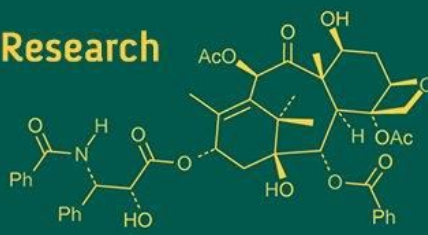
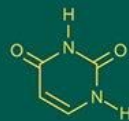
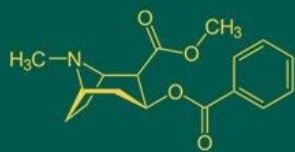


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Evaluation of diagnostic procedures of Dysglycemia: A study in a tertiary care hospital in Bangladesh

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Abstract

Dysglycemia, which includes impaired glucose tolerance, impaired fasting glucose, and diabetes mellitus, is an increasing global health issue, especially in developing countries like Bangladesh. Early and precise diagnosis is crucial for preventing complications and ensuring timely intervention. Diagnostic methods such as fasting blood glucose, oral glucose tolerance tests, and HbA1c levels are widely used, offering specific benefits and drawbacks. This study aimed to evaluate the diagnostic procedures for dysglycemia.

Methods: This cross-sectional study was conducted at the Department of Biochemistry and Molecular Biology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from March 2019 to February 2020. A total of 1,165 individuals attending the Endocrinology Outpatient Department at BSMMU for dysglycemia (prediabetes and diabetes) screening were enrolled using non-probability sampling. Data analysis was performed using SPSS version 23.0.

Results: This study assessed diabetes and prediabetes using ADA criteria. Prevalence of diabetes was 21.2% (2hPG), 15.9% (FPG), and 23.3% (HbA1C), with prediabetes rates of 28.4% (FPG), 24.5% (2hPG), and 37.8% (HbA1C). No significant difference between 2hPG and HbA1C was found, but FPG underestimated diabetes. Concordance among tools was 12.4%, and the highest detection rate (25.6%) occurred with 2hPG and HbA1C. Age-influenced diagnosis and good agreement were found among FPG, 2hPG, and HbA1C. FPG showed lower sensitivity but similar specificity to HbA1C.

Conclusion: This study highlights the variability in dysglycemia diagnostics, with HbA1C and 2hPG showing higher detection rates than FPG, which underestimates diabetes. Age influences diagnosis, and good agreement among FPG, 2hPG, and HbA1C emphasizes the need for careful diagnostic consideration.

Keywords: Diabetes mellitus, Dysglycemia, Fasting plasma glucose, FPG, Hemoglobin, HbA1C

1. Introduction

Diabetes mellitus (DM) poses a significant global health burden, affecting 451 million adults (8.8%) worldwide, with projections reaching 693 million (9.9%) by 2045 [1]. The Asia-Pacific region, a hotspot for diabetes, is impacted by rapid economic growth and sedentary lifestyles [2]. Dysglycemia, encompassing diabetes and prediabetes, is characterized by hyperglycemia linked to an increased risk of diabetic retinopathy, cardiovascular disease, and metabolic syndrome [3]. Prediabetes includes impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or elevated HbA1c levels [4]. Up to 70% of individuals with prediabetes progress to overt diabetes over their lifetime. Annual diabetes incidence varies, with rates of 6-9% in isolated IFG, 4-6% in isolated IGT, and 15-19% in combined IFG-IGT cases. HbA1c levels of 5.7-6.4% indicate a 7.5-year diabetes risk [5]. Late diagnosis, poor follow-up, and noncompliance may exacerbate the diabetes burden in this region [6]. Previously, dysglycemia diagnosis relied on FPG and 2-hour post-load plasma glucose (2hPG) via OGTT. Despite its sensitivity, this approach is limited by poor reproducibility and fasting requirements [7]. A meta-analysis of 96 population studies revealed HbA1c's sensitivity and specificity for diabetes detection as 30.5% and 99.7%, respectively, compared to FPG and 2hPG [8]. Statistically significant differences were observed among FPG, 2hPG, and HbA1c as diagnostic tools.

The diagnostic sensitivity was highest for HbA1c (69.6%), followed by 2hPG (64.2%), and FPG (43.2%) [9]. A community-based study in high-risk Thai participants reported dysglycemia in 51% of individuals, with diabetes prevalence determined by 2hPG being twice as high as that by FPG (11.0% vs. 5.4%) [10]. Early diabetes detection is essential for timely management and complication prevention [11, 12]. The American Diabetes Association (ADA) defines diabetes as $\text{FPG} \geq 126 \text{ mg/dL}$, $2\text{hPG} \geq 200 \text{ mg/dL}$, or $\text{HbA1c} \geq 6.5\%$ [12]. The ADA guidelines recommend repeating the same test for confirmation if only one of two diagnostic tests is above the cut-off, rather than conducting an additional test [12]. Currently, no method reliably ensures early detection of undiagnosed diabetes. While FPG and 2hPG are widely used for identifying at-risk individuals, many diabetic patients do not meet these criteria and remain undiagnosed. Such cases could be detected using OGTT-derived 2hPG [13]. Moreover, a recent study highlighted that HbA1c has a limited capacity to identify diabetes compared to 2hPG and FPG at current cut-points [14]. However, HbA1c offers practical advantages: it is standardized, exhibits low intra-individual variability, requires no fasting or preparation, and remains stable at room temperature post-collection. A cross-sectional study of 512 subjects reported normal glucose tolerance in 43.0% of participants, impaired glucose tolerance in 37.3%, and diabetes in 19.7%. The prevalence of diabetes using 2hPG was nearly double that identified by HbA1c (19.7% vs. 11.1%), with poor agreement between prediabetes and diabetes classifications defined by 2hPG and HbA1c [15]. Similar discordance has been observed in other Asian studies, suggesting that many diabetes cases may be missed when relying solely on HbA1c compared to 2hPG from OGTT [8]. This highlights the need for further investigation into the use of HbA1c for identifying prediabetes in the Asia Pacific region to enhance early dysglycemia detection. Further research is essential to determine optimal HbA1c cut-off points for diagnosing diabetes in high-risk Southeast Asian populations [15]. Discordance between diagnostic criteria was most evident in diabetes and prediabetes categories, with minimal differences in the normal group. Among those identified as diabetic by HbA1c, only 59% were confirmed by FPG, while 95% of those classified as normal by HbA1c were similarly categorized by FPG [7]. Overall, HbA1c detected more individuals at risk for diabetes than FPG. A cross-sectional study of 1113 adults found that 259 participants met at least one DM criterion (FPG, HbA1c, or 2hPG). Diabetes prevalence was 2.7% by FPG, 5.0% by HbA1c, and 22.5% by 2hPG, with a total of 23.3% classified as diabetic by any of these methods [15]. A cohort study of 1241 overweight and obese individuals revealed a prediabetes prevalence of 46.8% and newly diagnosed diabetes in 11.9% based on ADA criteria. Using HbA1c alone, 78 subjects were identified as diabetic, but 47.3% of newly diagnosed cases would have been missed without 2hPG testing. Among 581 prediabetic subjects, 1.4% had isolated IFG, 30.5% had IGT, 5.1% had combined IFG and IGT, and 9.8% had isolated elevated HbA1c. Notably, 44.2% of prediabetes cases ($\text{HbA1c} < 5.7\%$) would have been missed without 2hPG [8]. The study highlights the superior sensitivity of 2hPG in diagnosing diabetes, identifying more cases than FPG or

HbA1c [16]. Despite HbA1c's limitations, its role as a single screening tool remains uncertain. Combining multiple tests does not notably enhance diabetes detection, and relying solely on one test is inadequate for a thorough evaluation of dysglycemia [16].

2. Methodology

This cross-sectional study was conducted at the Department of Biochemistry & Molecular Biology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, from March 2019 to February 2020. A total of 1165 individuals attending the outpatient department of Endocrinology, BSMMU, for dysglycemia screening (prediabetes and diabetes) were included. Non-probability sampling was used for sample selection. The study received approval from the ethical committee of the hospital. This study included patients aged 20-75 years, of both genders, suspected to have dysglycemia based on a history of polydipsia, polyuria, polyphagia, family history of type 2 diabetes in first-degree relatives, history of gestational diabetes, obesity ($\text{BMI} \geq 30 \text{ kg/m}^2$), history of PCOS in females, and sudden weight loss or gain. Exclusion criteria comprised of patients with diagnosed diabetes mellitus, elevated SGPT (hepatic impairment), high serum creatinine (renal impairment), known thyroid, growth hormone, or adrenal disorders, anemia, hemoglobinopathies, $\text{BMI} < 18.5 \text{ kg/m}^2$, pregnancy, malignancy, acute or chronic infection, or a history of gastric bypass surgery. Data were analyzed using SPSS version 23.0.

3. Results

In this study, diabetes and prediabetes were defined according to the ADA criteria. The prevalence of diabetes was found to be 21.2% based on 2hPG, 15.9% based on FPG, and 23.3% based on HbA1c. Regarding prediabetes, the prevalence was 28.4% based on FPG, 24.5% based on 2hPG, and 37.8% based on HbA1c. Proportion tests revealed no significant difference between 2hPG and HbA1c in detecting diabetes mellitus. However, FPG significantly underestimated the frequency of diabetes mellitus compared to both 2hPG and HbA1c. Concordance among the three diagnostic tools for detecting diabetes mellitus occurred in only 12.4% of cases. The highest number of diabetic patients was detected using the combination of 2hPG and HbA1c (25.6%). However, when FPG was added to this combination, the detection rate dropped significantly to 12.4%. The frequency of diabetes detected using all three diagnostic tools was significantly different from that detected using any two diagnostic tools. Moreover, all three diagnostic tools identified more diabetic patients with increasing age, with a sharp contrast in detection between individuals below and above 40 years of age. Age was found to be a significant independent variable influencing the diagnosis of diabetes mellitus across all diagnostic tools (FPG, 2hPG, and HbA1c). The Kappa test indicated a moderate level of agreement between FPG and 2hPG (Kappa value 0.64) and between HbA1c and 2hPG (Kappa value 0.65) for diagnosing diabetes mellitus. Both values suggest a good agreement, though not classified as very good or excellent. Additionally, FPG showed less sensitivity compared to HbA1c. The specificity and accuracy of both FPG and HbA1c were approximately similar.

Table 1: Distribution of prediabetes and DM determined by three diagnostic tests.

Test	Diabetic		Prediabetic		Non-diabetic		Total
	n	%	n	%	n	%	
FPG (mmol/L)	185	15.9%	331	28.4%	649	55.7%	1165
2 hPG (mmol/L)	247	21.2%	286	24.5%	632	54.2%	
HbA1C	271	23.3%	440	37.8%	454	39%	

FPG: Fasting Plasma Glucose, **2hPG:** Two-hour plasma glucose after oral glucose load, **HbA1C:** Hemoglobin A1C

Table 2: Comparison of the frequency of DM determined by three diagnostic tools.

Diagnostic tools	P-Value
FPG (15.9%) vs 2hPG (21.2%)	<0.05
2hPG (21.2%) vs HbA1C (23.3%)	>0.05
FPG (15.9%) vs HbA1C (23.3%)	<0.05

Table 3: Concordance and discordance of three diagnostic tools in the diagnosis of DM

Tools	Concordance		Discordance	
	N	%	N	%
FPG (≥ 7.0 mmol/l) + 2hPG (≥ 11.1 mmol/l) + HbA1C (≥ 6.5 %)	144	12.40%	1021	87.60%

Table 4: Comparative picture of concordance and discordance of three diagnostic tools in the diagnosis of DM.

Different combinations of tools	N	%
FPG (≥ 7.0 mmol/l) + 2hPG (≥ 11.1 mmol/l) + HbA1C (≥ 6.5 %)	144	12.40%
FPG (≥ 7.0 mmol/l) + 2hPG (≥ 11.1 mmol/l)	212	18.20%
2hPG (≥ 11.1 mmol/l) + HbA1C (≥ 6.5 %)	298	25.60%
FPG (≥ 7.0 mmol/l) + HbA1C (≥ 6.5 %)	236	20.30%

Table 5: Comparison of DM detection rates with different combinations of FPG, 2hPG, and HbA1C.

Different Combination of 3 Diagnostic Tools	P-Value
FPG+2hPG+HbA1C (12.4%) vs FPG+2hPG (18.2%)	<0.05
FPG+2hPG+HbA1C (12.4%) vs 2hrPG+ HbA1C (25.6%)	<0.05
FPG+2hPG+HbA1C (12.4%) vs FPG+HbA1C (20.3%)	<0.05
2hPG+ HbA1C (25.6%) vs FPG+HbA1C (20.3%)	<0.05
2hPG+ HbA1C (25.6%) vs FPG+2hrPG (18.2%)	<0.05
2hPG+ FPG (18.2%) vs FPG+HbA1C (20.3%)	>0.05

Table 6: Frequency of DM determined by three diagnostic tools in different age groups

Test	Different age group							
	<30 years		30-40 years		40-50 years		>50 years	
	(N=320)		(N=384)		(N=270)		(N=191)	
	N	%	N	%	N	%	N	%
FPG	22	6.90%	51	13.30%	61	22.60%	51	26.70%
2hPG	29	9.10%	74	19.30%	81	30%	63	33.00%
HbA1C	27	8.40%	86	22.40%	93	34.40%	65	34.00%

Table 14: Comparative Picture of the performance of FPG & HbA1C for diagnosis of DM compared to 2hPG.

Test	Sensitivity	Specificity	Accuracy	PPV	NPV	LR+	LR-
FPG	61.54%	96.41%	89.01%	82.16%	90.31%	17.12%	0.40%
HbA1C	77.70%	91.90%	88.40%	70.80%	93.80%	9.00%	0.24%

Table 15: Receiver operating characteristic curve showing performance of FPG for diagnosis of DM.

Test	Gold Standard	AUC
FPG	2hPG after oral glucose load	0.92

Table 7: The frequency of diabetes determined by the three diagnostic tools differed between males and females.

Test	DM in male		DM in female	
	(N=420)		(N=745)	
	N	%	N	%
FPG (mmol/L)	126	30%	205	27.50%
2 hPG (mmol/L)	101	24%	193	25.90%
HbA1C (%)	150	35.70%	290	38.90%

Table 8: Binary logistic regression of predictors influencing diagnosis of DM by FPG.

Variables	P-Value	Exp. (B)	95% CI
Age	<0.05	1.658	1.417-1.942
Sex	>0.05	0.75	0.539-1.044

Table 9: Binary logistic regression of predictors influencing diagnosis of DM by 2hPG.

Variables	P-Value	Exp. (B)	95% CI
Age	<0.05	1.651	1.434-1.902
Sex	>0.05	0.825	0.612-1.111

Table 10: Binary Logistic Regression of predictors influencing diagnosis of DM by HbA1C.

Variables	P-Value	Exp. (B)	95% CI
Age	<0.05	1.68	1.464-1.928
Sex	>0.05	0.784	0.587-1.048

Table 11: Agreement between FPG and 2hPG (OGTT) in the diagnosis of DM.

FPG	Glycemic status (2hPG)		Total	Kappa value
	Diabetic	Non-diabetic		
Diabetic	152 (a)	33(b)	185	0.64
Non-diabetic	95 (c)	885(d)	980	
Total	247	918	1165	

Table 12: Agreement between HbA1C and 2hPG in diagnosis of DM.

HbA1c	Glycemic status (2 hPG)		Total	Kappa value
	Diabetic	Non-diabetic		
Diabetic	192 (a)	79(b)	271	0.65
Non-diabetic	55(c)	839(d)	894	
Total	247	918	1165	

Table 13: Agreement between HbA1C and FPG in the diagnosis of DM.

HbA1c	Glycemic status (FPG)		Total	Kappa value
	Diabetic	Non-diabetic		
Diabetic	164 (a)	107(b)	271	0.65
Non-diabetic	21(c)	873(d)	894	
Total	185	980	1165	

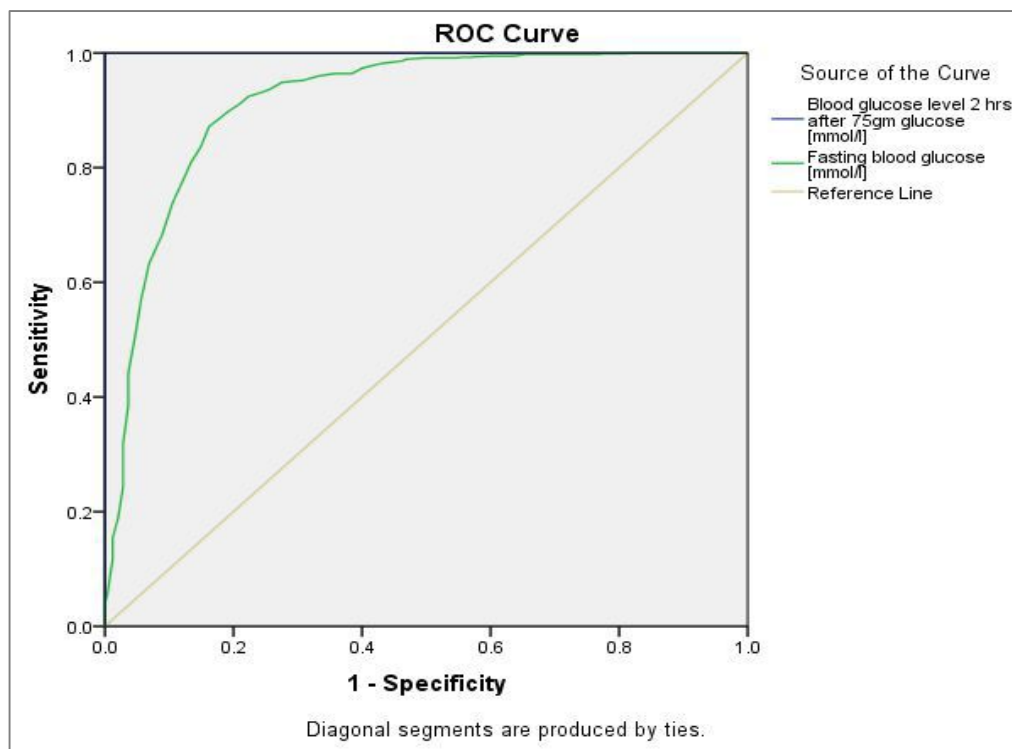


Fig 1: Receiver operating characteristic curve showing performance of FPG for diagnosis of DM

Table 16: Receiver operating characteristic curve showing performance of HbA1C for diagnosis of DM.

Test	Gold standard	AUC
HbA1C	2hPG after oral glucose load	0.92

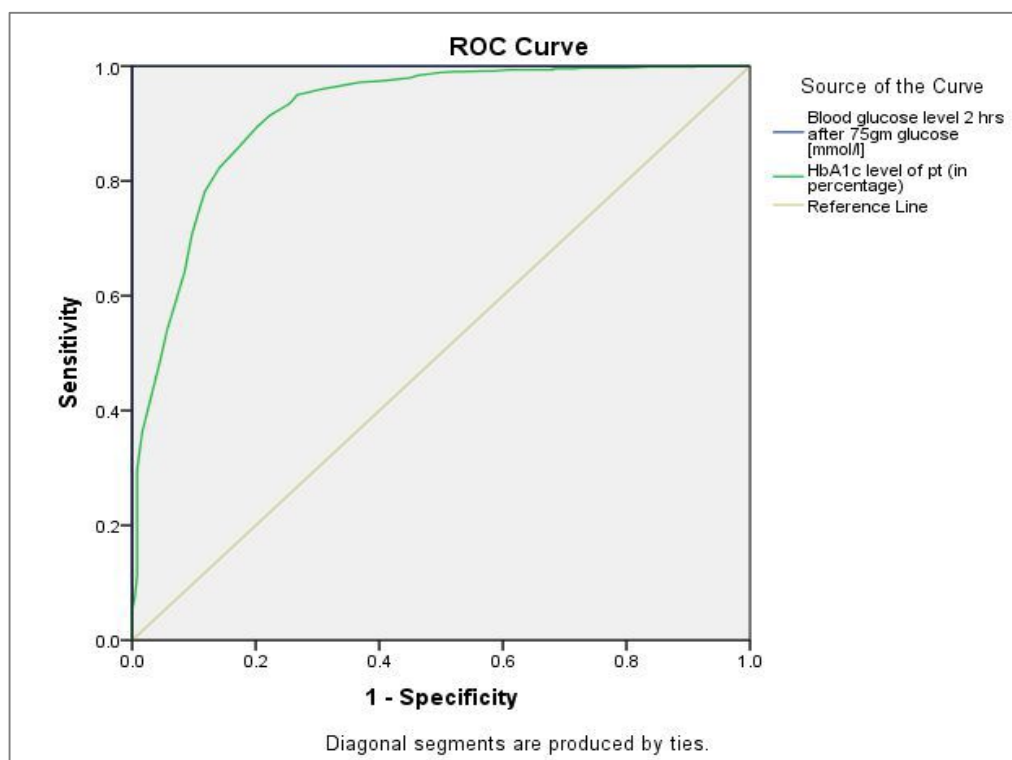


Fig 2: Receiver operating characteristic curve showing performance of HbA1C for diagnosis of DM.

4. Discussion

This study aimed to evaluate the prevalence and diagnostic accuracy of diabetes mellitus using three common diagnostic tools: FPG, 2-hour post load plasma glucose (2hPG), and HbA1C, based on the American Diabetes Association (ADA) criteria. The results highlighted differences in the detection

rates of diabetes across these tools and their varying diagnostic reliability. The study found that the prevalence of diabetes was highest when measured by HbA1C (23.3%), followed by 2hPG (21.2%), and lowest with FPG (15.9%). These results are in agreement with several studies that suggest HbA1C may detect a higher proportion of diabetes

cases compared to FPG^[17], which could be due to HbA1C's ability to reflect long-term glycemic control, unlike FPG, which measures a single point in time^[18]. In contrast, the use of FPG as a screening tool significantly underestimated the prevalence of diabetes compared to both 2hPG and HbA1C, as demonstrated by the lower detection rates with FPG. This finding is consistent with other research indicating that FPG has lower sensitivity in diagnosing diabetes, especially when compared to HbA1C and 2hPG^[19]. Regarding prediabetes, a higher prevalence was observed using HbA1C (37.8%), followed by FPG (28.4%) and 2hPG (24.5%). The disparity in prediabetes detection is aligned with previous studies suggesting that HbA1C may capture more individuals at risk for developing diabetes due to its broader criteria for impaired glucose regulation^[20]. Furthermore, the study revealed that combining 2hPG and HbA1C detected the most diabetic cases (25.6%), underscoring the utility of using multiple diagnostic methods for a more accurate diagnosis, as supported by prior research advocating a combined approach for better diagnostic sensitivity^[21]. However, the addition of FPG to this combination led to a notable reduction in the detection rate (12.4%), highlighting FPG's relatively lower diagnostic capacity in comparison to the other methods. The low concordance rate of 12.4% among all three diagnostic tests suggests that no single test is fully reliable in detecting diabetes mellitus, supporting the recommendation for using a combination of tests for a more comprehensive assessment of glucose metabolism disorders^[22]. The finding that the diagnostic tools were more effective in detecting diabetes in older individuals, particularly those above 40 years of age, emphasizes the importance of considering age as a critical factor in the diagnosis of diabetes^[23]. Age-related differences in insulin sensitivity and glucose tolerance likely explain this trend, as older adults are at a higher risk for developing diabetes. The good agreement between FPG and 2hPG (Kappa value 0.64) and between HbA1C and 2hPG (Kappa value 0.65) suggests that these diagnostic tests provide similar results but are not perfectly aligned. These findings are consistent with studies that report good agreement between different diagnostic tools for diabetes diagnosis^[24]. The relatively lower sensitivity of FPG further supports its limitations in accurately identifying diabetes, especially when compared to HbA1C, which has better diagnostic sensitivity and is widely used for monitoring long-term glycemic control^[25]. However, the specificity and accuracy of FPG and HbA1C were similar, which indicates that while both tests are reliable, HbA1C may be a more comprehensive tool for diagnosing and monitoring diabetes. Overall, this study highlights the complexities of diagnosing diabetes and the varying effectiveness of different diagnostic tools. While HbA1C appears to be the most reliable tool for detecting diabetes, combining multiple tests may provide the best diagnostic accuracy, especially in populations at higher risk. The findings also underscore the importance of considering factors such as age and the limitations of FPG in clinical decision-making regarding diabetes diagnosis and management.

5. Conclusion & Recommendation

Based on these findings, the study highlights the variability in diagnostic procedures for dysglycemia, with HbA1C and 2hPG providing higher detection rates compared to FPG. While FPG significantly underestimates diabetes prevalence, 2hPG and HbA1C show better concordance in identifying

diabetic patients. Age is a significant factor influencing diagnosis across all diagnostic tools. The good agreement among FPG, 2hPG, and HbA1C suggests the need for careful consideration of diagnostic criteria in identifying dysglycemia, especially in different age groups.

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7. Conflict of interest

None declared.

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