Original Article

Combining serum 1,5-anhydroglucitol with fasting plasma glucose to detect diabetes mellitus in a community-based population with hypertension

Yuexing Yuan^, Jinfeng Cheng, Cheng Chen, Yao Wang

Department of Endocrinology, Zhongda Hospital, Institute of Diabetes, Medical School, Southeast University, Nanjing, China

Contributions: (I) Conception and design: Y Yuan, Y Wang; (II) Administrative support: Y Yuan; (III) Provision of study materials or patients: J Cheng, C Chen; (IV) Collection and assembly of data: Y Yuan, J Cheng, C Chen; (V) Data analysis and interpretation: J Cheng, C Chen; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Yao Wang, PhD. Department of Endocrinology, Zhongda Hospital, Institute of Diabetes, Medical School, Southeast University, Nanjing 210009, China. Email: wang_yao100@163.com.

Background: The early diagnosis and treatment of diabetes mellitus has significant clinical benefits. However, the current diagnostic tools available for community-based populations are limited. This study sought to evaluate the clinical benefits of combining serum 1,5-anhydroglucitol (1,5-AG) with fasting plasma glucose (FPG) to detect diabetes in a community-based population with hypertension.

Methods: A total of 359 subjects were enrolled in this diagnostic study, all of whom underwent a 75-g oral glucose tolerance test (OGTT). Venous blood samples were collected to measure FPG, 2 h postprandial plasma glucose (2h-PG), and hemoglobin A1c (HbA1c). Serum 1,5-AG levels were tested using the Glycomark assay, and a receiver operating characteristic (ROC) curve was used to assess the diagnostic value of this tool for diabetes and determine the optimal cut-point value to provide the maximum Youden's index. A Spearman correlation analysis was performed to analyze the relationship between 1,5-AG and other indexes.

Results: A total of 102 participants were diagnosed with diabetes, indicating a prevalence of 28.4% in the community-based population. The Spearman correlation analysis showed that 1,5-AG was negatively correlated with FPG and 2h-PG (r=–0.367 and –0.487, respectively; both P<0.05). For the estimation of 2h-PG ≥11.1 mmol/L using 1,5-AG, the area under the curve (AUC) for the ROC analysis was 0.850 (95% confidence interval: 0.809–0.891). The corresponding optimal cut-off for 1,5-AG was 13.23 μg/mL, which yielded a sensitivity of 89.7% and a specificity of 73.5%. Compared with FPG alone, FPG combined with 1,5-AG had a higher sensitivity for detecting diabetes (97.1% *vs.* 47.1%; P<0.001).

Conclusions: FPG combined with 1,5-AG substantially improved the sensitivity in detecting diabetes relative to FPG alone in a community-based population with hypertension, and may be a simple and efficient tool for screening diabetes.

Keywords: Diabetes detection; type 2 diabetes; fasting plasma glucose (FPG); 1,5-anhydroglucitol (1,5-AG); hemoglobin A1c (HbA1c)

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^ ORCID: 0000-0002-2535-9955.

Introduction

Hypertension is closely related to diabetes, and has become a major problem affecting human health. As China's population ages and lifestyle have changed, the prevalence of diabetes has soared from 0.67 percent in 1980 to 10.9 percent in 2013 (1-6). Unfortunately, diabetes is often not diagnosed until complications appear, and a large proportion of diabetic patients (i.e., 68.6%) remains undiagnosed in Mainland China, while 52.6% remain undiagnosed in Hong Kong and Taiwan (7). The prevalence of hypertension in adults over 18 years of age has also reached 27.9% (8). The annual incidence of stroke in the hypertensive population is 250/100,000, and the annual incidence of coronary heart disease events is 50/100,000 (9). In China, 24.3% of hypertensive patients in outpatient clinics also have diabetes (10), while about 30% of type 2 diabetes patients in outpatient clinics have hypertension (11). The co-existence of diabetes and hypertension can further increase the risk of occurrence and progression of cardiovascular diseases, stroke, nephropathy, and retinopathy, and seriously affect the quality of life and clinical prognosis of patients. Conversely, the control of hypertension can significantly reduce the risk of the occurrence and the development of diabetic complications (12).

There have been many studies on diabetes and hypertension. However, most of the previous studies were to determine the target of blood pressure control in patients with diabetes, or to compare the complications between patients with hypertension and diabetes (13,14). There were few diagnostic tests on hypertension combined with diabetes. Screening diabetes in hypertensive patients could help to control plasma glucose and blood pressure and the risk factors of cardiovascular and cerebrovascular diseases early on. It would also be instructive in adjusting antihypertensive drugs. For example, the use of thiazide diuretics in large doses for a long time may lead to an increase in blood sugar, β-blockers can cover up hypoglycemic reactions (e.g., an increased heart rate), and Angiotensin-Converting Enzyme Inhibitors and Angiotensin II Receptor Antagonists are the preferred antihypertensive agents in diabetes mellitus with hypertension (15). Thus, early detection, early diagnosis, and early intervention are very important for patients with hypertension and diabetes.

To date, conventional approaches to screening for diabetes have included the evaluation of fasting plasma glucose (FPG), hemoglobin A1c (HbA1c), and 2 h postprandial plasma glucose (2h-PG) after an oral glucose tolerance test (OGTT) (16-18). However, the application of an OGTT is limited due to the complexity of the operation process and its vulnerability to many factors. Thus, FPG is more commonly used in diabetes screening than the OGTT in clinical practice. However, the majority of diabetic patients in China are characterized as hyperglycemic after meals alone. In the absence of an OGTT, screenings based only on FPG detection would fail to detect approximately 50% of patients with postprandial hyperglycemia (19).

1,5-anhydroglucitol (1,5-AG) accurately reflects a patient's average blood glucose level for the past 3–7 days (20,21). Previous studies have shown that serum 1,5-AG reveals postprandial glucose and blood glucose fluctuations (20,22,23). In addition, some studies have also explored the use of serum 1,5-AG in diabetes screening (23,24). This study sought to assess the clinical value and the ability of an early diagnosis tool that uses serum 1,5-AG combined with FPG to screen for diabetes in a community-based population with hypertension. We present the following article in accordance with the STARD reporting checklist (available at https://dx.doi.org/10.21037/apm-21-1305).

Methods

Subjects

In this diagnostic study, a total of 1,035 subjects with high - risk factors for diabetes were recruited using an advertisement that was placed at 8 Community Health Service Centers in Nanjing, China, from September 2010 to September 2011. Of these 1,035 subjects, 517 had a clear history of hypertension or were taking oral antihypertensive drugs, and 158 subjects had no response rate or missing data. A total of 359 subjects were enrolled in this study. Eligible subjects were enrolled into the study after they provided written informed consent. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Research Ethics Committee of the Zhongda Hospital (No.:2017ZDSYLL006-P01).

All subjects underwent a 75 g OGTT to measure FPG, 2h-PG, and HbA1c. Blood samples were collected to examine serum 1,5-AG. The definition of diabetes was based on that of the 1999 World Health Organization (WHO) Diagnostic Criteria for Diabetes.

Data collection

Human body-related indicators

The height (m), weight (kg), waist circumference (cm),

and hip circumference (cm) of all subjects were measured by special personnel, and body mass index (BMI) (weight divided by height square kg/m^2) and waist-to-hip ratio (WHR) were calculated. We measured the waist circumference at the horizontal midpoint of the line between the anterior superior iliac crest and the lower margin of the 12th rib. We measured the hip position in front of the symphysis pubis and behind where the gluteus maximus is most convex. All subjects' blood pressure and heart rates were measured.

Laboratory measurements

All blood samples were taken from the anterior cubit vein. FPG (fasting 8–12 h) and 75 g anhydrous glucose load were detected using 2h-PG. Blood glucose was determined using an intravenous plasma glucose oxidase assay (the LX-20 automatic biochemical analyzer from Beckmann Cult Company, US). HbA1c was detected by high-performance liquid chromatography (D-10 HbA1c Analyzer, Bio-Rad, USA). Serum 1,5-AG was determined using the Glycomark method (Tomen America, New York, NY, USA) and the Hitachi 917 automatic analyzer (Roche Diagnostics, Indianapolis, IN, USA).

Statistical analysis

Excel [2010] was used to establish the database, and SPSS 18.0 software (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. The continuous normal distribution data are expressed as mean ± standard deviation. A one-way analysis of variance was used to compare the means between the groups. The continuous non-normal distribution data are presented as medians (quartile intervals), and the Kruskal-Wallis test was used for comparisons between groups. The Chi-square test was used to compare the discontinuous distribution data. The receiver operating characteristic (ROC) curve was used to obtain the optimal cut-point of serum 1,5-AG and diabetes diagnosis (with the largest Youden index). Simple correlations were analyzed using the Spearman correlation analysis. A $P<0.05$ was considered statistically significant.

Results

Subjects' characteristics

The general clinical data gathered for each gender group and total group are presented in *Table 1*. On average, subjects were aged 64.96±8.26 years (range, 43 to 88 years), Of the subjects, 143 were male and 216 were female. Females had a lower WHR than males ($P<0.05$).

Glycemic status and categories

Sixty-seven subjects had normal glucose tolerance (NGT), 90 had impaired glucose regulation (IGR), and 102 had diabetes (see *Tables 1* and 2). Thus, the prevalence of diabetes in the population was 28.4%. Among the diabetic subjects, 16 (15.7%) and 45 (44.1%) had isolated FPG and 2h-PG, respectively, and 41 (40.2%) displayed both FPG and 2h-PG. Of the 90 subjects with IGR, 21 (26.7%) and 54 (60%) had IFG and IGT, respectively. Subjects in the diabetes group had higher BMI, systolic blood pressure (SBP), FPG, 2h-PG, and HbA1c than those in the NGT group (all $P<0.05$; see *Table 2*).

Correlations among 1,5-AG level and other clinical variables

The Spearman analysis showed that 1,5-AG was negatively correlated with age, SBP, diastolic blood pressure (DBP), FPG, 2h-PG and HbA1c; the correlation coefficients were –0.117, –0.226, –0.144, –0.367, –0.487, and –0.281, respectively (all $P<0.05$).

The diagnostic value of 1,5-AG in screening diabetes and the critical cut-off value

The ROC curve reflects the diagnosis of the 1,5-AG reaction with 2h-PG ≥11.1 mmol/L (see *Figure 1*). The area under the curve (AUC) was 0.850 (95% confidence interval 0.809 to 0.891) when 1,5-AG screening 2h-PG ≥11.1 mmol/L. At the 1,5-AG level of 13.23 μg/mL, the Youden index reached the maximum, with a sensitivity of 89.7%, and a specificity of 73.5%. When FPG ≥7.0 mmol/L only was used to screen for diabetes, 54 subjects were identified, and 48 subjects were not diagnosed; thus, there was a missed diagnosis rate of 47.1%. When 1,5-AG ≤13.23 μg/mL combined with FPG ≥7.0 mmol/L were used to screen for diabetes, 156 subjects with diabetes were identified, of which 99 subjects were truly diabetic. The sensitivity was as high as 97.1% (99/102), the specificity was 79.0% (203/257), and the positive predictive value was 63.5% (63.5). The negative predictive value was 98.5% (200/203).

Table 1 Clinical characteristics of study subjects

Characteristics	Total (n=359)	Male (n=143)	Female (n=216)	P value
Age (year)	64.96±8.26	65.44±7.80	64.64±8.55	0.374
BMI (kg/m^2)	25.20±3.34	25.52±2.99	24.98±3.53	0.135
WHR	0.89±0.07	0.90±0.06	0.88±0.07	0.001
SBP (mmHg)	138.05±17.16	137.83±17.09	138.20±17.25	0.840
DBP (mmHg)	83.46±10.38	84.33±10.92	82.89±10.00	0.199
HR (bpm)	74.08±8.69	73.69±9.27	74.34±8.30	0.484
FPG (mmol/L)	5.89±1.57	5.92±1.57	5.86±1.56	0.707
2h-PG (mmol/L)	9.24±5.09	9.20±4.70	9.26±5.34	0.915
HbA1c (%)	6.25±1.03	6.24±0.98	6.25±1.07	0.911
1,5-AG (ug/mL)	18.05±9.19	18.17±9.68	17.97±8.87	0.840
NGT (%)	167 (46.5)	61 (42.6)	106 (49.1)	0.233
IGR (%)	90 (25.1)	38 (26.6)	52 (24.0)	0.593
DM (%)	102 (28.4)	44 (30.8)	58 (26.9)	0.420

Continuous data are expressed as mean ± standard deviation. Data were compared using an independent *t*-test or a Chi-square test. BMI, body mass index; WHR, waist-to-hip ratio; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; FPG, fasting plasma glucose; 2 h-PG, 2 h-postprandial plasma glucose; HbA1c, hemoglobin A1c; 1,5-AG, 1,5-anhydroglucitol; NGT, normal glucose tolerance; IGR, impaired glucose regulation; DM, diabetes mellitus.

Table 2 Clinical characteristics of subjects in the DM, IGR, and NGT groups

Characteristics	DM (n=102)	IGR (n=90)	NGT (n=167)	P value
Age (year)	65.59±7.68	64.64±9.60	64.75±7.85	0.663
BMI (kg/m^2)	26.03±3.50	25.61±2.94	24.47±3.30	<0.001
WHR	0.89±0.07	0.89±0.06	0.89±0.07	0.893
SBP (mmHg)	142.62±16.97	135.56±17.97	136.60±16.39	0.006
DBP (mmHg)	84.35±11.85	83.81±10.97	82.73±9.02	0.432
HR (times/min)	75.25±8.38	73.66±9.06	73.59±8.67	0.273
FPG (mmol/L)	7.43±2.01	5.75±0.70	5.02±0.59	<0.001
2h-PG (mmol/L)	15.17±5.86	8.38±1.75	6.08±1.09	<0.001
HbA1c (%)	7.14±1.44	6.13±0.48	5.76±0.43	<0.001
1,5-AG (ug/mL)	10.03±4.59	18.23±7.31	21.77±9.19	<0.001

Continuous data are expressed as mean ± standard deviation. Data were compared using an independent *t*-test or a Chi-square test. DM, diabetes mellitus; IGR, impaired glucose regulation; NGT, normal glucose tolerance; BMI, body mass index; WHR, waist-to-hip ratio; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; FPG, fasting plasma glucose; 2 h-PG, 2 h-postprandial plasma glucose; HbA1c, hemoglobin A1c; 1,5-AG, 1,5-anhydroglucitol.

Discussion

In this cross-sectional study, we found that the prevalence of diabetes among people with hypertension in the Nanjing community was 28.4%. Thus, the prevalence in the Nanjing community was significantly higher than that of the adult Chinese population in general. The high

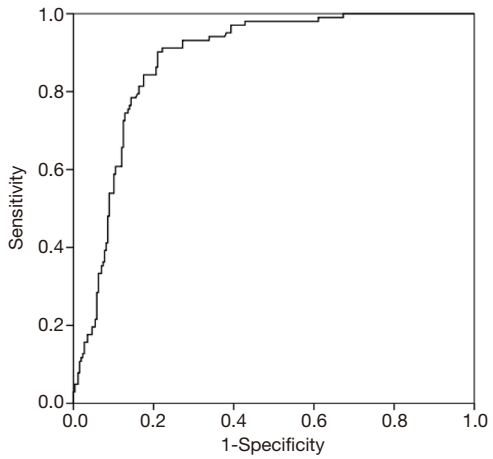

Figure 1 Receiver operating characteristic curve of 1,5-AG test to detect a 2 h-plasma glucose ≥11.1 mmol/L. The area under the curve was 0.850 (95% confidence interval: 0.809 to 0.891) with the respective 1,5-AG cut-off value of 13.23 μg/mL in identifying 2h-PG ≥11.1 mmol/L. 1,5-AG, 1,5-anhydroglucitol; 2h-PG, 2 h postprandial plasma glucose.

prevalence of diabetes and prediabetes in people with hypertension emphasizes the necessity of timely screenings for diabetes.

Consistent with the results of previous studies (20,22,24), serum 1,5-AG was highly negatively correlated with FBG, PBG, and HbA1c. Given that a large portion of the Chinese population suffers from elevated postprandial blood glucose alone but has normal fasting blood glucose, and the contribution of postprandial high blood glucose to cardiovascular disease is clear, the probability of developing cardiovascular and cerebrovascular diseases in diabetic patients with hypertension is significantly higher than that in patients with hypertension or diabetes alone. It has been demonstrated confirmed that low serum 1.5-Ag levels may be a marker of acute ischemic stroke (AIS) or transient ischemic attack (TIA) risk in well-controlled diabetics (25). Nevertheless, studies have shown that 1,5-AG may be an important indicator not only for the evaluation of coronary heart disease and stroke (25-28), but also for the assessment of nephropathy and retinopathy (29-31). There is evidence that 1,5-AG is a reliable glycemic marker for type 2 diabetes, even in patients with stages 1–3 chronic kidney disease (29). Despite the exclusion of subjects with previously diagnosed chronic kidney disease or acute kidney injuries in past year initially, our study did not assess kidney function at present, which might weaken the robustness of our main results.

Previous studies (22) have shown that 1,5-AG is closely related to postprandial blood glucose. In this study, 1,5-AG was used to replace postprandial blood glucose, which reduced the amount of blood required for collection and the waiting time of patients. The results confirmed that 1,5-AG combined with FPG significantly improved the sensitivity of detecting abnormal glucose and diabetes, and reduced the rate of missed diagnoses. Thus, 1,5-AG combined with FPG represents a promising tool for diabetes screening.

In this study, we found that FPG combined with 1,5-AG significantly improved the efficacy of blood glucose screening compared to FPG alone. The diagnostic specificity was relatively low; however, the combination of FPG and 1,5-AG showed the range of potential patients who may require a 75 g standard OGTT diagnosis. Based on these results, at least 50% of OGTTs are not necessary. In addition, as blood only needs to be taken from patients once, patients' discomfort is minimal. Thus, this tool could also greatly improve patient compliance.

This study had a number of limitations. First, the subjects were recruited from the Nanjing Community Health Service Center, which may have led to a selection bias. Second, the glycemic status was determined based on FPG and 2h-PG measurements after 75 g of oral glucose stimulation, and repeated 2h-OGTT therapy was not performed due to poor compliance. Third, the sample size of this study was relatively small, and results might vary due to geographical and behavioral differences. Thus, prospective studies based on the incidence of diabetic retinopathy need to be conducted with large samples from multiple cities in the future.

In conclusion, our study showed that FPG combined with 1,5-AG is a highly sensitive, simple and economical method for detecting glucose metabolism abnormalities. It could also narrow the target population and prevent unnecessary OGTT procedures from being conducted. The combined measurement of FPG and 1,5-AG may not have the same diagnostic value of a 2h-OGTT, but it provides a promising alternative for diabetes screening.

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Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://dx.doi.org/10.21037/apm-21-1305

Data Sharing Statement: Available at https://dx.doi.org/10.21037/apm-21-1305

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/apm-21-1305). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Eligible subjects were enrolled into the study after they provided written informed consent. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Research Ethics Committee of the Zhongda Hospital (No.:2017ZDSYLL006-P01).

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