study, individuals with T2DM had higher blood glucose levels, particularly in short postprandial periods. This finding is consistent with a study conducted by Engelgau MM et al. [37] Therefore, it is expected that short postprandial periods will result in better performance.

Finally, according to this study, using RCBG instead of venous blood for laboratory tests could significantly reduce the cost (RCBG vs. OGTT vs. HbA1c: 0.18 USD vs. 2.73 USD vs. 5.46 BDT). This finding is consistent with a study conducted by Meriggi E et al [38] (data not shown). By using RCBG, there is no need to use vacutainers or blood collection tubes, syringes, transportation, salaries for laboratory staff, auto-analyzers, or other laboratory equipment and reagents, which can result in substantial cost savings.

Of strength, to the best of our knowledge, this study was one of the first in Bangladesh to analyze the effectiveness of RCBG in diagnosing T2DM. The study had a reasonably large sample size and was conducted in 16 BADAS centers, covering all eight administrative divisions of Bangladesh, creating a nationwide representation of this survey. The study used OGTT as the gold standard diabetes test, and the fasting state of the participants was secured. Additionally, the study checked HbA1c, and RBG, recommended by IDF and WHO for diagnosing T2DM. This enhanced the translation of the findings to real-world practice. All the investigators, clinicians, anthropometrics, and bio-technicians were recruited from the BADAS centers and hospitals. Moreover, all laboratory analyses were performed in the BADAS laboratory facilities, which are highly credible

within the country. The laboratory's quality control was assessed both internally and externally. It's worth noting that around 58% of people living with diabetes, residing in both urban and rural areas of Bangladesh, receive treatment and care for their condition at BADAS. [39]

It is crucial to acknowledge that there are several limitations to this study. First and foremost, the data was collected at a single point in time, making it a cross-sectional study that cannot establish a cause-and-effect relationship. Secondly, the diagnosis of T2DM was based on a single OGTT, HbA1c, and RCBG measurement, which are typically repeated in clinical practice to confirm the diagnosis. Thirdly, the study aimed to find the ideal cut-off points for diabetes diagnostic tests but did not explore how well each method could predict chronic diabetes complications. Fourthly, the study excluded individuals with diagnosed diabetes and prediabetes based on self-report, which has high sensitivity and specificity for diagnosed diabetes, but may not be as accurate for prediabetes. Fifthly, this study did not assess individual metabolic differences, variations in food intake before the test, or the inherent variability of capillary blood glucose measurements, which limits the explanation of glycemic variance. Sixth, the clinical and anthropometric measurements were only performed once, which increases the possibility of measurement errors as there was no second observer to control this. Finally, the study was conducted only in BADAS centers and hospitals, so the results should be interpreted with caution. Future follow-up studies are required to provide more valuable conclusions.

In conclusion, the RCBG test can be an effective diagnostic tool for identifying T2DM with satisfactory test properties. It is also gaining interest in epidemiological research for detecting undiagnosed diabetes, gestational diabetes, and others. [40-44] According to the study findings, RCBG should be considered in daily clinical practice during the diagnosis of T2DM. The optimal cut-off level of RCBG ≥8.7 mmol/l can be used as a diagnostic criterion for T2DM, especially in resource-scarce regions of Bangladesh. However, further research is needed for broader dissemination.

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Author contributions

BB contributed to study planning, statistical analysis plan, wrote the statistical methods section, ran the statistical analysis and wrote the manuscript. TS and SBM collected and researched the data and wrote the manuscript. TA, FA, NKQ and ASM drafted sections of the article and contributed to discussion. RI, SP, SUM, RIC, RO, DCR, SRC, SSA, SA, TA contributed to data collection and drafted sections of the article. FP, MAS, HM, MRA, AKAK reviewed/edited the manuscript.

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Data availability

Data are available upon reasonable request from BB, the study principal investigator.

Declarations

Ethics approval and consent to participate

Informed consent was obtained from each participant and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the Ethical Review Committee of BADAS (BADAS-ERC/EC 122100331).

Competing interests

No potential conflict of interest.

Consent for publication

Not applicable.

Patient and Public Involvement

Patients and the public were not involved in the design, conduct, analysis, or dissemination plans of this research.

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Table 1. Basic characteristics of the study participants by gender

Variable	Total	Male	Female	P value
Number	3200	1520 (47.5%)	1680 (52.5%)	
Age (years)	44.4 (43.9, 44.8)	45.9 (45.3, 46.6)	42.9 (42.3, 43.5)	<0.001
Age, %				<0.001
<30 years	11.1 (10.0, 12.2)	8.6 (7.1, 10.0)	13.5 (11.8, 15.1)	
30-39 years	23.9 (22.4, 25.4)	22.4 (20.3, 24.5)	25.2 (23.2, 27.3)	
40-49 years	29.9 (28.3, 31.5)	30.0 (27.8, 32.3)	29.8 (27.6, 32.0)	
≥50 years	35.1 (33.4, 36.7)	38.9 (36.5, 41.4)	31.5 (29.3, 33.7)	
F/H DM, %	53.3 (51.6, 55.1)	54.6 (52.0, 57.1)	52.3 (49.9, 54.7)	0.198
BMI (kg/m^2)	25.9 (25.8, 26.1)	25.3 (25.1, 25.5)	26.5 (26.3, 26.7)	<0.001
Obese, %	57.1 (55.3, 58.8)	52.0 (49.4, 54.6)	61.6 (59.2, 64.1)	<0.001
WC (cm)	92.4 (91.9, 92.8)	92.4 (91.9, 93.0)	92.4 (91.8, 92.9)	0.836
Abdominal obesity, %	73.3 (71.8, 74.9)	58.6 (56.1, 61.2)	86.5 (84.9, 88.2)	<0.001
SBP (mmHg)	119.8 (119.3, 120.1)	121.3 (120.6, 121.9)	118.4 (117.8, 119.1)	<0.001
DBP (mmHg)	78.6 (78.3, 78.9)	79.5 (79.1, 79.9)	77.7 (77.3, 78.1)	<0.001
HTN, %	29.8 (28.2, 31.4)	30.5 (28.2, 32.8)	29.2 (27.0, 31.4)	0.436
DM symptom (present), %	63.1 (61.4, 64.8)	61.3 (58.8, 63.8)	64.7 (62.4, 67.0)	0.047
FPG (mmol/l)	7.9 (7.8, 8.1)	8.0 (7.8, 8.2)	7.9 (7.7, 8.1)	0.545
2hPG (mmol/l)	12.5 (12.2, 12.8)	12.6 (12.2, 12.9)	12.5 (12.2, 12.8)	0.682
DM, %	49.5 (47.8, 51.3)	49.6 (47.1, 52.1)	49.5 (47.1, 51.9)	0.937
HbA1c (%)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	0.724
DM (≥6.5%), %	48.9 (47.2, 50.7)	50.0 (47.4, 52.5)	48.0 (45.6, 50.4)	0.273
RCBG (mmol/l)	10.6 (10.4, 10.8)	10.6 (10.3, 10.8)	10.6 (10.3, 10.9)	0.789
DM (≥11.1+ symptom), %	33.2 (31.1, 35.3)	32.7 (29.7, 35.8)	33.6 (30.7, 36.4)	0.704
One NCD RF, %	96.0 (95.3, 96.7)	96.7 (85.8, 97.6)	95.3 (94.3, 96.3)	0.042

Data are presented as mean (95% confidence interval) and percentage (95% confidence interval) as needed. (Abbreviation: DM, diabetes mellitus; F/H, family history; BMI, body mass index; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; HTN, hypertension; FPG, fasting plasma glucose; 2hPG, 2 hours after plasma glucose, HbA1c, glycated hemoglobin; RCBG, random capillary blood glucose; NCD RF, non-communicable disease risk factors obese, BMI ≥25 kg/m^2; abdominal obesity, WC- male ≥90 cm or female ≥80 cm; NCD RF, including smoking, physical inactivity, consume <5 servings of vegetables and fruits daily, obese, diabetes and hypertension.

Table 2. Correlation (P values) between RCBG, FBG, 2hAG, and HbA1c.

	RCBG (mmol/l)	FPG (mmol/l)	2hAG (mmol/l)	HbA1c %
RCBG (mmol/l)	1	0.828 (<0.001)	0.840 (<0.001)	0.826 (<0.001)
FPG (mmol/l)	0.828 (<0.001)	1	0.900 (<0.001)	0.880 (<0.001)
2hPG (mmol/l)	0.840 (<0.001)	0.900 (<0.001)	1	0.865 (<0.001)
HbA1c %	0.826 (<0.001)	0.880 (<0.001)	0.865 (<0.001)	1

Abbreviation: RCBG, Random capillary blood glucose; FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin.

Table 3. Comparison of diagnostic performance of FPG, 2hPG, HbA1c, and RCBG (both proposed and currently used cut-off point) to diagnose T2DM.

	SN (%)	SP (%)	PPV (%)	NPV (%)	Diagnosis (%)	Accuracy (%)	Agreement (k)	NNTS
FPG (≥7 mmol/l)	84	100	100	86.4	41.6	92.1	0.841	2.86
2hPG (≥11.1 mmol/l)	91.7	100	100	92.4	45.4	95.9	0.917	2.40
HbA1c (≥6.5%)	86.8	88.6	88.3	87.2	48.9	87.7	0.755	2.36
RCBG (≥11.1 mmol/l)	63.1	97.8	96.6	73.0	32.3	80.6	0.611	4.91
RCBG (≥11.1 mmol/l) + typical symptom	64.4	97.9	96.8	73.4	33.2	81.2	0.623	4.68
RCBG (≥8.7 mmol/l)	80.4	89.0	87.7	82.3	45.4	84.7	0.695	2.74
RCBG (≥8.7 mmol/l) + typical symptom	79.6	88.1	87.0	81.3	45.6	83.9	0.677	2.76

Abbreviation: FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin; RCBG, Random capillary blood glucose; SN, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value; k, kappa statistics.; NNTS, number need to treat for screening

Figure 1. Concordance of random capillary blood glucose (RCBG) with fasting plasma glucose (FPG), 2 hours plasma glucose (2hPG), glycated hemoglobin (HbA1c)

Figure 2. Diagnostic cut-off point of random capillary blood glucose (RCBG) and compare its performance to diagnose diabetes with fasting plasma glucose (FPG ≥7 mmol/l), 2 hours plasma glucose (2hPG ≥11.1 mmol/l), glycated hemoglobin (HbA1c ≥6.5%).

Figure 3. Random capillary blood glucose (RCBG) levels in participants with or without symptoms, measured at different time points (same day vs. next day)

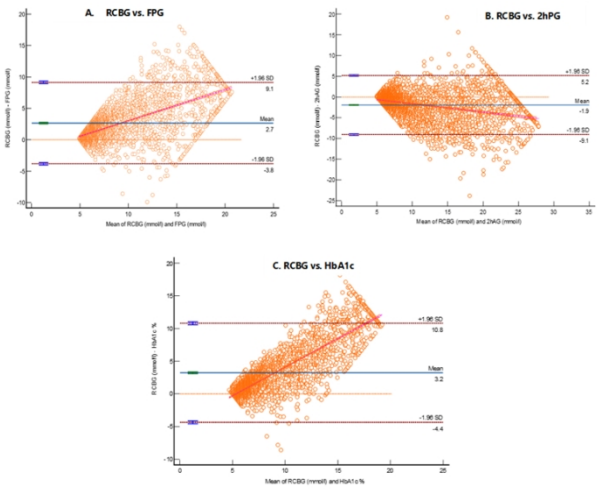

Figure 1. Concordance of random capillary blood glucose (RCBG) with fasting plasma glucose (FPG), 2 hours plasma glucose (2hPG), glycated hemoglobin (HbA1c)

338x190mm (96 x 96 DPI)

Figure 2A. Receiver operating characteristics (ROC) curve of random capillary blood glucose (RCBG) to diagnose diabetes.

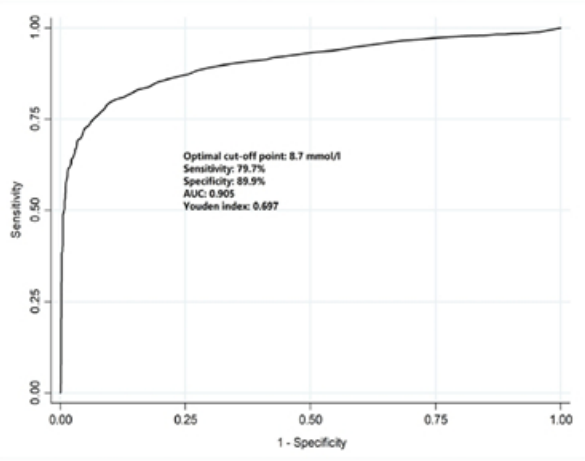

Figure 2B. The area under the receiver operating characteristics (ROC) curves of fasting plasma glucose (FPG), 2 hours plasma glucose (2hPG), glycated hemoglobin (HbA1c), and random capillary blood glucose (RCBG) to diagnose diabetes.

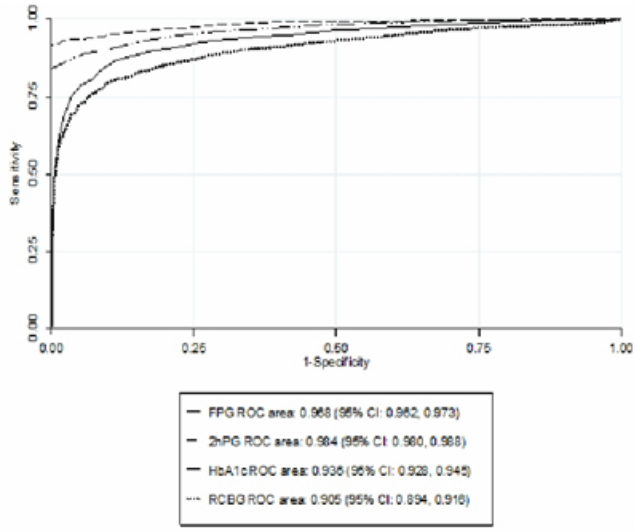

Figure 2. Diagnostic cut-off point of random capillary blood glucose (RCBG) and compare its performance to diagnose diabetes with fasting plasma glucose (FPG ≥7 mmol/l), 2 hours plasma glucose (2hPG ≥11.1 mmol/l), glycated hemoglobin (HbA1c ≥6.5%).

405x501mm (38 x 38 DPI)

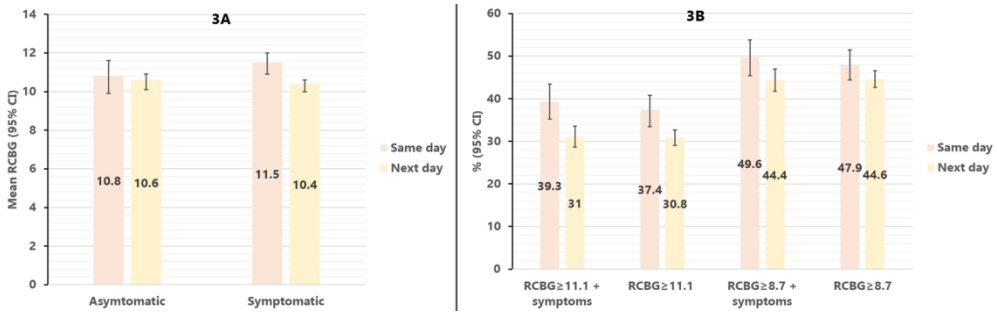

Figure 3. Random capillary blood glucose (RCBG) levels in participants with or without symptoms, measured at different time points (same day vs. next day)

830x255mm (59 x 59 DPI)

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Random Capillary Blood Glucose in the Diagnosis of Diabetes: A Cross-Sectional Study in Bangladesh

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Random Capillary Blood Glucose in the Diagnosis of Diabetes: A Cross-Sectional Study in Bangladesh

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Abstract

Objective

To assess the effectiveness of random capillary blood glucose as a diagnostic tool for type 2 diabetes and determine optimal cut-off values for adults in Bangladesh.

Design

Cross-sectional diagnostic accuracy study.

Setting

Sixteen diabetes centres were selected randomly from all eight administrative divisions of Bangladesh.

Participants

A total of 3,200 adults aged 18 years and older were recruited using systematic random sampling between May and September 2022.

Primary and secondary outcome measures

The primary outcome was the diagnostic accuracy of random capillary blood glucose compared to fasting plasma glucose, 2-hour plasma glucose after a 75-gram glucose load, and glycated haemoglobin. Secondary outcomes included sensitivity, specificity, area under the curve, and agreement with the other diagnostic tests.

Results

Random capillary blood glucose showed a strong positive correlation and high concordance with fasting plasma glucose, 2-hour plasma glucose, and glycated haemoglobin. A cut-off value of ≥8.7 mmol/l demonstrated improved diagnostic performance compared to the currently used cut-off of ≥11.1 mmol/l. This new threshold yielded higher sensitivity, specificity, area under the curve, and agreement with other standard diagnostic tests. Notably, hyperglycaemic symptoms were not required for diagnosis. The number needed to screen to identify one case of type 2 diabetes using the ≥8.7 mmol/l cut-off was 2.74, lower than that for fasting plasma glucose (2.86) and random capillary blood glucose ≥11.1 mmol/l (4.68).

Conclusions

Random capillary blood glucose may be an effective and affordable diagnostic tool for type 2

diabetes in resource-limited settings. The proposed cut-off of ≥8.7 mmol/l offers improved diagnostic accuracy and reflects the population's glucose distribution pattern.

Keywords:

Type 2 diabetes, random capillary blood glucose, diagnostic accuracy, Bangladesh, screening, oral glucose tolerance test, primary care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A large, systematically sampled population was included from all eight administrative divisions of Bangladesh.
- All biochemical measurements were conducted using quality-controlled, centralized laboratory procedures.
- The use of OGTT as a reference standard enhances diagnostic comparison.
- The study's focus on a specific population may limit its generalizability to other regions or ethnic groups.
- This study did not assess individual metabolic differences, variations in food intake before the test, different time points or the inherent variability of RCBG measurements, which limits the explanation of glycaemic variance.

Introduction

Type 2 diabetes mellitus (T2DM) is a growing public health concern in Bangladesh, with an estimated 13.9 million people affected in 2024.[1] Alarmingly, 43% of these individuals remain undiagnosed, especially in rural and underserved populations, where diagnostic services are limited.[2–4] Many patients present with complications such as neuropathy, retinopathy, and cardiovascular disease at the time of diagnosis, increasing the burden on both the health system and individual patients.[5–7]

Screening and early intervention have been shown to be effective strategies for reducing T2DM incidence. Major trials such as the Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS) demonstrated that lifestyle modifications and pharmacological interventions could prevent or delay the onset of T2DM in high-risk individuals.[8,9] Despite the promise of these interventions, screening tools remain a challenge in low- and middle-income countries (LMICs) like Bangladesh.

Standard diagnostic criteria for diabetes include fasting plasma glucose (FPG), the 2-hour plasma glucose (2hPG) after an oral glucose tolerance test (OGTT), and glycated hemoglobin (HbA1c), as recommended by the American Diabetes Association (ADA) and the World Health Organization (WHO).[10,11] However, these tests require specialized laboratory equipment, patient compliance with fasting, and trained personnel—resources that are often lacking in rural healthcare settings in Bangladesh.

HbA1c, though useful in many high-resource settings, is expensive and often not standardized in Bangladeshi laboratories. It is also influenced by several factors, including age, pregnancy, hemoglobinopathies, and ethnicity, making it unsuitable for large population screening programs.[12, 13] As a result, these challenges have prompted a shift toward simpler, more accessible screening methods.

Random capillary blood glucose (RCBG) testing is widely used in outpatient clinics and community health camps across Bangladesh. It is low-cost, non-invasive, and does not require fasting. Despite these advantages, RCBG has not been validated against all three standard diagnostic methods in the Bangladeshi population. Health providers often use the global threshold of ≥11.1 mmol/l, which may not be suitable for detecting asymptomatic or early-stage diabetes.

Several international studies have explored the diagnostic accuracy of RCBG. In India, a threshold of 6.1 mmol/l showed good sensitivity for diabetes detection.[14] Similar observations were reported from Thailand and China, reinforcing RCBG's diagnostic potential in different ethnic and resource settings.[15,16] However, variations in cut-off points across populations highlight the need for population-specific thresholds.

To date, no large-scale study in Bangladesh has systematically evaluated the performance of RCBG in comparison with FPG, 2hPG, and HbA1c using standardized diagnostic protocols in a population-based screening context. Therefore, this study aims to assess the diagnostic accuracy of RCBG and to determine an optimal cut-off value for detecting T2DM in the adult Bangladeshi population

Methods

Study design and study site

This cross-sectional diagnostic accuracy study was conducted between May and September 2022 at 16 centres of the Diabetic Association of Bangladesh (BADAS). BADAS provides outpatient and inpatient services to approximately 12,000 to 15,000 individuals daily through 130 small, medium, and large centres and hospitals across the country. Study centres were randomly selected from within and outside the capital, Dhaka, covering all eight administrative divisions of Bangladesh. Participants were recruited using a systematic random sampling approach, whereby every second eligible individual presenting for diabetes screening was invited to participate.

Participants and sampling procedure

The sample size was calculated based on a national prevalence of T2DM of 8.3%, as reported in the 2018 Bangladesh STEPS survey.[17] Using the standard formula for estimating proportions- $n = \frac{Z^2P(1-P)}{d^2}$, where n is the required sample size, Z is the Z-score (1.96 for 95% confidence), P is the expected prevalence (8.3%), and d is the margin of error—a minimum sample size of 2,830 was obtained. Allowing for a 10% non-response rate, the final required sample was 3,113 individuals. A total of approximately 3,200 participants aged 18 years or older were ultimately enrolled, all of whom provided informed consent. Individuals were excluded if they had a known diagnosis of T2DM, were taking medications known to affect glucose metabolism, had chronic illnesses at the

time of screening, were unable or unwilling to provide informed consent or communicate with study personnel, or were pregnant.

Recruitment was based on the calculated sample size, with an aim to enrol 200 participants from each of the 16 randomly selected BADAS centres, targeting a total of 3,200 adults. A systematic random sampling method was employed, inviting every second eligible adult presenting for diabetes screening to participate. Owing to the high patient volume at BADAS centres, the required sample was achieved within the study timeframe. A total of 3,320 individuals were approached, of whom 3,200 consented and were included in the final analysis. The recruitment and inclusion process are summarised in the STARD compliant flow diagram (**Figure 1**).

Data collection

Planning of the study

Prior to study initiation, an expert panel comprising an epidemiologist, diabetologist/endocrinologist, statistician, and biochemist convened with the project team leader to review and refine the study design. Recommendations from this panel were incorporated into the final protocol. One physician, one laboratory technician, and three volunteers were appointed at each study centre to oversee implementation. All field staff received two days of structured theoretical and practical training before the commencement of data collection.

Eligible participants were provided with a detailed participant information sheet and given adequate time to ask questions and clarify concerns. Informed written consent was obtained only after confirming the participant's comprehension of the study procedures. Individuals who did not demonstrate full understanding were excluded.

Following consent, data were collected using a three-step process aligned with the modified WHO STEPS approach: face-to-face interview (Step 1), physical measurements (Step 2), and collection of biological samples (Step 3).

Fasting blood samples were collected to measure FPG and HbA1c. Participants then consumed a 75 g oral glucose solution, followed by a second blood sample collected two hours later for the 2hPG test. During the 2-hour interval, trained interviewers administered a structured questionnaire based on the WHO STEPwise approach to collect sociodemographic and behavioral information.

Sociodemographic variables included age (in completed years), sex (male or female), marital status (currently married, never married, divorced/separated, or widowed), education level (no formal education, primary, secondary, higher secondary, or graduate and above), occupation (unemployed, informal, formal, or retired), and monthly household income. Residential status was defined as urban or rural using administrative classification. Family history of diabetes in first-degree relatives was recorded.

Behavioral variables included tobacco use (current, former, or never), alcohol consumption (defined as any use in the past 30 days), physical activity, and dietary habits (frequency of daily fruit and vegetable consumption).

Anthropometric measurements included height, weight, and waist and hip circumference, recorded using standardized protocols. Blood pressure (BP) was measured using a mercury sphygmomanometer.

After the 2-hour interval, blood samples were analyzed for OGTT using a calibrated glucose analyzer. RCBG was measured using a portable glucometer (OneTouch Ultra II, Lifescan, Milpitas, CA, USA) based on the glucose oxidase assay. RCBG testing was conducted either on the same day (between 2:30 pm and 7:30 pm) or the following morning (between 8:30 am and 2:30 pm) using fresh capillary whole blood obtained by finger prick from the participant's left middle finger.

Measurements of anthropometric parameters and blood pressure

Anthropometric measurements were performed with participants wearing light clothing and no shoes. Weight was measured using electronic digital LCD scales, calibrated daily with a standard weight. Height was recorded with the participant standing erect against a flat, wall-mounted stadiometer. Waist circumference (WC) was measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, and hip circumference at the widest portion of the buttocks. Both measurements were obtained using a non-stretchable measuring tape with participants in a standing position. All values were recorded to the nearest 0.1 cm, following WHO STEPS protocol. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Waist-to-hip ratio (WHR) was derived from waist and hip circumference measurements.

To ensure the accuracy of BP readings, participants were seated and rested for five minutes prior to measurement. BP was measured on the right arm using a mercury sphygmomanometer fitted with a standard adult cuff. Systolic BP (SBP) was recorded at the first appearance of Korotkoff sounds (phase I), and diastolic BP (DBP) at their disappearance (phase V). Readings were taken to the nearest 2 mmHg based on the top of the mercury column.

Intra-observer variability was assessed by repeating the BP measurement on the same individual after a five-minute interval. Inter-observer variability was evaluated by having two trained observers independently measure BP within a 10-minute window. The intra-observer and inter-observer coefficients of variation (CV) were 2.6% and 3.3%, respectively.

Blood glucose estimation

Upon arrival, a 5 mL fasting venous blood sample was collected from each participant for measurement of FPG and HbA1c. An additional 2 mL venous blood sample was drawn two hours after the administration of a 75 g oral glucose solution. Blood samples intended for plasma glucose analysis were collected in tubes containing sodium fluoride and potassium oxalate (1:3 ratio) and centrifuged immediately. Plasma glucose was measured using the glucose oxidase method on the Dimension RxL Max platform (Siemens AG, Erlangen, Germany).

To ensure quality control, every 10th sample was re-analyzed for 2hPG using the same enzymatic method. HbA1c samples were collected in ethylenediaminetetraacetic acid (EDTA) vials (2 mg/mL) and analyzed on the same day using the Bio-Rad D-10 system (Bio-Rad Laboratories, Hercules, CA, USA), which employs high-performance liquid chromatography (HPLC)-based ion-exchange chromatography. The analytical range was aligned with the Diabetes Control and Complications Trial (DCCT) and National Glycohemoglobin Standardization Program (NGSP) recommendations, with a reference range of 4.0–6.0%.

All glucose meters used in the study were plasma-calibrated and provided reliable readings within a hematocrit range of 30–50%, without hematocrit correction. The intra- and inter-assay CV for venous glucose ranged from 0.88% to 1.88%. The mean CV for RCBG was 4.8%. All participants were informed of their glucose results as soon as the analyses were completed.

Definition of variables

General obesity was defined as a BMI of ≥25 kg/m^2 for both sexes. Central obesity was defined using WC cut-offs of ≥90 cm for men and ≥80 cm for women. WHR thresholds were ≥0.90 for men and ≥0.80 for women.[18] [19] T2DM was defined as FPG ≥7.0 mmol/l and/or 2hPG ≥11.1 mmol/l[11] Additionally, HbA1c ≥6.5% and RCBG ≥11.1 mmol/l with symptoms were considered diagnostic for T2DM.[11] Diabetes symptoms were defined as the presence of at least one classic hyperglycemic symptom, including polyuria, polydipsia, polyphagia, unexplained weight loss, or generalized weakness, consistent with WHO diagnostic criteria.[11] Hypertension (HTN) was defined as a mean SBP of ≥140 mmHg, a DBP of ≥90 mmHg, or current use of antihypertensive medication.[20] Smoking status was categorized as current smoker or non/ex-smoker. Socioeconomic status was stratified into three groups based on self-reported monthly household expenditure: low (<10,000 Bangladeshi Taka [BDT]; approximately USD 91), medium (10,000–20,000 BDT), and high (>20,000 BDT). Education level was categorized as: no formal education (unable to read or write), undergraduate (primary to higher secondary), and graduate (college or above). Physical activity was graded on a three-level ordinal scale based on self-reported leisure-time walking duration: light (<30 minutes/day), moderate (30–60 minutes/day), and heavy (>60 minutes/day). For analysis, this was converted into a binary variable: inactive (grade 1, <30 minutes/day) and active (grades 2 and 3, ≥30 minutes/day). [21] [22] Inadequate fruit and vegetable consumption was defined as fewer than five servings per day, in accordance with WHO STEPS guidelines. This variable was included in the composite calculation of participants with at least one NCD risk factor. [23]

Statistical analysis

Continuous variables were presented as means with 95% confidence intervals (CIs), and categorical variables as percentages with 95% CIs. Differences in means between groups were assessed using the independent samples t-test, while differences in proportions were evaluated using the χ^2 test.

The associations between RCBG and FPG, 2hPG, and HbA1c were examined using Pearson's correlation coefficients (r) and simple linear regression analysis. Bland-Altman plots were

generated to assess the mean difference (bias) and limits of agreement between RCBG and FPG, 2hPG, and HbA1c measurements.

Receiver operating characteristic (ROC) curve analysis was employed to assess the diagnostic accuracy of RCBG for detecting diabetes, using the OGTT as the reference standard. ROC curves were also generated to compare the diagnostic performance of RCBG, FPG, 2hPG, and HbA1c. Optimal cut-off points were determined by maximizing the Youden Index.

The agreement between different diagnostic methods (RCBG, FPG, 2hPG, and HbA1c) was assessed using the kappa (κ) statistic. Values of $\kappa > 0.75$ were interpreted as excellent agreement beyond chance, values between 0.40 and 0.75 as fair to good agreement, and values <0.40 as poor agreement.

Diagnostic test characteristics, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% CIs, were calculated for various RCBG, FPG, and 2hPG, and HbA1c cut-off points. The number needed to screen (NNS), representing the number of individuals required to be screened to detect one true case of undiagnosed diabetes, was also calculated.

All statistical analyses were conducted using three software programs: PASW Statistics version 20 (SPSS Inc., Chicago, IL, USA) for data cleaning, management, and descriptive analysis; Stata version 14 (StataCorp LP, College Station, TX, USA) for regression and ROC analyses; and MedCalc version 20.1 (MedCalc Software Ltd, Ostend, Belgium) for determining optimal diagnostic thresholds based on the Youden Index.

All analyses were two-sided, and statistical significance was set at $p < 0.05$. The findings were reported in accordance with the STARD (Standards for Reporting of Diagnostic Accuracy Studies) guidelines.

Patient and Public Involvement

Patients and the public were not involved in the design, conduct, analysis, or dissemination plans of this research.

Results

Table 1 presents the baseline characteristics of the study participants stratified by sex. The mean age of participants was 44.4 years, with females being slightly younger than males. More than half of the participants reported a family history of diabetes. Low levels of physical activity and inadequate fruit and vegetable intake were common across both sexes. Obesity, defined by BMI, was more prevalent among females, and a significantly higher proportion of females had abdominal obesity. Mean SBP and DBP were significantly higher in males. While the overall prevalence of T2DM did not differ significantly by sex, males showed higher mean FPG levels, and females reported more T2DM-related symptoms. Biochemical parameters such as 2hPG, HbA1c, and RCBG were similar between sexes. A high proportion (96.0%) had at least one NCD risk factor.

Table 2 shows the correlation (p values) between RCBG, FBG, 2hAG, and HbA1c. All four blood glucose tests are positively correlated. The correlation of RCBG with FPG, 2hPG, and HbA1c was 0.828 ($p<0.001$), 0.840 ($p<0.001$), and 0.826 ($p<0.001$), respectively. The strongest linear relationship was observed between RCBG and 2hPG.

Figure 2 shows the concordance between RCBG, FBG, 2hAG, and HbA1c using Bland-Altman plots. The mean differences were 2.7 mmol/l (RCBG vs. FPG), 1.9 mmol/l (RCBG vs. 2hPG), and 3.2 mmol/l (RCBG vs. HbA1c). These results demonstrate a consistent slight positive bias in RCBG compared to the other diagnostic measures. Despite this, the narrow 95% limits of agreement indicate good concordance, suggesting RCBG as a reliable tool for diagnosing diabetes in resource-limited settings.

Figure 3 shows diagnostic performance of RCBG in comparison to FPG, 2hPG, and HbA1c for diagnosing diabetes. In figure 3A, ROC curve of RCBG showing an optimal cut-off of 8.7 mmol/l with a sensitivity of 79.7%, specificity of 89.1%, AUC of 0.905, and Youden index of 0.697. Figure 3B shows ROC curves comparing the diagnostic performance of FPG, 2hPG, HbA1c, and RCBG. FPG has the highest AUC (0.968), followed by 2hPG (0.964), HbA1c (0.936), and RCBG (0.905). This shows that RCBG has slightly lower diagnostic accuracy but is still a useful tool for diagnosing diabetes in resource-limited settings.

Table 3 summarizes the diagnostic performance of different tests for detecting T2DM, including FPG, 2hPG, HbA1c, and RCBG using both the current (≥11.1 mmol/l) and proposed (≥8.7 mmol/l)

cut-off points, with and without typical symptoms. Among all tests, 2hPG demonstrated the highest diagnostic accuracy (95.9%) and agreement (κ = 0.917), followed by FPG (accuracy 92.1%) and HbA1c (accuracy 87.7%). While RCBG with the conventional cut-off had lower sensitivity (63.1%) and agreement (κ = 0.611), the proposed RCBG threshold of ≥8.7 mmol/l improved sensitivity (80.4%), diagnostic accuracy (84.7%), and agreement (κ = 0.695). The NNS was lowest for HbA1c (2.36) and 2hPG (2.40), followed closely by RCBG ≥8.7 mmol/l (2.74), indicating the practical utility of the proposed threshold in population-level screening. The addition of typical hyperglycemic symptoms marginally improved RCBG performance at both thresholds.

Figure 4A illustrates the mean RCBG levels among asymptomatic and symptomatic individuals, stratified by whether confirmatory testing was conducted on the same day or the next day. Among symptomatic participants, the mean RCBG level was higher when confirmatory testing occurred on the same day (11.5 mmol/l) compared to next-day testing (10.4 mmol/l). A similar trend was observed among asymptomatic individuals, though the difference was less pronounced (10.8 mmol/l vs 10.6 mmol/l).

Figure 4B compares the diagnostic yield for type 2 diabetes mellitus (T2DM) across different RCBG-based criteria, also stratified by the timing of confirmatory testing. Across all cut-offs, same-day confirmatory testing resulted in a higher proportion of T2DM diagnoses compared to next-day testing. The highest detection rate (49.6%) was observed using the proposed RCBG cut-off of ≥8.7 mmol/l with symptoms, when testing was performed on the same day. This suggests that diagnostic yield may be influenced not only by glucose thresholds and symptom presence but also by the timing of diagnostic confirmation.

Discussion

This study is one of the first in Bangladesh to evaluate the diagnostic performance of RCBG against FPG, 2hPG, and HbA1c in detecting undiagnosed T2DM. With a large, systematically selected sample across all eight administrative divisions, our findings not only provide a population-specific RCBG threshold but also support its practical utility in resource-constrained settings.

More than 60% of the Bangladeshi population lives in rural areas where diagnostic infrastructure for FPG, 2hPG, or HbA1c is often lacking.[24] In these contexts, RCBG measured by handheld

glucometers is frequently the only diagnostic option. Despite this reality, limited evidence has been available to support specific RCBG thresholds tailored to local populations.

The study found a high rate of undiagnosed T2DM, ranging from 33.2% to 49.5%, as defined by different diagnostic methods including FPG, 2hPG, OGTT (both FPG or 2hPG), HbA1c, and RCBG. This finding is consistent with the IDF's 45%.[1] The revised RCBG threshold significantly improved the detection rate of previously undiagnosed T2DM, highlighting its potential utility for early identification and timely clinical management.

This study found strong correlations between RCBG and other diagnostic standards: 0.828 with FPG, 0.840 with 2hPG, and 0.826 with HbA1c ($p<0.001$ for all). These findings are consistent with prior studies from India,[14] Thailand,[15] and other LMICs, where RCBG has shown strong concordance with OGTT or laboratory-based diagnostics. In contrast to studies in high-income settings that use RCBG primarily with symptoms, our data suggest that RCBG alone—without symptom screening—can be a reliable diagnostic tool, particularly in mass screening programs.

Previous studies conducted in various regions have reported a wide range of optimal RCBG cut-off values, typically between 5.5 and 7.9 mmol/l, depending on population demographics, clinical settings, and diagnostic reference standards.[14, 15, 25-27] Although the RCBG cut-off identified in our study (8.7 mmol/l) is higher, this variation may be attributed to the unimodal glucose distribution in our sample, the specific use of OGTT as the reference standard, and differences in ethnicity and dietary patterns. Therefore, while the absolute value differs, our findings are aligned with the broader evidence supporting the utility of RCBG as a valid screening tool—particularly when population-specific validation is applied.

In addition, the RCBG cut-off value of ≥8.7 mmol/l showed a good agreement with OGTT, 2hPG, and HbA1c cut-off values for diagnosing T2DM than the currently used RCBG cut-off value of ≥11.1 mmol/l. One article by Caroll et al highlighted the potential negative consequences of medical screening, mainly a false-positive result.[28] This can lead to overdiagnosis and overtreatment, harming patients physically and financially. Our study showed that a value of ≥8.7 mmol/l had a 50% lower rate of false-positive cases than a value of ≥11.1 mmol/l. This indicates that the former cut-off value may be more useful in clinical practice.

Importantly, the current study demonstrates that adding the criterion of symptoms to RCBG thresholds did not improve diagnostic performance meaningfully. In fact, our data show that symptom-based diagnosis (RCBG ≥11.1 mmol/l + symptoms) had lower sensitivity and agreement (κ = 0.623) than the proposed RCBG ≥8.7 mmol/l threshold alone (κ = 0.695). This supports the idea that reliance on subjective symptoms may hinder early detection and should not be required for diagnosis in mass screening.

The diagnostic yield of RCBG was influenced by the timing of confirmatory testing. Same-day confirmatory testing yielded higher RCBG values and higher detection rates of T2DM, suggesting that RCBG is most effective when used during immediate screening encounters. Such operational insights are crucial for designing real-world diabetes screening programs, particularly in community-based settings and primary care units.

In terms of predictive efficiency, RCBG performed better than expected. Our logistic regression analysis showed that RCBG ≥8.7 mmol/l had a stronger association with OGTT-defined T2DM than the conventional ≥11.1 mmol/l cut-off (OR: 8.91 vs. 5.52). This reinforces the clinical relevance of the revised threshold. Furthermore, the NNS for RCBG ≥8.7 mmol/l was 2.74, closely aligning with NNS for FPG (2.86) and 2hPG (2.40), confirming its cost-effectiveness and practical relevance.

Cost analysis is an important consideration in health policy decision-making. RCBG is significantly less expensive (USD 0.18/test) than FPG (USD 2.73/test) or HbA1c (USD 5.46/test). This cost advantage is particularly compelling for LMICs like Bangladesh, where the national health budget per capita is limited. Prior economic analyses, such as those by Marley et al.[29] and Meriggi et al.[30] have also highlighted the economic feasibility of using RCBG for mass screening.

Furthermore, our results support the WHO and IDF's recommendations for opportunistic screening for T2DM using affordable point-of-care tools. This study aligns with the goals of the WHO Global Action Plan for NCDs and provides actionable evidence for countries developing national diabetes screening policies. Our proposed threshold fills a critical evidence gap and presents an opportunity to guide national diabetes screening guidelines in Bangladesh and similar LMICs.

Strengths of our study include a large, nationally representative sample collected from 16 centres across all administrative divisions, ensuring geographic and demographic diversity. The use of

WHO-recommended diagnostic tools (OGTT, HbA1c, and FPG) as gold standards enhances the validity of the findings. Laboratory quality control was ensured through internal and external validation at BADAS laboratories. The systematic random sampling method reduced selection bias, and the standardization of measurements further strengthens the reliability of the data. Additionally, trained clinicians and technicians from BADAS conducted the clinical and anthropometric assessments, contributing to data quality. substantial cost savings. It's worth noting that BADAS operates a comprehensive national diabetes care infrastructure, managing about 60% of diabetic patients in Bangladesh through its network of 130 diabetes centres, 350 accredited sub-district facilities, and 100 diabetes screening corners located in remote villages. This extensive, structured network contributes significantly to standardised clinical practice, quality care, and reliable data collection.[31]

However, this study also has limitations. The data were collected at a single time point, making it a cross-sectional analysis that cannot establish causal relationships. The diagnosis of T2DM was based on a single measurement of OGTT, HbA1c, and RCBG, whereas clinical practice typically requires repeat testing for confirmation. Although the study aimed to determine optimal cut-off values for diabetes diagnostic tools, it did not evaluate the ability of these methods to predict long-term diabetes-related complications. Additionally, individuals with previously diagnosed diabetes or prediabetes were excluded based on self-report. While self-reporting is generally reliable for identifying diagnosed diabetes, it may be less accurate for identifying prediabetes. The study also did not account for metabolic variability, differences in recent food intake, or the inherent fluctuations in capillary blood glucose measurements, which may influence glycemic readings. Furthermore, clinical and anthropometric assessments were conducted only once, without duplicate measurements or a second observer, increasing the potential for measurement error. Although systematic random sampling was applied across all eight administrative divisions, our recruitment exclusively from BADAS centres, which primarily serve individuals aware of their diabetes risk, might have led to overrepresentation of high-risk populations and thus potentially overestimated the diagnostic accuracy and prevalence rates. Consequently, generalising these findings to the broader Bangladeshi population or other healthcare settings should be done

cautiously. Further community-based studies are recommended to confirm and extend these findings to guide policy recommendations.

In conclusion, RCBG may serve as an effective and affordable preliminary diagnostic tool for identifying T2DM, particularly in resource-limited settings. The proposed cut-off of ≥8.7 mmol/l demonstrated improved diagnostic performance compared to the currently used threshold. However, these findings should be interpreted cautiously, and further validation studies are needed to assess long-term clinical outcomes and generalizability to other populations.

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Author contributions

BB contributed to study planning, statistical analysis plan, wrote the statistical methods section, ran the statistical analysis and wrote the manuscript. TS and SBM collected and researched the data and wrote the manuscript. TA, FA, NKQ and ASM drafted sections of the article and contributed to discussion. RI, SP, SUM, RIC, RO, DCR, SRC, SSA, SA, TA contributed to data collection and drafted sections of the article. FP, MAS, HM, MRA, AKAK reviewed/edited the manuscript. BB is the guarantor and accepts full responsibility for the work, had access to the data, and controlled the decision to publish.

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Data availability

Data are available upon reasonable request from BB, the study principal investigator.

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from each participant, and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the

Ethical Review Committee of Diabetic Association of Bangladesh (BADAS) (BADAS-ERC/EC 122100331).

Competing interests

No potential conflict of interest.

Consent for publication

Not applicable.

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Figure 1. STROBE flow diagram illustrating participant recruitment and inclusion. A total of 3,320 individuals were approached across 16 BADAS centres. Following exclusion of 120 individuals (due to ineligibility or refusal), 3,200 participants were enrolled using systematic random sampling (every 2nd eligible patient) and included in the final analysis.

Table 1. Basic characteristics of the study participants by sex				
Variable	**Total**	**Male**	**Female**	**P value**
Number	3200	1520 (47.5%)	1680 (52.5%)	
Age (years)	44.4 (43.9, 44.8)	45.9 (45.3, 46.6)	42.9 (42.3, 43.5)	<0.001
Age, %				<0.001
<30 years	11.1 (10.0, 12.2)	8.6 (7.1, 10.0)	13.5 (11.8, 15.1)	
30-39 years	23.9 (22.4, 25.4)	22.4 (20.3, 24.5)	25.2 (23.2, 27.3)	
40-49 years	29.9 (28.3, 31.5)	30.0 (27.8, 32.3)	29.8 (27.6, 32.0)	
≥50 years	35.1 (33.4, 36.7)	38.9 (36.5, 41.4)	31.5 (29.3, 33.7)	
F/H DM, %	53.3 (51.6, 55.1)	54.6 (52.0, 57.1)	52.3 (49.9, 54.7)	0.198
Leisure time physical activity (<30 min/day)	65.2 (62.9, 67.5)	62.0 (58.6, 65.2)	68.5 (65.3, 71.6)	0.005
Intake of vegetables & fruits (<5 servings/ day)	99.0 (98.5, 99.3)	99.3 (98.5, 99.7)	98..7 (98.0, 99.2)	0.174
BMI (kg/m^2)	25.9 (25.8, 26.1)	25.3 (25.1, 25.5)	26.5 (26.3, 26.7)	<0.001
Obese, %	57.1 (55.3, 58.8)	52.0 (49.4, 54.6)	61.6 (59.2, 64.1)	<0.001
WC (cm)	92.4 (91.9, 92.8)	92.4 (91.9, 93.0)	92.4 (91.8, 92.9)	0.836
Abdominal obesity, %	73.3 (71.8, 74.9)	58.6 (56.1, 61.2)	86.5 (84.9, 88.2)	<0.001
SBP (mmHg)	119.8 (119.3, 120.1)	121.3 (120.6, 121.9)	118.4 (117.8, 119.1)	<0.001
DBP (mmHg)	78.6 (78.3, 78.9)	79.5 (79.1, 79.9)	77.7 (77.3, 78.1)	<0.001
HTN, %	29.8 (28.2, 31.4)	30.5 (28.2, 32.8)	29.2 (27.0, 31.4)	0.436
DM symptom (present), %	63.1 (61.4, 64.8)	61.3 (58.8, 63.8)	64.7 (62.4, 67.0)	0.047
FPG (mmol/l)	7.9 (7.8, 8.1)	8.0 (7.8, 8.2)	7.9 (7.7, 8.1)	0.545
2hPG (mmol/l)	12.5 (12.2, 12.8)	12.6 (12.2, 12.9)	12.5 (12.2, 12.8)	0.682
DM, %	49.5 (47.8, 51.3)	49.6 (47.1, 52.1)	49.5 (47.1, 51.9)	0.937
HbA1c (%)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	0.724
DM (≥6.5%), %	48.9 (47.2, 50.7)	50.0 (47.4, 52.5)	48.0 (45.6, 50.4)	0.273
RCBG (mmol/l)	10.6 (10.4, 10.8)	10.6 (10.3, 10.8)	10.6 (10.3, 10.9)	0.789
DM (≥11.1+ symptom), %	33.2 (31.1, 35.3)	32.7 (29.7, 35.8)	33.6 (30.7, 36.4)	0.704
One NCD RF, %	96.0 (95.3, 96.7)	96.7 (85.8, 97.6)	95.3 (94.3, 96.3)	0.042

Data are presented as mean (95% confidence interval) and percentage (95% confidence interval) as needed. (Abbreviation: DM, diabetes mellitus; F/H, family history; BMI, body mass index; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; HTN, hypertension; FPG, fasting plasma glucose; 2hPG, 2 hours after plasma glucose, HbA1c, glycated hemoglobin; RCBG, random capillary blood glucose; NCD RF, non-communicable disease risk factors obese, BMI ≥25 kg/m^2; abdominal obesity, WC- male ≥90 cm or female ≥80 cm; NCD RF, including smoking, physical inactivity, consume <5 servings of vegetables and fruits daily, obese, diabetes and hypertension.

Table 2. Correlation (P values) between RCBG, FBG, 2hAG, and HbA1c.

	RCBG (mmol/l)	FPG (mmol/l)	2hAG (mmol/l)	HbA1c %
RCBG (mmol/l)	1	0.828 (<0.001)	0.840 (<0.001)	0.826 (<0.001)
FPG (mmol/l)	0.828 (<0.001)	1	0.900 (<0.001)	0.880 (<0.001)
2hPG (mmol/l)	0.840 (<0.001)	0.900 (<0.001)	1	0.865 (<0.001)
HbA1c %	0.826 (<0.001)	0.880 (<0.001)	0.865 (<0.001)	1

Abbreviation: RCBG, Random capillary blood glucose; FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin.

Table 3. Comparison of diagnostic performance of FPG, 2hPG, HbA1c, and RCBG (both proposed and currently used cut-off point) to diagnose T2DM.

	SN (%)	SP (%)	PPV (%)	NPV (%)	Diagnosis (%)	Accuracy (%)	Agreement (k)	NNS
FPG (≥7 mmol/l)	84	100	100	86.4	41.6	92.1	0.841	2.86
2hPG (≥11.1 mmol/l)	91.7	100	100	92.4	45.4	95.9	0.917	2.40
HbA1c (≥6.5%)	86.8	88.6	88.3	87.2	48.9	87.7	0.755	2.36
RCBG (≥11.1 mmol/l)	63.1	97.8	96.6	73.0	32.3	80.6	0.611	4.91
RCBG (≥11.1 mmol/l) + typical symptom	64.4	97.9	96.8	73.4	33.2	81.2	0.623	4.68
RCBG (≥8.7 mmol/l)	80.4	89.0	87.7	82.3	45.4	84.7	0.695	2.74
RCBG (≥8.7 mmol/l) + typical symptom	79.6	88.1	87.0	81.3	45.6	83.9	0.677	2.76

Abbreviation: FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin; RCBG, Random capillary blood glucose; SN, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value; k, kappa statistics.; NNS, number needed to be screening

Figure 2. Bland-Altman plots showing the agreement between random capillary blood glucose (RCBG) and (A) fasting plasma glucose (FPG), (B) 2-hour plasma glucose (2hPG), and (C) glycated hemoglobin (HbA1c).

Figure 3. Diagnostic performance of random capillary blood glucose (RCBG) in comparison to fasting plasma glucose (FPG), 2-hour plasma glucose (2hPG), and glycated hemoglobin (HbA1c) for diagnosing diabetes.

Figure 4. Comparison of random capillary blood glucose (RCBG) levels in participants with and without symptoms, measured at different time points (same day vs. next day).

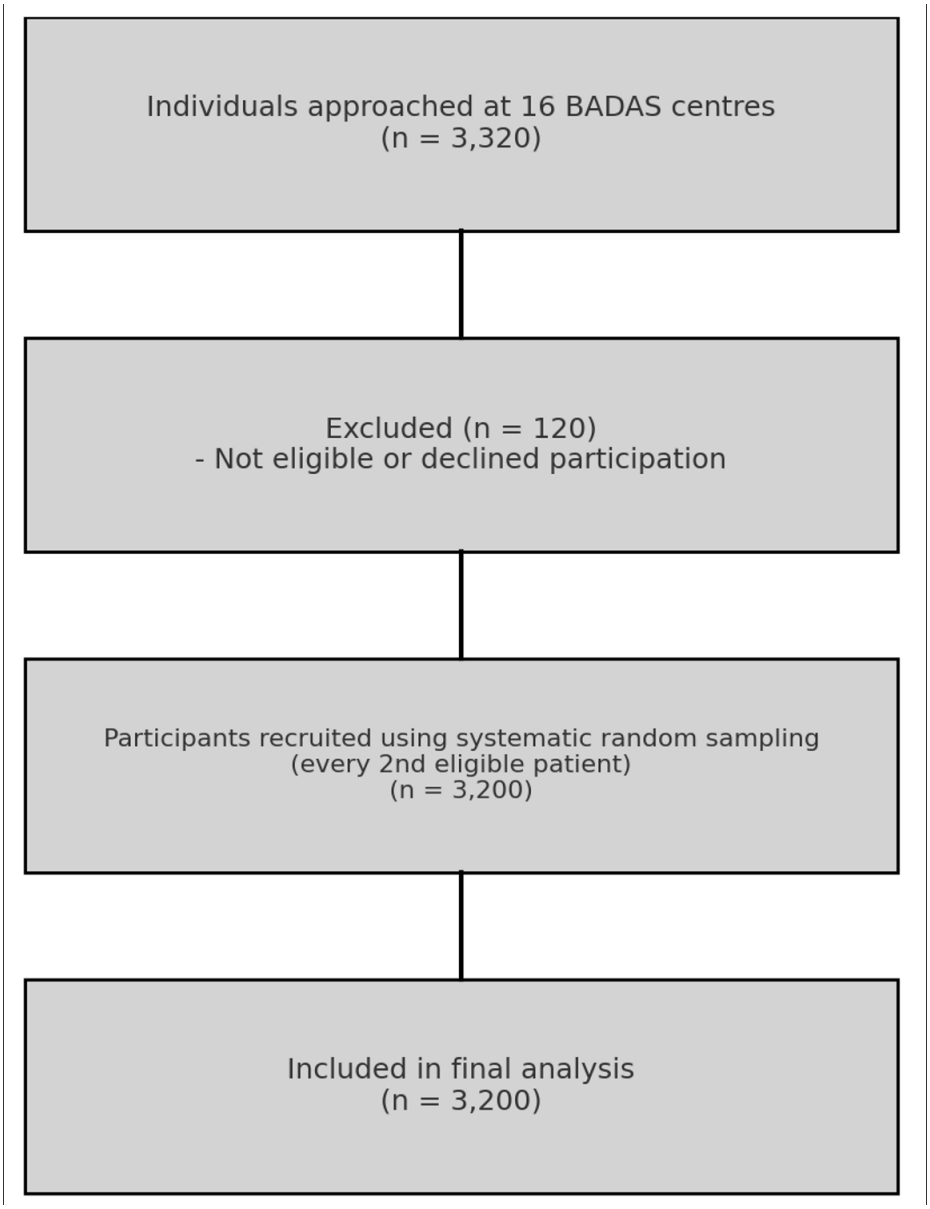

Figure 1. STROBE flow diagram illustrating participant recruitment and inclusion. A total of 3,320 individuals were approached across 16 BADAS centres. Following exclusion of 120 individuals (due to ineligibility or refusal), 3,200 participants were enrolled using systematic random sampling (every 2nd eligible patient) and included in the final analysis.

146x190mm (200 x 200 DPI)

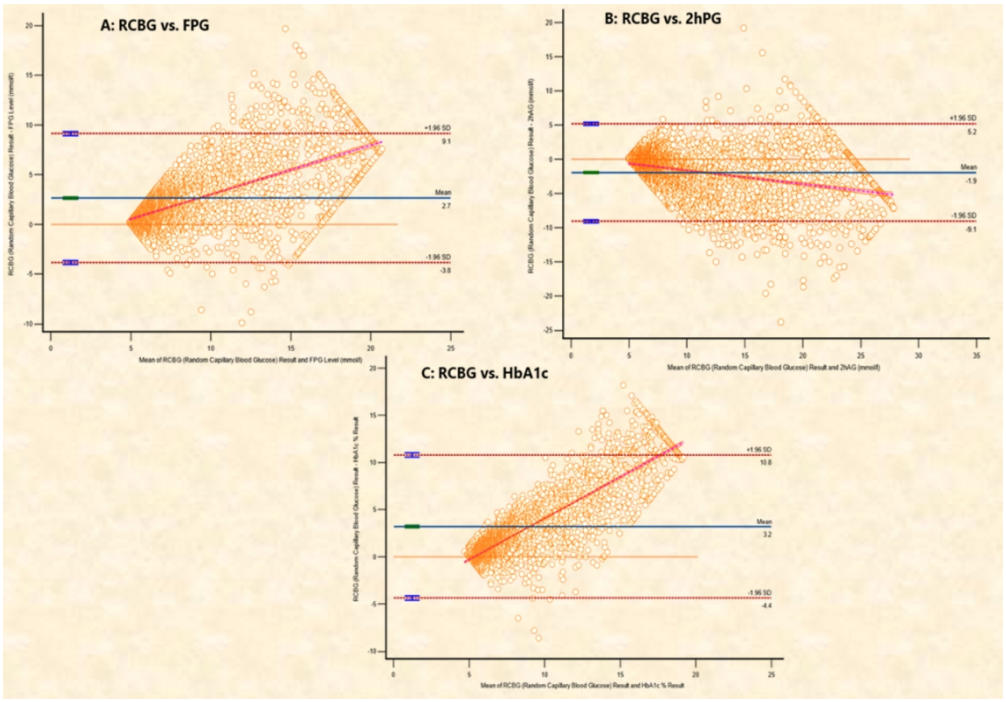

Figure 2. Bland-Altman plots showing the agreement between random capillary blood glucose (RCBG) and (A) fasting plasma glucose (FPG), (B) 2-hour plasma glucose (2hPG), and (C) glycated hemoglobin (HbA1c).

551x382mm (59 x 59 DPI)

Figure 2A. Receiver operating characteristics (ROC) curve of random capillary blood glucose (RCBG) to diagnose diabetes.

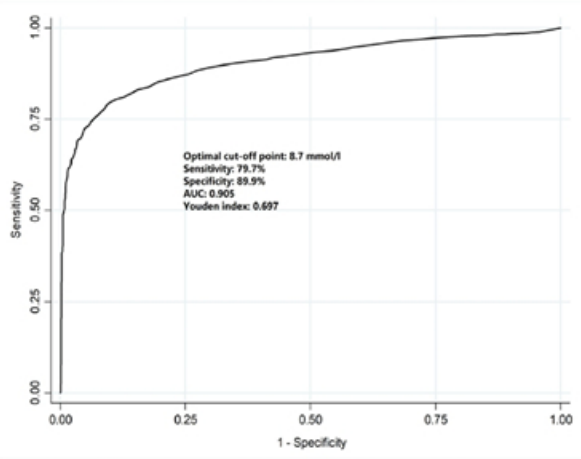

Figure 2B. The area under the receiver operating characteristics (ROC) curves of fasting plasma glucose (FPG), 2 hours plasma glucose (2hPG), glycated hemoglobin (HbA1c), and random capillary blood glucose (RCBG) to diagnose diabetes.

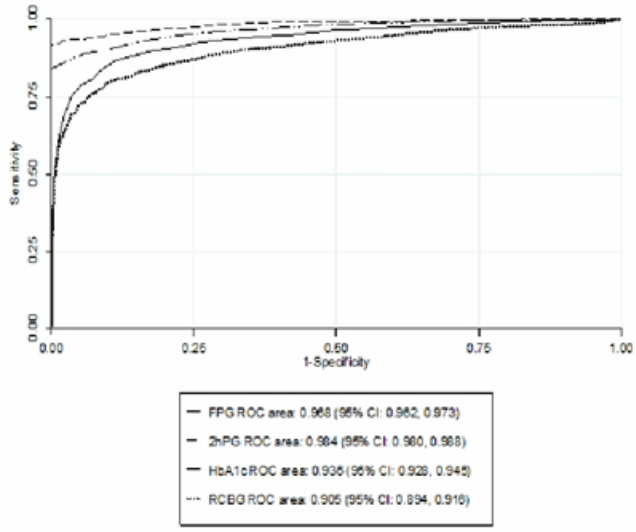

Figure 3. Diagnostic performance of random capillary blood glucose (RCBG) in comparison to fasting plasma glucose (FPG), 2-hour plasma glucose (2hPG), and glycated hemoglobin (HbA1c) for diagnosing diabetes.

405x501mm (38 x 38 DPI)

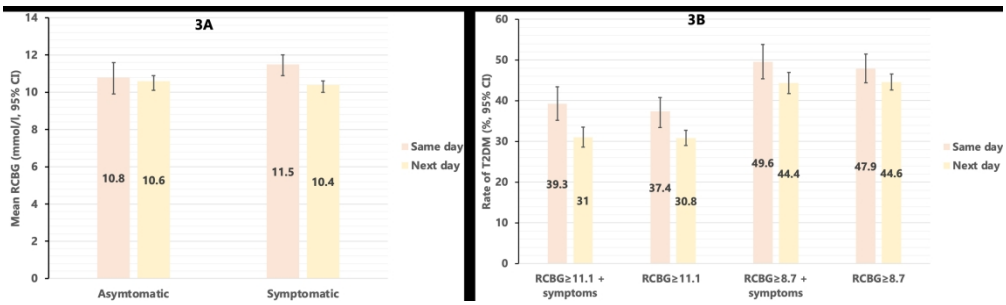

Figure 4. Comparison of random capillary blood glucose (RCBG) levels in participants with and without symptoms, measured at different time points (same day vs. next day).

338x99mm (300 x 300 DPI)

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Random Capillary Blood Glucose in the Diagnosis of Diabetes: A Cross-Sectional Study in Bangladesh

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Random Capillary Blood Glucose in the Diagnosis of Diabetes: A Cross-Sectional Study in Bangladesh

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Abstract

Objective

To assess the effectiveness of random capillary blood glucose as a diagnostic tool for type 2 diabetes and determine optimal cut-off values for adults in Bangladesh.

Design

Cross-sectional diagnostic accuracy study.

Setting

Sixteen diabetes centres were selected randomly from all eight administrative divisions of Bangladesh.

Participants

A total of 3,200 adults aged 18 years and older were recruited using systematic random sampling between May and September 2022.

Primary and secondary outcome measures

The primary outcome was the diagnostic accuracy of random capillary blood glucose compared to fasting plasma glucose, 2-hour plasma glucose after a 75-gram glucose load, and glycated haemoglobin. Secondary outcomes included sensitivity, specificity, area under the curve, and agreement with the other diagnostic tests.

Results

Random capillary blood glucose showed a strong positive correlation and high concordance with fasting plasma glucose, 2-hour plasma glucose, and glycated haemoglobin. A cut-off value of ≥8.7 mmol/l demonstrated improved diagnostic performance compared to the currently used cut-off of ≥11.1 mmol/l. This new threshold yielded higher sensitivity, specificity, area under the curve, and agreement with other standard diagnostic tests. Notably, hyperglycaemic symptoms were not required for diagnosis. The number needed to screen to identify one case of type 2 diabetes using the ≥8.7 mmol/l cut-off was 2.74, lower than that for fasting plasma glucose (2.86) and random capillary blood glucose ≥11.1 mmol/l (4.68).

Conclusions

Random capillary blood glucose may be an effective and affordable diagnostic tool for type 2

diabetes in resource-limited settings. The proposed cut-off of ≥8.7 mmol/l offers improved diagnostic accuracy and reflects the population's glucose distribution pattern.

Keywords:

Type 2 diabetes, random capillary blood glucose, diagnostic accuracy, Bangladesh, screening, oral glucose tolerance test, primary care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A large, systematically sampled population was included from all eight administrative divisions of Bangladesh.
- All biochemical measurements were conducted using quality-controlled, centralized laboratory procedures.
- The use of OGTT as a reference standard enhances diagnostic comparison.
- The study's focus on a specific population may limit its generalizability to other regions or ethnic groups.
- This study did not assess individual metabolic differences, variations in food intake before the test, different time points or the inherent variability of RCBG measurements, which limits the explanation of glycaemic variance.

Introduction

Type 2 diabetes mellitus (T2DM) is a growing public health concern in Bangladesh, with an estimated 13.9 million people affected in 2024.[1] Alarmingly, 43% of these individuals remain undiagnosed, especially in rural and underserved populations, where diagnostic services are limited.[2–4] Many patients present with complications such as neuropathy, retinopathy, and cardiovascular disease at the time of diagnosis, increasing the burden on both the health system and individual patients.[5–7]

Screening and early intervention have been shown to be effective strategies for reducing T2DM incidence. Major trials such as the Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS) demonstrated that lifestyle modifications and pharmacological interventions could prevent or delay the onset of T2DM in high-risk individuals.[8,9] Despite the promise of these interventions, screening tools remain a challenge in low- and middle-income countries (LMICs) like Bangladesh.

Standard diagnostic criteria for diabetes include fasting plasma glucose (FPG), the 2-hour plasma glucose (2hPG) after an oral glucose tolerance test (OGTT), and glycated hemoglobin (HbA1c), as recommended by the American Diabetes Association (ADA) and the World Health Organization (WHO).[10,11] However, these tests require specialized laboratory equipment, patient compliance with fasting, and trained personnel—resources that are often lacking in rural healthcare settings in Bangladesh.

HbA1c, though useful in many high-resource settings, is expensive and often not standardized in Bangladeshi laboratories. It is also influenced by several factors, including age, pregnancy, hemoglobinopathies, and ethnicity, making it unsuitable for large population screening programs.[12, 13] As a result, these challenges have prompted a shift toward simpler, more accessible screening methods.

Random capillary blood glucose (RCBG) testing is widely used in outpatient clinics and community health camps across Bangladesh. It is low-cost, non-invasive, and does not require fasting. Despite these advantages, RCBG has not been validated against all three standard diagnostic methods in the Bangladeshi population. Health providers often use the global threshold of ≥11.1 mmol/l, which may not be suitable for detecting asymptomatic or early-stage diabetes.

Several international studies have explored the diagnostic accuracy of RCBG. In India, a threshold of 6.1 mmol/l showed good sensitivity for diabetes detection.[14] Similar observations were reported from Thailand and China, reinforcing RCBG's diagnostic potential in different ethnic and resource settings.[15,16] However, variations in cut-off points across populations highlight the need for population-specific thresholds.

To date, no large-scale study in Bangladesh has systematically evaluated the performance of RCBG in comparison with FPG, 2hPG, and HbA1c using standardized diagnostic protocols in a population-based screening context. Therefore, this study aims to assess the diagnostic accuracy of RCBG and to determine an optimal cut-off value for detecting T2DM in the adult Bangladeshi population

Methods

Study design and study site

This cross-sectional diagnostic accuracy study was conducted between May and September 2022 at 16 centres of the Diabetic Association of Bangladesh (BADAS). BADAS provides outpatient and inpatient services to approximately 12,000 to 15,000 individuals daily through 130 small, medium, and large centres and hospitals across the country. Study centres were randomly selected from within and outside the capital, Dhaka, covering all eight administrative divisions of Bangladesh. Participants were recruited using a systematic random sampling approach, whereby every second eligible individual presenting for diabetes screening was invited to participate.

Participants and sampling procedure

The sample size was calculated based on a national prevalence of T2DM of 8.3%, as reported in the 2018 Bangladesh STEPS survey.[17] Using the standard formula for estimating proportions- $n = \frac{Z^2P(1-P)}{d^2}$, where n is the required sample size, Z is the Z-score (1.96 for 95% confidence), P is the expected prevalence (8.3%), and d is the margin of error—a minimum sample size of 2,830 was obtained. Allowing for a 10% non-response rate, the final required sample was 3,113 individuals. Participants were eligible for inclusion if they were aged 18 years or older and provided written informed consent. Individuals were excluded if they had a known diagnosis of type 2 diabetes mellitus (T2DM), were taking medications known to affect glucose metabolism, had any chronic

illness at the time of screening, were pregnant, or were unwilling or unable to provide informed consent or communicate with the study personnel.

Based on the calculated sample size, we aimed to recruit 200 participants from each of the 16 selected BADAS centres, yielding a total of 3,200 participants. A systematic random sampling technique was employed, whereby every second eligible adult presenting for diabetes screening was invited to participate. Given the high patient volume at BADAS centres, the target sample size was achieved within the study period. In total, 3,320 individuals were approached, of whom exactly 3,200 met eligibility criteria, provided informed consent, and were included in the final analysis. A STARD-compliant flow diagram (**Figure 1**) illustrates the recruitment and inclusion process.

Data collection

Planning of the study

Prior to study initiation, an expert panel comprising an epidemiologist, diabetologist/endocrinologist, statistician, and biochemist convened with the project team leader to review and refine the study design. Recommendations from this panel were incorporated into the final protocol. One physician, one laboratory technician, and three volunteers were appointed at each study centre to oversee implementation. All field staff received two days of structured theoretical and practical training before the commencement of data collection.

Eligible participants were provided with a detailed participant information sheet and given adequate time to ask questions and clarify concerns. Informed written consent was obtained only after confirming the participant's comprehension of the study procedures. Individuals who did not demonstrate full understanding were excluded.

Following consent, data were collected using a three-step process aligned with the modified WHO STEPS approach: face-to-face interview (Step 1), physical measurements (Step 2), and collection of biological samples (Step 3).

Fasting blood samples were collected to measure FPG and HbA1c. Participants then consumed a 75 g oral glucose solution, followed by a second blood sample collected two hours later for the 2hPG test. During the 2-hour interval, trained interviewers administered a structured questionnaire based on the WHO STEPwise approach to collect sociodemographic and behavioral information.

Sociodemographic variables included age (in completed years), sex (male or female), marital status (currently married, never married, divorced/separated, or widowed), education level (no formal education, primary, secondary, higher secondary, or graduate and above), occupation (unemployed, informal, formal, or retired), and monthly household income. Residential status was defined as urban or rural using administrative classification. Family history of diabetes in first-degree relatives was recorded.

Behavioral variables included tobacco use (current, former, or never), alcohol consumption (defined as any use in the past 30 days), physical activity, and dietary habits (frequency of daily fruit and vegetable consumption).

Anthropometric measurements included height, weight, and waist and hip circumference, recorded using standardized protocols. Blood pressure (BP) was measured using a mercury sphygmomanometer.

After the 2-hour interval, blood samples were analyzed for OGTT using a calibrated glucose analyzer. RCBG was measured using a portable glucometer (OneTouch Ultra II, Lifescan, Milpitas, CA, USA) based on the glucose oxidase assay. RCBG testing was conducted either on the same day (between 2:30 pm and 7:30 pm) or the following morning (between 8:30 am and 2:30 pm) using fresh capillary whole blood obtained by finger prick from the participant's left middle finger.

Measurements of anthropometric parameters and blood pressure

Anthropometric measurements were performed with participants wearing light clothing and no shoes. Weight was measured using electronic digital LCD scales, calibrated daily with a standard weight. Height was recorded with the participant standing erect against a flat, wall-mounted stadiometer. Waist circumference (WC) was measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, and hip circumference at the widest portion of the buttocks. Both measurements were obtained using a non-stretchable measuring tape with participants in a standing position. All values were recorded to the nearest 0.1 cm, following WHO STEPS protocol. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Waist-to-hip ratio (WHR) was derived from waist and hip circumference measurements.

To ensure the accuracy of BP readings, participants were seated and rested for five minutes prior to measurement. BP was measured on the right arm using a mercury sphygmomanometer fitted with a standard adult cuff. Systolic BP (SBP) was recorded at the first appearance of Korotkoff sounds (phase I), and diastolic BP (DBP) at their disappearance (phase V). Readings were taken to the nearest 2 mmHg based on the top of the mercury column.

Intra-observer variability was assessed by repeating the BP measurement on the same individual after a five-minute interval. Inter-observer variability was evaluated by having two trained observers independently measure BP within a 10-minute window. The intra-observer and inter-observer coefficients of variation (CV) were 2.6% and 3.3%, respectively.

Blood glucose estimation

Upon arrival, a 5 mL fasting venous blood sample was collected from each participant for measurement of FPG and HbA1c. An additional 2 mL venous blood sample was drawn two hours after the administration of a 75 g oral glucose solution. Blood samples intended for plasma glucose analysis were collected in tubes containing sodium fluoride and potassium oxalate (1:3 ratio) and centrifuged immediately. Plasma glucose was measured using the glucose oxidase method on the Dimension RxL Max platform (Siemens AG, Erlangen, Germany).

To ensure quality control, every 10th sample was re-analyzed for 2hPG using the same enzymatic method. HbA1c samples were collected in ethylenediaminetetraacetic acid (EDTA) vials (2 mg/mL) and analyzed on the same day using the Bio-Rad D-10 system (Bio-Rad Laboratories, Hercules, CA, USA), which employs high-performance liquid chromatography (HPLC)-based ion-exchange chromatography. The analytical range was aligned with the Diabetes Control and Complications Trial (DCCT) and National Glycohemoglobin Standardization Program (NGSP) recommendations, with a reference range of 4.0–6.0%.

All glucose meters used in the study were plasma-calibrated and provided reliable readings within a hematocrit range of 30–50%, without hematocrit correction. The intra- and inter-assay CV for venous glucose ranged from 0.88% to 1.88%. The mean CV for RCBG was 4.8%. All participants were informed of their glucose results as soon as the analyses were completed.

Definition of variables

General obesity was defined as a BMI of ≥25 kg/m^2 for both sexes. Central obesity was defined using WC cut-offs of ≥90 cm for men and ≥80 cm for women. WHR thresholds were ≥0.90 for men and ≥0.80 for women.[18] [19] T2DM was defined as FPG ≥7.0 mmol/l and/or 2hPG ≥11.1 mmol/l[11] Additionally, HbA1c ≥6.5% and RCBG ≥11.1 mmol/l with symptoms were considered diagnostic for T2DM.[11] Diabetes symptoms were defined as the presence of at least one classic hyperglycemic symptom, including polyuria, polydipsia, polyphagia, unexplained weight loss, or generalized weakness, consistent with WHO diagnostic criteria.[11] Hypertension (HTN) was defined as a mean SBP of ≥140 mmHg, a DBP of ≥90 mmHg, or current use of antihypertensive medication.[20] Smoking status was categorized as current smoker or non/ex-smoker. Socioeconomic status was stratified into three groups based on self-reported monthly household expenditure: low (<10,000 Bangladeshi Taka [BDT]; approximately USD 91), medium (10,000–20,000 BDT), and high (>20,000 BDT). Education level was categorized as: no formal education (unable to read or write), undergraduate (primary to higher secondary), and graduate (college or above). Physical activity was graded on a three-level ordinal scale based on self-reported leisure-time walking duration: light (<30 minutes/day), moderate (30–60 minutes/day), and heavy (>60 minutes/day). For analysis, this was converted into a binary variable: inactive (grade 1, <30 minutes/day) and active (grades 2 and 3, ≥30 minutes/day). [21] [22] Inadequate fruit and vegetable consumption was defined as fewer than five servings per day, in accordance with WHO STEPS guidelines. This variable was included in the composite calculation of participants with at least one NCD risk factor. [23] Residential status was classified as urban or rural based on administrative definitions.[24]

Statistical analysis

Continuous variables were presented as means with 95% confidence intervals (CIs), and categorical variables as percentages with 95% CIs. Differences in means between groups were assessed using the independent samples t-test, while differences in proportions were evaluated using the χ^2 test.

The associations between RCBG and FPG, 2hPG, and HbA1c were examined using Pearson's correlation coefficients (r) and simple linear regression analysis. Bland-Altman plots were

generated to assess the mean difference (bias) and limits of agreement between RCBG and FPG, 2hPG, and HbA1c measurements.

Receiver operating characteristic (ROC) curve analysis was employed to assess the diagnostic accuracy of RCBG for detecting diabetes, using the OGTT as the reference standard. ROC curves were also generated to compare the diagnostic performance of RCBG, FPG, 2hPG, and HbA1c. Optimal cut-off points were determined by maximizing the Youden Index.

The agreement between different diagnostic methods (RCBG, FPG, 2hPG, and HbA1c) was assessed using the kappa (κ) statistic. Values of $\kappa > 0.75$ were interpreted as excellent agreement beyond chance, values between 0.40 and 0.75 as fair to good agreement, and values <0.40 as poor agreement.

Diagnostic test characteristics, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% CIs, were calculated for various RCBG, FPG, and 2hPG, and HbA1c cut-off points. The number needed to screen (NNS), representing the number of individuals required to be screened to detect one true case of undiagnosed diabetes, was also calculated.

All statistical analyses were conducted using three software programs: PASW Statistics version 20 (SPSS Inc., Chicago, IL, USA) for data cleaning, management, and descriptive analysis; Stata version 14 (StataCorp LP, College Station, TX, USA) for regression and ROC analyses; and MedCalc version 20.1 (MedCalc Software Ltd, Ostend, Belgium) for determining optimal diagnostic thresholds based on the Youden Index.

All analyses were two-sided, and statistical significance was set at $p < 0.05$. The findings were reported in accordance with the STARD (Standards for Reporting of Diagnostic Accuracy Studies) guidelines.

Patient and Public Involvement

Patients and the public were not involved in the design, conduct, analysis, or dissemination plans of this research.

Results

Table 1 presents the baseline characteristics of the study participants stratified by sex. The mean age of participants was 44.4 years, with females being slightly younger than males. More than half of the participants reported a family history of diabetes. Low levels of physical activity and inadequate fruit and vegetable intake were common across both sexes. Obesity, defined by BMI, was more prevalent among females, and a significantly higher proportion of females had abdominal obesity. Mean SBP and DBP were significantly higher in males. While the overall prevalence of T2DM did not differ significantly by sex, males showed higher mean FPG levels, and females reported more T2DM-related symptoms. Biochemical parameters such as 2hPG, HbA1c, and RCBG were similar between sexes. A high proportion (96.0%) had at least one NCD risk factor.

Table 2 shows the correlation (p values) between RCBG, FBG, 2hAG, and HbA1c. All four blood glucose tests are positively correlated. The correlation of RCBG with FPG, 2hPG, and HbA1c was 0.828 ($p<0.001$), 0.840 ($p<0.001$), and 0.826 ($p<0.001$), respectively. The strongest linear relationship was observed between RCBG and 2hPG.

Figure 2 shows the concordance between RCBG, FBG, 2hAG, and HbA1c using Bland-Altman plots. The mean differences were 2.7 mmol/l (RCBG vs. FPG), 1.9 mmol/l (RCBG vs. 2hPG), and 3.2 mmol/l (RCBG vs. HbA1c). These results demonstrate a consistent slight positive bias in RCBG compared to the other diagnostic measures. Despite this, the narrow 95% limits of agreement indicate good concordance, suggesting RCBG as a reliable tool for diagnosing diabetes in resource-limited settings.

Figure 3 shows diagnostic performance of RCBG in comparison to FPG, 2hPG, and HbA1c for diagnosing diabetes. In figure 3A, ROC curve of RCBG showing an optimal cut-off of 8.7 mmol/l with a sensitivity of 79.7%, specificity of 89.1%, AUC of 0.905, and Youden index of 0.697. Figure 3B shows ROC curves comparing the diagnostic performance of FPG, 2hPG, HbA1c, and RCBG. FPG has the highest AUC (0.968), followed by 2hPG (0.964), HbA1c (0.936), and RCBG (0.905). This shows that RCBG has slightly lower diagnostic accuracy but is still a useful tool for diagnosing diabetes in resource-limited settings.

Table 3 summarizes the diagnostic performance of different tests for detecting T2DM, including FPG, 2hPG, HbA1c, and RCBG using both the current (≥11.1 mmol/l) and proposed (≥8.7 mmol/l)

cut-off points, with and without typical symptoms. Among all tests, 2hPG demonstrated the highest diagnostic accuracy (95.9%) and agreement (κ = 0.917), followed by FPG (accuracy 92.1%) and HbA1c (accuracy 87.7%). While RCBG with the conventional cut-off had lower sensitivity (63.1%) and agreement (κ = 0.611), the proposed RCBG threshold of ≥8.7 mmol/l improved sensitivity (80.4%), diagnostic accuracy (84.7%), and agreement (κ = 0.695). The NNS was lowest for HbA1c (2.36) and 2hPG (2.40), followed closely by RCBG ≥8.7 mmol/l (2.74), indicating the practical utility of the proposed threshold in population-level screening. The addition of typical hyperglycemic symptoms marginally improved RCBG performance at both thresholds.

Figure 4A illustrates the mean RCBG levels among asymptomatic and symptomatic individuals, stratified by whether confirmatory testing was conducted on the same day or the next day. Among symptomatic participants, the mean RCBG level was higher when confirmatory testing occurred on the same day (11.5 mmol/l) compared to next-day testing (10.4 mmol/l). A similar trend was observed among asymptomatic individuals, though the difference was less pronounced (10.8 mmol/l vs 10.6 mmol/l).

Figure 4B compares the diagnostic yield for type 2 diabetes mellitus (T2DM) across different RCBG-based criteria, also stratified by the timing of confirmatory testing. Across all cut-offs, same-day confirmatory testing resulted in a higher proportion of T2DM diagnoses compared to next-day testing. The highest detection rate (49.6%) was observed using the proposed RCBG cut-off of ≥8.7 mmol/l with symptoms, when testing was performed on the same day. This suggests that diagnostic yield may be influenced not only by glucose thresholds and symptom presence but also by the timing of diagnostic confirmation.

Discussion

This study is one of the first in Bangladesh to evaluate the diagnostic performance of RCBG against FPG, 2hPG, and HbA1c in detecting undiagnosed T2DM. With a large, systematically selected sample across all eight administrative divisions, our findings not only provide a population-specific RCBG threshold but also support its practical utility in resource-constrained settings.

More than 60% of the Bangladeshi population lives in rural areas where diagnostic infrastructure for FPG, 2hPG, or HbA1c is often lacking.[24] In these contexts, RCBG measured by handheld

glucometers is frequently the only diagnostic option. Despite this reality, limited evidence has been available to support specific RCBG thresholds tailored to local populations.

The study found a high rate of undiagnosed T2DM, ranging from 33.2% to 49.5%, as defined by different diagnostic methods including FPG, 2hPG, OGTT (both FPG or 2hPG), HbA1c, and RCBG. This finding is consistent with the IDF's 45%.[1] The revised RCBG threshold significantly improved the detection rate of previously undiagnosed T2DM, highlighting its potential utility for early identification and timely clinical management.

This study found strong correlations between RCBG and other diagnostic standards: 0.828 with FPG, 0.840 with 2hPG, and 0.826 with HbA1c ($p<0.001$ for all). These findings are consistent with prior studies from India,[14] Thailand,[15] and other LMICs, where RCBG has shown strong concordance with OGTT or laboratory-based diagnostics. In contrast to studies in high-income settings that use RCBG primarily with symptoms, our data suggest that RCBG alone—without symptom screening—can be a reliable diagnostic tool, particularly in mass screening programs.

Previous studies conducted in various regions have reported a wide range of optimal RCBG cut-off values, typically between 5.5 and 7.9 mmol/l, depending on population demographics, clinical settings, and diagnostic reference standards.[14, 15, 25-27] Although the RCBG cut-off identified in our study (8.7 mmol/l) is higher, this variation may be attributed to the unimodal glucose distribution in our sample, the specific use of OGTT as the reference standard, and differences in ethnicity and dietary patterns. Therefore, while the absolute value differs, our findings are aligned with the broader evidence supporting the utility of RCBG as a valid screening tool—particularly when population-specific validation is applied.

In addition, the RCBG cut-off value of ≥8.7 mmol/l showed a good agreement with OGTT, 2hPG, and HbA1c cut-off values for diagnosing T2DM than the currently used RCBG cut-off value of ≥11.1 mmol/l. One article by Caroll et al highlighted the potential negative consequences of medical screening, mainly a false-positive result.[28] This can lead to overdiagnosis and overtreatment, harming patients physically and financially. Our study showed that a value of ≥8.7 mmol/l had a 50% lower rate of false-positive cases than a value of ≥11.1 mmol/l. This indicates that the former cut-off value may be more useful in clinical practice.

Importantly, the current study demonstrates that adding the criterion of symptoms to RCBG thresholds did not improve diagnostic performance meaningfully. In fact, our data show that symptom-based diagnosis (RCBG ≥11.1 mmol/l + symptoms) had lower sensitivity and agreement (κ = 0.623) than the proposed RCBG ≥8.7 mmol/l threshold alone (κ = 0.695). This supports the idea that reliance on subjective symptoms may hinder early detection and should not be required for diagnosis in mass screening.

The diagnostic yield of RCBG was influenced by the timing of confirmatory testing. Same-day confirmatory testing yielded higher RCBG values and higher detection rates of T2DM, suggesting that RCBG is most effective when used during immediate screening encounters. Such operational insights are crucial for designing real-world diabetes screening programs, particularly in community-based settings and primary care units.

In terms of predictive efficiency, RCBG performed better than expected. Our logistic regression analysis showed that RCBG ≥8.7 mmol/l had a stronger association with OGTT-defined T2DM than the conventional ≥11.1 mmol/l cut-off (OR: 8.91 vs. 5.52). This reinforces the clinical relevance of the revised threshold. Furthermore, the NNS for RCBG ≥8.7 mmol/l was 2.74, closely aligning with NNS for FPG (2.86) and 2hPG (2.40), confirming its cost-effectiveness and practical relevance.

Cost analysis is an important consideration in health policy decision-making. RCBG is significantly less expensive (USD 0.18/test) than FPG (USD 2.73/test) or HbA1c (USD 5.46/test). This cost advantage is particularly compelling for LMICs like Bangladesh, where the national health budget per capita is limited. Prior economic analyses, such as those by Marley et al.[29] and Meriggi et al.[30] have also highlighted the economic feasibility of using RCBG for mass screening.

Furthermore, our results support the WHO and IDF's recommendations for opportunistic screening for T2DM using affordable point-of-care tools. This study aligns with the goals of the WHO Global Action Plan for NCDs and provides actionable evidence for countries developing national diabetes screening policies. Our proposed threshold fills a critical evidence gap and presents an opportunity to guide national diabetes screening guidelines in Bangladesh and similar LMICs.

Strengths of our study include a large, nationally representative sample collected from 16 centres across all administrative divisions, ensuring geographic and demographic diversity. The use of

WHO-recommended diagnostic tools (OGTT, HbA1c, and FPG) as gold standards enhances the validity of the findings. Laboratory quality control was ensured through internal and external validation at BADAS laboratories. The systematic random sampling method reduced selection bias, and the standardization of measurements further strengthens the reliability of the data. Additionally, trained clinicians and technicians from BADAS conducted the clinical and anthropometric assessments, contributing to data quality. substantial cost savings. It's worth noting that BADAS operates a comprehensive national diabetes care infrastructure, managing about 60% of diabetic patients in Bangladesh through its network of 130 diabetes centres, 350 accredited sub-district facilities, and 100 diabetes screening corners located in remote villages. This extensive, structured network contributes significantly to standardised clinical practice, quality care, and reliable data collection.[31]

However, this study also has limitations. The data were collected at a single time point, making it a cross-sectional analysis that cannot establish causal relationships. The diagnosis of T2DM was based on a single measurement of OGTT, HbA1c, and RCBG, whereas clinical practice typically requires repeat testing for confirmation. Although the study aimed to determine optimal cut-off values for diabetes diagnostic tools, it did not evaluate the ability of these methods to predict long-term diabetes-related complications. Additionally, individuals with previously diagnosed diabetes or prediabetes were excluded based on self-report. While self-reporting is generally reliable for identifying diagnosed diabetes, it may be less accurate for identifying prediabetes. The study also did not account for metabolic variability, differences in recent food intake, or the inherent fluctuations in capillary blood glucose measurements, which may influence glycemic readings. Furthermore, clinical and anthropometric assessments were conducted only once, without duplicate measurements or a second observer, increasing the potential for measurement error. Although systematic random sampling was applied across all eight administrative divisions, our recruitment exclusively from BADAS centres, which primarily serve individuals aware of their diabetes risk, might have led to overrepresentation of high-risk populations and thus potentially overestimated the diagnostic accuracy and prevalence rates. Consequently, generalising these findings to the broader Bangladeshi population or other healthcare settings should be done

cautiously. Further community-based studies are recommended to confirm and extend these findings to guide policy recommendations.

In conclusion, RCBG may serve as an effective and affordable preliminary diagnostic tool for identifying T2DM, particularly in resource-limited settings. The proposed cut-off of ≥8.7 mmol/l demonstrated improved diagnostic performance compared to the currently used threshold. However, these findings should be interpreted cautiously, and further validation studies are needed to assess long-term clinical outcomes and generalizability to other populations.

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Author contributions

BB contributed to study planning, statistical analysis plan, wrote the statistical methods section, ran the statistical analysis and wrote the manuscript. TS and SBM collected and researched the data and wrote the manuscript. TA, FA, NKQ and ASM drafted sections of the article and contributed to discussion. RI, SP, SUM, RIC, RO, DCR, SRC, SSA, SA, TA contributed to data collection and drafted sections of the article. FP, MAS, HM, MRA, AKAK reviewed/edited the manuscript. BB is the guarantor and accepts full responsibility for the work, had access to the data, and controlled the decision to publish.

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Data availability

Data are available upon reasonable request from BB, the study principal investigator.

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from each participant, and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the

Ethical Review Committee of Diabetic Association of Bangladesh (BADAS) (BADAS-ERC/EC 122100331).

Competing interests

No potential conflict of interest.

Consent for publication

Not applicable.

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Figure 1. STROBE flow diagram of participant recruitment A total of 3,320 individuals were approached across 16 BADAS centres. Following exclusion of 120 individuals, 3,200 participants were enrolled using systematic random sampling (every 2nd eligible patient) and included in the final analysis.

Table 1. Basic characteristics of the study participants by sex

Variable	Total	Male	Female	P value
Number	3200	1520 (47.5%)	1680 (52.5%)	
Age (years)	44.4 (43.9, 44.8)	45.9 (45.3, 46.6)	42.9 (42.3, 43.5)	<0.001
Age, %				<0.001
<30 years	11.1 (10.0, 12.2)	8.6 (7.1, 10.0)	13.5 (11.8, 15.1)	
30-39 years	23.9 (22.4, 25.4)	22.4 (20.3, 24.5)	25.2 (23.2, 27.3)	
40-49 years	29.9 (28.3, 31.5)	30.0 (27.8, 32.3)	29.8 (27.6, 32.0)	
≥50 years	35.1 (33.4, 36.7)	38.9 (36.5, 41.4)	31.5 (29.3, 33.7)	
F/H DM, %	53.3 (51.6, 55.1)	54.6 (52.0, 57.1)	52.3 (49.9, 54.7)	0.198
Leisure time physical activity (<30 min/day)	65.2 (62.9, 67.5)	62.0 (58.6, 65.2)	68.5 (65.3, 71.6)	0.005
Intake of vegetables & fruits (<5 servings/ day)	99.0 (98.5, 99.3)	99.3 (98.5, 99.7)	98..7 (98.0, 99.2)	0.174
BMI (kg/m^2)	25.9 (25.8, 26.1)	25.3 (25.1, 25.5)	26.5 (26.3, 26.7)	<0.001
Obese, %	57.1 (55.3, 58.8)	52.0 (49.4, 54.6)	61.6 (59.2, 64.1)	<0.001
WC (cm)	92.4 (91.9, 92.8)	92.4 (91.9, 93.0)	92.4 (91.8, 92.9)	0.836
Abdominal obesity, %	73.3 (71.8, 74.9)	58.6 (56.1, 61.2)	86.5 (84.9, 88.2)	<0.001
SBP (mmHg)	119.8 (119.3, 120.1)	121.3 (120.6, 121.9)	118.4 (117.8, 119.1)	<0.001
DBP (mmHg)	78.6 (78.3, 78.9)	79.5 (79.1, 79.9)	77.7 (77.3, 78.1)	<0.001
HTN, %	29.8 (28.2, 31.4)	30.5 (28.2, 32.8)	29.2 (27.0, 31.4)	0.436
DM symptom (present), %	63.1 (61.4, 64.8)	61.3 (58.8, 63.8)	64.7 (62.4, 67.0)	0.047
FPG (mmol/l)	7.9 (7.8, 8.1)	8.0 (7.8, 8.2)	7.9 (7.7, 8.1)	0.545
2hPG (mmol/l)	12.5 (12.2, 12.8)	12.6 (12.2, 12.9)	12.5 (12.2, 12.8)	0.682
DM, %	49.5 (47.8, 51.3)	49.6 (47.1, 52.1)	49.5 (47.1, 51.9)	0.937
HbA1c (%)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	7.4 (7.3, 7.5)	0.724
DM (≥6.5%), %	48.9 (47.2, 50.7)	50.0 (47.4, 52.5)	48.0 (45.6, 50.4)	0.273
RCBG (mmol/l)	10.6 (10.4, 10.8)	10.6 (10.3, 10.8)	10.6 (10.3, 10.9)	0.789
DM (≥11.1+ symptom), %	33.2 (31.1, 35.3)	32.7 (29.7, 35.8)	33.6 (30.7, 36.4)	0.704
One NCD RF, %	96.0 (95.3, 96.7)	96.7 (85.8, 97.6)	95.3 (94.3, 96.3)	0.042

Data are presented as mean (95% confidence interval) and percentage (95% confidence interval) as needed. (Abbreviation: DM, diabetes mellitus; F/H, family history; BMI, body mass index; WC, waist circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure; HTN, hypertension; FPG, fasting plasma glucose; 2hPG, 2 hours after plasma glucose, HbA1c, glycated hemoglobin; RCBG, random capillary blood glucose; NCD RF, non-communicable disease risk factors obese, BMI ≥25 kg/m^2; abdominal obesity, WC- male ≥90 cm or female ≥80 cm; NCD RF, including smoking, physical inactivity, consume <5 servings of vegetables and fruits daily, obese, diabetes and hypertension.

Table 2. Correlation (P values) between RCBG, FBG, 2hAG, and HbA1c.

	RCBG (mmol/l)	FPG (mmol/l)	2hAG (mmol/l)	HbA1c %
RCBG (mmol/l)	1	0.828 (<0.001)	0.840 (<0.001)	0.826 (<0.001)
FPG (mmol/l)	0.828 (<0.001)	1	0.900 (<0.001)	0.880 (<0.001)
2hPG (mmol/l)	0.840 (<0.001)	0.900 (<0.001)	1	0.865 (<0.001)
HbA1c %	0.826 (<0.001)	0.880 (<0.001)	0.865 (<0.001)	1

Abbreviation: RCBG, Random capillary blood glucose; FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin.

Table 3. Comparison of diagnostic performance of FPG, 2hPG, HbA1c, and RCBG (both proposed and currently used cut-off point) to diagnose T2DM.

	SN (%)	SP (%)	PPV (%)	NPV (%)	Diagnosis (%)	Accuracy (%)	Agreement (k)	NNS
FPG (≥7 mmol/l)	84	100	100	86.4	41.6	92.1	0.841	2.86
2hPG (≥11.1 mmol/l)	91.7	100	100	92.4	45.4	95.9	0.917	2.40
HbA1c (≥6.5%)	86.8	88.6	88.3	87.2	48.9	87.7	0.755	2.36
RCBG (≥11.1 mmol/l)	63.1	97.8	96.6	73.0	32.3	80.6	0.611	4.91
RCBG (≥11.1 mmol/l) + typical symptom	64.4	97.9	96.8	73.4	33.2	81.2	0.623	4.68
RCBG (≥8.7 mmol/l)	80.4	89.0	87.7	82.3	45.4	84.7	0.695	2.74
RCBG (≥8.7 mmol/l) + typical symptom	79.6	88.1	87.0	81.3	45.6	83.9	0.677	2.76

Abbreviation: FPG, fasting plasma glucose; 2hPG, 2 hours plasma glucose; HbA1c, glycated hemoglobin; RCBG, Random capillary blood glucose; SN, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value; k, kappa statistics.; NNS, number needed to be screening

Figure 2. Bland-Altman plots showing the agreement between random capillary blood glucose (RCBG) and (A) fasting plasma glucose (FPG), (B) 2-hour plasma glucose (2hPG), and (C) glycated hemoglobin (HbA1c).

Figure 3. Diagnostic performance of random capillary blood glucose (RCBG) in comparison to fasting plasma glucose (FPG), 2-hour plasma glucose (2hPG), and glycated hemoglobin (HbA1c) for diagnosing diabetes.

Figure 4. Comparison of random capillary blood glucose (RCBG) levels in participants with and without symptoms, measured at different time points (same day vs. next day).

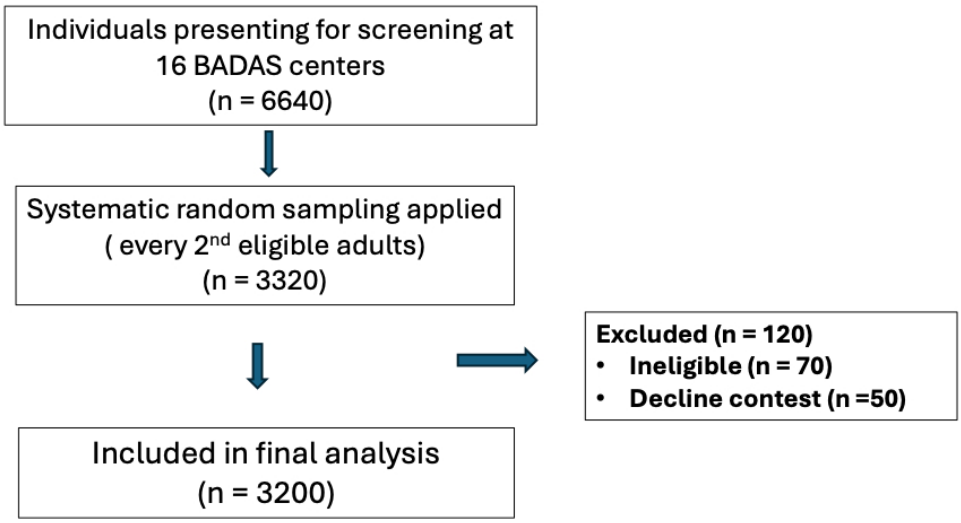

Figure 1. STROBE flow diagram of participant recruitment A total of 3,320 individuals were approached across 16 BADAS centres. Following exclusion of 120 individuals, 3,200 participants were enrolled using systematic random sampling (every 2nd eligible patient) and included in the final analysis.

311x174mm (72 x 72 DPI)

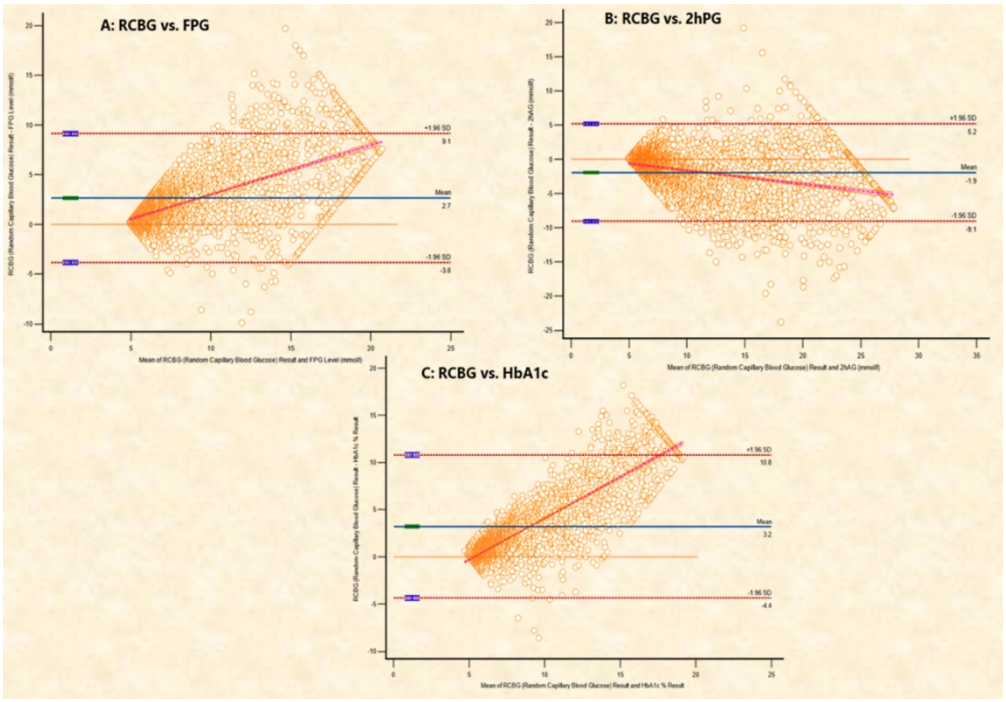

Figure 2. Bland-Altman plots showing the agreement between random capillary blood glucose (RCBG) and (A) fasting plasma glucose (FPG), (B) 2-hour plasma glucose (2hPG), and (C) glycated hemoglobin (HbA1c).

551x382mm (59 x 59 DPI)

Figure 2A. Receiver operating characteristics (ROC) curve of random capillary blood glucose (RCBG) to diagnose diabetes.

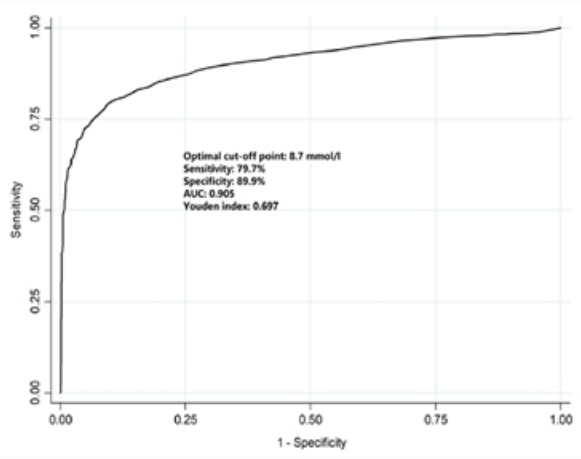

Figure 2B. The area under the receiver operating characteristics (ROC) curves of fasting plasma glucose (FPG), 2 hours plasma glucose (2hPG), glycated hemoglobin (HbA1c), and random capillary blood glucose (RCBG) to diagnose diabetes.

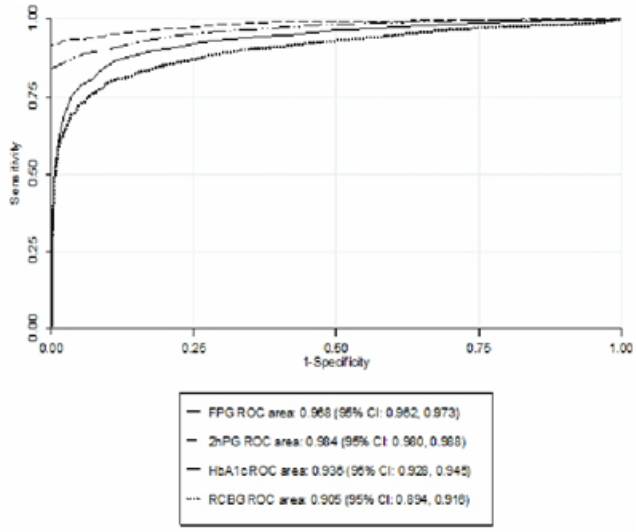

Figure 3. Diagnostic performance of random capillary blood glucose (RCBG) in comparison to fasting plasma glucose (FPG), 2-hour plasma glucose (2hPG), and glycated hemoglobin (HbA1c) for diagnosing diabetes.

405x501mm (38 x 38 DPI)

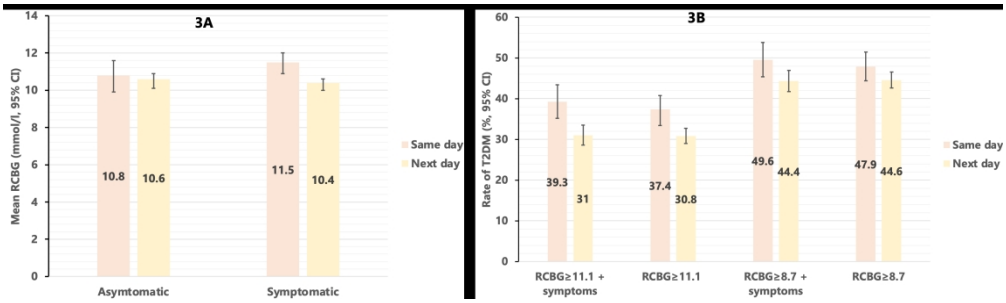

Figure 4. Comparison of random capillary blood glucose (RCBG) levels in participants with and without symptoms, measured at different time points (same day vs. next day).

338x99mm (330 x 330 DPI)