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RESEARCH PAPER

# Role of Fasting Plasma Glucose, 2-hour Post Load Plasma Glucose and Glycated Hemoglobin to Diagnose Diabetes Mellitus Among Bangladeshi Adults Attending a Tertiary Care Hospital: Concordance and Discordance

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## Abstract

**Background:** Diabetes mellitus (DM) and its associated complication is getting a big concern day by day around the whole world including Bangladesh. Fasting plasma glucose (FPG),2hour post load plasma glucose (2hPG) and glycated hemoglobin (HbA1C) are commonly used diagnostic tools to diagnose diabetes mellitus (DM) but there is disparity and discordance among these three diagnostic tools in detection of DM.

**Objective:** The aim was to address the issue of concordance and discordance among the three diagnostic tools (FPG, 2hPG,HbA1C) in detection of diabetes mellitus.

**Method :**This cross sectional analytical study was conducted among the individuals attending for screening of diabetes mellitus to outpatient department of endocrinology, Bangladesh Medical University (BMU), Dhaka during the period of March 2019 to February 2020.A total 1165 subjects were recruited by non-probability sampling technique. Individuals were identified as diabetic by positivity of any of the three tools (FPG,2hPG and HbA1C) and individuals were regarded as nondiabetic by negativity of all three tools simultaneously. Frequency of diabetes mellitus detected by these three tools were compared among them to determine their concordance(agreement) or discordance(disagreement) by Kappa test. Data were analyzed using SPSS.

**Results:** This study shows that; out of 1165 study subjects, 339(29%) were diabetic by any tool positivity and 826(71%) were non diabetic by all three tools negativity. The frequency of diabetes was found 15.9% detected by FPG, 21.2% detected by 2hPG and 23.2% detected by HbA1C. Here, 2hPG and HbA1C detected almost similar number of diabetic population but FPG underestimates the diagnosis of DM significantly. In agreement test, all three diagnostic tools showed merely good agreement with the lowest kappa value, which was not satisfactory from clinical point of view. In case of missed diagnosis; FPG alone missed 45.5%, 2hPG 27.0% and HbA1c 20.0% of diabetic patients. The rate of missed diagnosis by HbA1c found to be lowest.

**Conclusions:** DM detection rate was found highest by use of HbA1C and lowest by FPG; on the other hand, FPG showed highest missed diagnosis and HbA1C showed the lowest. No clinically satisfactory agreement (concordance) was found among the three diagnostic tools (FPG,2hPG and HbA1C) for diagnosis of DM.

**Key Words:** Diabetes mellitus, Fasting plasma glucose, 2hour post load plasma glucose, HbA1C, Concordance, Discordance.

## Introduction

Diabetes mellitus (DM) and its associated morbidity and mortality are increasingly becoming a serious burden for society in developed as well as developing countries. Diabetes Mellitus (DM) is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Previously, fasting plasma glucose (FPG)and 2 hour post load plasma glucose (2hPG) derived from oral glucose tolerance test (OGTT) were used as a criterion for diagnosis of diabetes mellitus. In recent years, glycated hemoglobin (HbA1C), has been recommended as a tool for the diagnosis and treatment monitoring of diabetes mellitus. The results

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of a single test could be misleading due to a number of factors such as reproducibility of the test, ethnicity, hemoglobinopathies, red blood cell turnover. So, physicians has taken this issue into account and recommend that when two tests are performed and just one is above the cut-off point, the same test should be repeated to confirm the diagnoses, rather than performing an additional screening test.[1] As HbA1C level can be determined with a single blood sample, it has practical advantages and is less burdensome.[2] A number of studies on various ethnic populations report that, screening based on the HbA1C level may lead to the identification of fewer new cases of diabetes and prediabetes than screening with the OGTT derived 2hPG.[3,4] Discordance between HbA1C and 2hPG were consistent with other studies in Asian population. These studies indicated that a substantial number of diabetes cases would be missed by using the HbA1C test alone compared with OGTT based 2hPG.[5-8] Among those with diabetes detected by HbA1C criteria, only 59% were classified as having diabetes by FPG criteria. However, among the normal group detected by HbA1C criteria, 95% were also normal by FPG criteria. Thus, overall, HbA1C identified more people at risk of diabetes than did FPG.[9] 2hPG appears to be the most sensitive test for diagnosing DM as it detects significantly more cases than FPG or HbA1C.[10] The combination of two or three tests do not increase the detection of new cases of DM; on the other hand a single test can't appropriately evaluate the whole dysglycemic population.[10] So, our aim was to evaluate the degree of similarity (concordance) or disparity (discordance) among the three diagnostic tools used for diagnosis of DM in our population.

## Materials and Methods

This cross sectional analytical study was conducted from March 2019 to February 2020 at the Department of Biochemistry and Molecular Biology, Bangladesh Medical University (BMU), Dhaka, Bangladesh.The study was conducted on 1165 subjects ( 420 male,745 female). Individuals aging between 20-75years, who were suspected to have diabetes mellitus according to history (like history of polydipsia, polyuria, polyphagia, family history of type 2 diabetes in first degree relatives , history of gestational diabetes, sudden weight loss etc) were selected by non-probability sampling technique from endocrinology outpatient department, Bangladesh Medical University (BMU). Purpose and procedure of the study was explained in detail , informed written consent was taken from all the study subjects before collection of blood samples and prepared for oral glucose tolerance test. Subjects were instructed to take unrestricted carbohydrate diet (minimum 150-200 gm/day) for 3 days prior to the test. After taking drug history they were instructed to avoid the drugs affecting blood glucose level (e.g. ß blocker, OCP) & also to avoid smoking & exercise before the test. Finally they were advised to have overnight fasting (8-10hrs) before the day of test. After previous day overnight fasting every study subject were advised to come in the next morning by 8 AM. Fasting blood sample was collected for estimation of FPG & HbA1C. Then subjects were allowed to take glucose load 75gm with 300 ml of water. After 2hrs of this glucose load intake, another blood sample was taken to estimate the 2hPG. Exclusion criteria were diagnosed case of DM, high SGPT, high serum creatinine ,known thyroid, adrenal and growth hormone disorder, anaemia, hemoglobinopathies, BMI<18.5 kg/m², pregnancy, lactation , malignancy, acute or chronic infection, gastric bypass surgery. FPG, 2hPG and HbA1C were done in all study subjects to detect diabetic individuals according to the American Diabetic Association (ADA) criteria.[FPG ≥7.0 mmol/L, 2hPG ≥11.1 mmol/L or HbA1C ≥6.5%].[1] An individual was regarded diabetic if any of the three diagnostic tool (FPG, 2hPG, HbA1C) found positive and nondiabetic if all the three diagnostic tool found negative simultaneously. To determine concordance and discordance among the three diagnostic tools for diagnosis of DM; Kohen's Kappa test was done. Data was analyzed with the help of Software Statistical Package for Social Sciences (SPSS).

## Results

In this study , out of 1165 study subjects 339(29%) patients were found to be diabetic by any tool positivity and 826(71%) patients were found non diabetic by all three tools negativity. The prevalence of diabetes based on 2hPG, was 21.2%; based on FPG was15.9% and based on HbA1C was 23.2% (table I).

**Table I:** Frequency of diabetes mellitus determined by three diagnostic tools in total study population (N=1165)

| Diagnostic tool positivity | Diabetic n(%) | Nondiabetic n(%) |
|---|---|---|
| Any of the three tools (FPG, 2 hPG, HbA1C) | 339(29%) | 826 (71.00) |
| FPG | 185(15.9) | 980(84.1) |
| 2 hPG | 247(21.2) | 918(78.8) |
| HbA1C | 271(23.2) | 894(76.8) |

Here, HbA1C detects more diabetic population than two other tools.

**Table II:** Agreement between FPG and 2hPG in diagnosis of diabetes mellitus (N=1165)

| 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 | |

Kappa value for FPG and 2 hr PG was found 0.64.Though it indicates good agreement between fasting plasma glucose (FPG) and 2h PG (OGTT) in diagnosis of DM but the kappa value 0.64 was in the lower range of good agreement. It is neither very good nor excellent from clinical aspect (table II).

Kappa value for HbA1C and 2hPG was found 0.65. Though it indicates good agreement between HbA1C and 2hPG (OGTT) in diagnosis of DM but the kappa value 0.65 was in the lower range of good agreement. It is neither very good nor excellent from clinical aspect (table IIII).

Kappa value for HbA1C and FPG was found 0.65. Though it indicates good agreement between fasting plasma glucose (FPG) and HbA1C in diagnosis of DM but the kappa value 0.65 was in the lower range of good agreement. It is neither very good nor excellent from clinical aspect (Table IV).

Among 1165 study subjects 339(29%) patients were found to be diabetic by any tool positivity. FPG alone

**Table III:** Agreement between HbA1C and 2hPG in diagnosis of diabetes mellitus (N=1165)

| HbA1C | Glycemic status (2hPG) | | 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 IV:** Agreement between HbA1C and FPG in diagnosis of diabetes mellitus (N=1165)

| 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 | |

**Table V:** Missed diagnosis by the individual diagnostic tool among the total 339 diabetic patients (detected by any tool positivity)

| Diagnostic Tool | DM detected | Number of missed diagnosis | Frequency of missed diagnosis |
|---|---|---|---|
| FPG | 185 | 154(339–185) | 45.4% |
| 2hPG | 247 | 92(339–247) | 27.0% |
| HbA1C | 271 | 68(339–271) | 20.0% |

*Data shows multiple response.

missed 45.4% diabetic patients. 2hPG alone missed 27.0% and HbA1C alone missed 20.0% of diabetic patients. So, in this regard FPG seems to show lowest performance (Table V).

## Discussion

This study mainly focused on assessing the agreement and disagreement among the currently recommended diagnostic tools, used for diagnosis of diabetes. In this study, among 1165 study subjects, FPG, 2hPG and HbA1C detected 15.9%, 21.2% and 23.2% diabetic population respectively. Here, 2hPG and HbA1C detected almost similar number of diabetic population but FPG underestimates this diagnosis significantly compared to 2hPG and HbA1C. The International Expert Committee (2009) stated that prevalence of diabetes in some populations may not be same when diagnosis is based on HbA1C compared with diagnosis with glucose measurements.[11] A study containing large cohort of 8696 population, found 291 (3.3%) diabetes mellitus detected by 2hPG and 502 (5.8%) diabetes mellitus identified by HbA1C.[12] Another study found that, among 1190 participants prevalence of diabetes was 12.9% based on 2hPG, 11.9% based on FPG and 13.1% based on HbA1C.[13] This result also depicts that 2hPG and HbA1C detect almost same amount of diabetic population. Ho-Pham et al. (2017) found discordance between HbA1C and FPG in the diagnosis of diabetes.[10] This observation has also been noted in other Asian populations and African population , but not in US adults.[14-18] FPG as a diagnostic tool identified only 15.9% study population as diabetic in our study. Theoretically, FPG and HbA1C provide different information about glycemic status. It is, therefore not surprising that the individuals classified as diabetic by FPG may be normal by HbA1C. The International Expert Committee (1997) report acknowledged that even at the lower FPG cut point, the FPG and 2hPG were not perfectly concordant. An individual could have diabetes using one test but not the other.[19] This discrepancy has been confirmed in numerous subsequent reports and may be due to the fact that although both tests are measures of glycemia, they reflect different physiological measures of acute glucose metabolism.[20] This study showed FPG alone detects lowest number of diabetic patients. Several observations showed that FPG alone does not have sufficient sensitivity to screen for diabetes.[21-23] The Danish Inter 99 Study showed that the HbA1C,as a screening test for DM ,increased the prevalence of diabetes by 60% compared with the use of 2hPG.[13] Another study showed prevalence of diabetes was 12.2% (n=31) with FPG and 16.1% (n=41) with 2hPG but in case of HbA1C it rose to 27.6% ($p< 0.01$).[24] We have got mere good agreement among three diagnostic tests with lowest kappa value of “good agreement” range. This was not satisfactory from clinical and practical point of view in assessing the performance of a diagnostic test. Marini et al.(2011) stated that HbA1C showed a moderate agreement with FPG and 2hPG for diagnosing diabetes.[25] Thewjitcharoen et al. (2019) found fair agreement between HbA1C and 2hPG ($k=0.36$).[8] All these studies are in agreement with our findings of clinically non satisfactory agreement among three tools for diagnosis of diabetes mellitus. Most important finding of present study was FPG alone missed 45.5%, 2hPG 27.0% and HbA1C 20.0% of diabetic patients respectively. This similar finding was found in another study where Hu et al. (2010) stated that, among 795 subjects, FPG could detect only 54.5% of diabetic subjects and 45.5% remained unidentified.[26] Possible explanation for this fact is that most of the undiagnosed diabetic patients in our country are chorinc patient with insidious onset; they do not go for frequent health checkup; so the FPG and 2hPG fail to depict the actual picture of glycemic control of these individuals though rate of missed diagnosis becomes less by HbA1C as it can reflect the long term glycemic control.

## Conclusions

Diabetes mellitus detection rate found highest by use of HbA1C and lowest by use of FPG. Individually FPG shows highest missed diagnosis and HbA1C shows lowest missed diagnosis. No clinically

satisfactory agreement (concordance) was found among the three diagnostic tools (FPG,2hPG and HbA1C) for diagnosis of DM.

## Recommendations

None of the three diagnostic tools (FPG, 2hPG and HbA1C) could be regarded as the single best diagnostic tool for diagnosis of DM ,although HbA1C found better compared to FPG and 2hPG. So, for diagnosis of diabetes mellitus (DM) all three (FPG, 2hPG and HbA1C) tests should be done simultaneously.

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