

Postprint of a Study on the Screening Effectiveness and Strategies of Fasting Plasma Glucose and Glycated Hemoglobin for Type 2 Diabetes and Prediabetes

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Abstract

Background Currently, hospital physical examination centers and communities primarily employ fasting plasma glucose and glycated hemoglobin as indicators for assessing blood glucose levels. Existing studies have investigated the diagnostic value of these two indicators when used alone or in combination; however, such research has focused solely on the accuracy of the indicators while neglecting their practical value. The present study constructs screening strategies for type 2 diabetes mellitus and prediabetes based on real-world scenarios to facilitate early detection and management of populations with abnormal glucose metabolism.

Objective To develop screening strategies and cutoff values for type 2 diabetes mellitus and prediabetes utilizing fasting plasma glucose and glycated hemoglobin indicators, thereby improving the detection rate of individuals with diabetes and prediabetes.

Methods A total of 527 examinees who underwent physical examination at a hospital in Shanghai and received 2-hour postprandial glucose testing between September and November 2023 were enrolled. The sensitivity, specificity, positive predictive value, negative predictive value, Youden's index, screening cost, and cost-effectiveness of different screening cutoff values were compared between two screening processes: fasting plasma glucose alone and fasting plasma glucose combined with glycated hemoglobin.

Results Among the 527 examinees, 74 (14.04%) had type 2 diabetes mellitus, 141 (26.76%) had prediabetes, and 312 (59.2%) had normal glucose levels. In the screening strategy using fasting plasma glucose alone, the fasting plasma glucose cutoff value corresponding to the maximum Youden's index of 0.461

was 5.4 mmol/L, with a sensitivity of 54.42%, specificity of 91.67%, and cost-effectiveness of 233.97 yuan per person. The optimal screening cutoff value for fasting plasma glucose was 5.9 mmol/L, with a sensitivity of 33.02%, specificity of 99.68%, Youden's index of 0.327, and cost-effectiveness of 212.55 yuan per person. In the screening strategy combining fasting plasma glucose and glycated hemoglobin, the glycated hemoglobin cutoff value corresponding to the maximum Youden's index of 0.433 was 6.1%, with a sensitivity of 51.63%, specificity of 91.67%, and cost-effectiveness of 480.23 yuan per person. The optimal screening cutoff value of glycated hemoglobin for abnormal glucose metabolism was 5.9%, with a sensitivity of 73.95, specificity of 65.71, Youden's index of 0.370, and cost-effectiveness of 475.62 yuan per person.

Conclusion When using fasting plasma glucose as a single indicator to screen populations with abnormal glucose metabolism status, lowering the screening cutoff value to 5.9 mmol/L demonstrates favorable screening efficacy and cost-effectiveness. Glycated hemoglobin can serve as an effective supplementary screening tool. The supplementary application of glycated hemoglobin (cutoff value of 5.9%) to screen individuals with normal fasting plasma glucose can identify more people with actual abnormal glucose metabolism status, thereby improving their compliance with glucose tolerance testing and providing additional possibilities for optimizing screening strategies.

Full Text

Screening Effectiveness and Strategy of Fasting Plasma Glucose and Glycosylated Hemoglobin for Type 2 Diabetes and Prediabetes

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Abstract

Background: Currently, hospital physical examination centers and community health facilities primarily use fasting plasma glucose (FPG) and glycosylated hemoglobin (HbA1c) to evaluate blood glucose levels. Previous studies have explored the diagnostic value of these two indicators used separately or in

combination, but they have focused solely on accuracy while neglecting practical applicability. Based on real-world scenarios, this study constructs screening strategies for type 2 diabetes and prediabetes to enable early detection and management of individuals with abnormal glucose metabolism.

Objective: To develop screening strategies and thresholds for type 2 diabetes and prediabetes using FPG and HbA1c indicators, thereby improving detection rates among populations with diabetes and prediabetes.

Methods: We included 527 individuals who underwent physical examinations and 2-hour postprandial glucose testing at a Shanghai hospital between September and November 2023. We compared the sensitivity, specificity, positive predictive value, negative predictive value, Youden index, screening costs, and cost-effectiveness of different screening thresholds in two screening protocols: FPG alone and FPG combined with HbA1c.

Results: Among the 527 participants, 74 (14.04%) had type 2 diabetes, 141 (26.76%) had prediabetes, and 312 (59.2%) had normal glucose levels. In the FPG-only screening strategy, the maximum Youden index of 0.461 corresponded to an FPG threshold of 5.4 mmol/L, with sensitivity of 54.42%, specificity of 91.67%, and cost-effectiveness of 233.97 yuan per person. The optimal FPG screening threshold was 5.9 mmol/L, with sensitivity of 33.02%, specificity of 99.68%, Youden index of 0.327, and cost-effectiveness of 212.55 yuan per person. In the combined FPG and HbA1c strategy, the maximum Youden index of 0.433 corresponded to an HbA1c threshold of 6.1%, with sensitivity of 51.63%, specificity of 91.67%, and cost-effectiveness of 480.23 yuan per person. The optimal HbA1c threshold for abnormal glucose metabolism was 5.9%, with sensitivity of 73.95%, specificity of 65.71%, Youden index of 0.370, and cost-effectiveness of 475.62 yuan per person.

Conclusion: When using FPG as a single indicator to screen for abnormal glucose metabolism, lowering the screening threshold to 5.9 mmol/L demonstrates good screening effectiveness and economic efficiency. HbA1c can serve as an effective supplementary screening tool. Supplemental application of HbA1c (threshold 5.9%) for individuals with normal FPG can identify more people with actual abnormal glucose metabolism, thereby improving their compliance with glucose tolerance tests and providing additional possibilities for optimizing screening strategies.

Keywords: Blood glucose; Fasting plasma glucose; Glycated hemoglobin A; Prediabetic state; Glucose metabolism disorders; Screening

1. Introduction

Diabetes mellitus is a group of endocrine and metabolic syndromes primarily characterized by chronically elevated blood glucose due to insufficient insulin

secretion and/or insulin resistance, which can lead to various complications including diabetic retinopathy, cardiovascular disease, diabetic foot, and diabetic nephropathy [1]. Prediabetes, also known as impaired glucose regulation, encompasses impaired fasting glucose (IFG), impaired glucose tolerance (IGT), and mixed states of both conditions [2]. Without early detection, management, and intervention, a substantial proportion of individuals with prediabetes will progress to diabetes, causing irreversible health consequences. The Da Qing Diabetes Prevention Outcome Study demonstrated that early lifestyle intervention in populations with impaired glucose regulation can reduce diabetes incidence and complications [3]. According to the International Diabetes Federation, over 200 million adults with diabetes remained undiagnosed globally in 2017, with an undiagnosed rate of nearly 50%. In China, more than 60 million diabetic patients were unaware of their condition [4]. A survey of Shanghai residents aged 35 and above showed that the awareness rate of type 2 diabetes prevalence was only 57.18% [5], further underscoring the importance of diabetes screening. Therefore, early screening and diagnosis are prerequisites for effective management and treatment of diabetes and prediabetes.

Currently, most hospital physical examination departments rely on fasting plasma glucose (FPG) and glycosylated hemoglobin (HbA1c) for blood glucose assessment. FPG testing is the most frequently used clinical practice for evaluating glucose metabolism status, providing a direct measure of instantaneous blood glucose levels [6]. It is relatively inexpensive, simple to perform, and suitable for large-scale population screening. Although HbA1c testing is slightly more costly, it is not affected by temporary blood glucose fluctuations and remains relatively stable in the bloodstream [7]. Lu et al. [8] found that HbA1c testing in health examinations is convenient and reproducible, making it an effective supplementary screening tool. HbA1c has been increasingly widely used in clinical practice and has gradually become popularized in developed regions of China. As China's health service system continues to develop, more regions will have the capacity to perform this test.

Since individuals with prediabetes are often identified during type 2 diabetes screening processes, this study collectively refers to prediabetes and type 2 diabetes as "abnormal glucose metabolism," treating them as a combined screening endpoint. Researchers such as Zhou [9] and Zhang et al. [10] have explored the diagnostic value of FPG and HbA1c used separately or in combination. However, these studies have only considered indicator accuracy without examining their practical application value. Therefore, based on existing FPG and HbA1c test results, this study comprehensively evaluates the accuracy, economic efficiency, and population compliance of these indicators to assess their screening value for type 2 diabetes and prediabetes, and to construct corresponding screening strategies.

2. Subjects and Methods

2.1 Study Subjects

We selected individuals who underwent physical examinations and 2-hour postprandial glucose testing at the Physical Examination Center of Wusong Hospital affiliated with Fudan University Zhongshan Hospital in Shanghai between September and November 2023. Inclusion criteria were: (1) age 35-74 years, and (2) voluntary participation with signed informed consent. Exclusion criteria were: (1) self-reported history of diabetes, including type 1 diabetes, type 2 diabetes, or prediabetes; (2) current use of hypoglycemic medications or undergoing hypoglycemic treatment; and (3) pregnant women.

This study was approved by the Medical Research Ethics Committee of the School of Public Health, Fudan University (IRB#2023-05-1047). All participants provided informed consent and voluntarily joined the study.

2.2 Detection Indicators and Cost Calculation

Participants underwent glucose metabolism screening. After fasting venous blood collection, FPG and HbA1c were measured. Participants then received a standard steamed bun meal (100 g white flour bun), and postprandial blood was drawn exactly 2 hours after the first bite.

Screening costs comprised testing costs and time opportunity costs. Testing costs included project testing fees and material expenses. Project testing fees were extracted from physical examination center records: HbA1c testing cost 58 yuan per person, oral glucose tolerance test (OGTT) cost 25 yuan per person, and FPG testing cost 5 yuan per person. Material expenses referred to costs during OGTT, primarily involving disposable blood collection needles, paper cups, glucose, and other supplies, totaling approximately 8 yuan per person. Time opportunity costs were estimated based on Shanghai's 2023 average monthly salary of 12,307 yuan for employed workers, with 22 working days per month and 8 working hours per day, yielding an average hourly wage of 70 yuan. We calculated 2 hours of waiting time per positive case for OGTT.

2.3 Diagnostic Criteria

Diagnostic criteria followed the "Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes (2020 Edition)" [11] and the "Expert Consensus on Intervention for Prediabetes in Chinese Adults (2023 Edition)." Diagnostic grouping criteria were: Type 2 diabetes: $\text{FPG} \geq 7.0 \text{ mmol/L}$ and/or 2-hour postprandial glucose (2hPG) $\geq 11.1 \text{ mmol/L}$. Prediabetes included: IFG: $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ and $2\text{hPG} < 7.8 \text{ mmol/L}$; IGT: $\text{FPG} < 7.0 \text{ mmol/L}$ and $7.8 \text{ mmol/L} \leq 2\text{hPG} < 11.1 \text{ mmol/L}$; and mixed state: $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ and $7.8 \text{ mmol/L} \leq 2\text{hPG} < 11.1 \text{ mmol/L}$.

2.4 Statistical Methods

We used Stata 17.0 software for data processing. Categorical data were expressed as frequency and percentage, and chi-square tests were used to compare differences in test results among populations with different characteristics. Sensitivity, specificity, positive predictive value, negative predictive value, and Youden index were used to evaluate the diagnostic performance of FPG and HbA1c at different screening thresholds for detecting diabetes and prediabetes. The significance level was set at $\alpha = 0.05$.

3. Results

3.1 Glucose Metabolism Screening Results

A total of 527 participants were included. Glucose metabolism screening identified 141 individuals (26.8%) with prediabetes and 74 (14.0%) with type 2 diabetes. The cohort comprised 142 males (26.9%) and 385 females (73.1%). Age distribution was: 35-44 years: 140 (26.6%); 45-54 years: 166 (31.5%); 55-64 years: 118 (22.4%); and 65-74 years: 103 (19.5%). FPG abnormalities were found in 62 participants (11.8%), 2-hour postprandial glucose abnormalities in 212 (40.2%), and HbA1c abnormalities in 318 (60.3%). Significant differences were observed in gender, age, FPG, HbA1c, and 2-hour postprandial glucose among individuals with different glucose metabolism statuses ($P < 0.05$).

3.2 Screening Effectiveness of FPG for Abnormal Glucose Metabolism

Using FPG to screen the physical examination population, 34 individuals (6.45%) with $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ were predicted to have “abnormal glucose metabolism status” and required further OGTT for definitive diagnosis. A total of 465 participants (88.24%) with $\text{FPG} < 6.1 \text{ mmol/L}$ were predicted to have “normal glucose.” When using 5.4 mmol/L as the FPG screening threshold, the Youden index reached its maximum value, with sensitivity, specificity, positive predictive value, negative predictive value, and Youden index of 54.42%, 91.67%, 81.82%, 74.48%, and 0.461, respectively.

3.3 Screening Effectiveness of Combined FPG and HbA1c for Abnormal Glucose Metabolism

Using combined FPG and HbA1c screening in the physical examination population, individuals with $\text{FPG} \geq 6.1 \text{ mmol/L}$ were predicted to have “abnormal glucose metabolism status” and required OGTT. Among the 465 participants (88.24%) with $\text{FPG} < 6.1 \text{ mmol/L}$, HbA1c was used for secondary screening. Of these, 28 (6.02%) had $\text{HbA1c} \geq 6.5\%$ and were predicted to have “abnormal glucose metabolism status,” requiring OGTT, while 437 (93.98%) had $\text{HbA1c} < 6.5\%$ and were predicted to have “normal glucose.” When using 6.1% as the HbA1c screening threshold, the Youden index reached its maximum, with sensitivity, specificity, positive predictive value, negative predictive value, and

Youden index of 51.63%, 91.67%, 81.02%, 73.33%, and 0.411, respectively. The screening flowchart for FPG and HbA1c is shown in [Figure 1: see original paper].

3.4 FPG-Based Screening Strategy

In the FPG screening strategy, individuals with $\text{FPG} \geq 7.0$ mmol/L were diagnosed with diabetes and enrolled in diabetes management and treatment. Those with $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ were screening-positive and underwent OGTT. Individuals with $\text{FPG} < 6.1$ mmol/L were screening-negative and received follow-up monitoring. After lowering the FPG screening threshold, we calculated the cost-effectiveness of different thresholds. Cost accounting for screening 527 participants using FPG showed that when $\text{FPG} \geq 5.4$ mmol/L (maximum Youden index) was used as the abnormal glucose metabolism threshold, the cost-effectiveness was 233.97 yuan per person. When $\text{FPG} \geq 5.9$ mmol/L was used as the threshold, the cost-effectiveness was 212.55 yuan per person, representing the lowest cost-effectiveness ratio.

3.5 Combined FPG and HbA1c Screening Strategy

In the combined FPG and HbA1c screening strategy, individuals with $\text{FPG} \geq 7.0$ mmol/L were diagnosed with diabetes and enrolled in management. Those with $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ underwent OGTT. Participants with $\text{FPG} < 6.1$ mmol/L received HbA1c testing; those with $\text{HbA1c} \geq 6.5\%$ were screening-positive and required OGTT, while those with $\text{HbA1c} < 6.5\%$ were screening-negative and received follow-up. After lowering the HbA1c screening threshold, we calculated cost-effectiveness. Cost accounting for screening 527 participants using both FPG and HbA1c showed that when $\text{HbA1c} \geq 6.1\%$ (maximum Youden index) was used as the abnormal glucose metabolism threshold, the cost-effectiveness ratio was 480.23 yuan per person. When $\text{HbA1c} \geq 5.9\%$ was used as the threshold, the cost-effectiveness ratio was 475.62 yuan per person, representing the lowest cost-effectiveness ratio.

4. Discussion

4.1 Feasibility of Screening Strategies Using FPG and HbA1c

Currently, with urbanization, population aging, and changing disease patterns, chronic non-communicable diseases such as diabetes pose serious threats to public health. Our study found a type 2 diabetes prevalence of 14.04%, which is lower than the previously reported 17.6% in Shanghai, while the prediabetes prevalence of 26.76% is higher than the previously reported 16.5% [12], suggesting an upward trend in prediabetes prevalence in Shanghai. Without early detection and management, this will lead to a significant increase in diabetes patients. Physical examination is an important approach for identifying abnormal glucose metabolism in residents, enabling early detection of prediabetes and diabetes [13]. FPG and HbA1c are primary indicators reflecting glucose

metabolism status and are widely used clinically to monitor blood glucose levels [14,15]. Based on real-world physical examination practices, constructing screening strategies using FPG and HbA1c can maximize detection of diabetes and prediabetes populations without increasing blood collection frequency, making diabetes and prediabetes screening more convenient and implementable.

4.2 Promotional Value of FPG-Based Diabetes Screening Strategies

FPG ≥ 7.0 mmol/L is widely used as a diabetes diagnostic standard. However, previous studies have confirmed that FPG ≥ 7.0 mmol/L has low sensitivity for early diabetes screening, and the diagnostic threshold for early diabetes should be lowered to reduce missed diagnoses [16]. Our results show that when using FPG to screen for “prediabetes and type 2 diabetes” among 527 participants, a screening threshold of FPG ≥ 5.4 mmol/L yielded optimal screening effectiveness with sensitivity of 54.42%, specificity of 91.67%, positive predictive value of 81.82%, negative predictive value of 74.48%, and Youden index of 0.461, which was higher than other thresholds. However, effective screening strategies must consider not only accuracy but also practical feasibility and economic efficiency [17]. Cost accounting revealed that when using FPG ≥ 5.9 mmol/L as the screening-positive threshold, the total screening cost was 15,091 yuan, with a cost of 212.55 yuan per abnormal glucose metabolism case identified, representing the lowest cost-effectiveness ratio. Compared to the 5.4 mmol/L threshold, this reduced the number of individuals requiring OGTT, making it more acceptable to screening participants. From the healthcare provider perspective, using FPG to screen for abnormal glucose metabolism is suitable for large-scale population screening, maximizing detection of abnormal glucose metabolism populations without increasing community health service capacity. Therefore, in hospital or community physical examination populations, FPG screening can be implemented: individuals with FPG ≥ 7.0 mmol/L are diagnosed with diabetes and enrolled in management; those with $5.9 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ undergo OGTT; and those with FPG < 5.9 mmol/L receive follow-up monitoring and regular blood glucose surveillance.

4.3 Development of Dual-Indicator Screening Strategy Based on FPG and HbA1c

For some developed regions, HbA1c is already a routine test in hospital physical examination centers. Using FPG ≥ 7.0 mmol/L and HbA1c $\geq 6.5\%$ as screening thresholds, combined FPG and HbA1c testing achieved sensitivity, specificity, and Youden index of 39.07%, 98.08%, and 0.372, respectively, which was superior to FPG alone and improved diagnostic efficacy, consistent with findings from Chen [19] and Tan et al. [20]. Lowering the FPG screening threshold can include more high-risk individuals, though this population progresses to diabetes slowly [21]. For individuals with normal FPG, incorporating existing HbA1c indicators can improve detection rates of abnormal glucose metabolism at relatively low cost. Cost accounting showed that screening 527 participants

using both FPG and HbA1c, with HbA1c $\geq 5.9\%$ as the screening-positive threshold, required total costs of 75,623 yuan, with a cost of 475.62 yuan per abnormal case identified, representing the lowest cost-effectiveness ratio among all thresholds. Therefore, if using combined FPG and HbA1c screening, the following approach is recommended: screen with FPG first; individuals with FPG ≥ 7.0 mmol/L are diagnosed with diabetes and enrolled in management; those with $6.1 \text{ mmol/L} \leq \text{FPG} < 7.0 \text{ mmol/L}$ undergo OGTT; individuals with FPG < 6.1 mmol/L receive HbA1c testing, with HbA1c $\geq 5.9\%$ as screening-positive requiring OGTT, and HbA1c $< 5.9\%$ as screening-negative requiring follow-up monitoring.

In summary, in screening strategies focusing on FPG, lowering the FPG positive screening threshold can further improve detection rates of abnormal glucose metabolism in general populations with good screening effectiveness and economic efficiency. For populations already undergoing HbA1c testing, the HbA1c indicator can identify more individuals with normal FPG but actual abnormal glucose metabolism. In real-world screening practice, detection results from both FPG and HbA1c can be used to improve compliance with 2-hour postprandial glucose testing and provide additional possibilities for optimizing screening strategies.

Author Contributions

ZHANG Lei was responsible for data collection, analysis, and manuscript writing. CHEN Kaiyue was responsible for data organization and chart preparation. ZHANG Huanyu was responsible for manuscript revision. LI Xiaohong and GUO Ying were responsible for research objectives, article conception and design, and overall responsibility for the article.

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