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ABOUT COVER

Peer Review of *World Journal of Diabetes*, Erkan Gokce, MD, Professor, Department of Radiology, Tokat Gaziosmanpasa University, School of Medicine, Tokat 60100, Türkiye. drerkangokce@gmail.com

AIMS AND SCOPE

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Observational Study

Cut-off value of glycated hemoglobin A1c for detecting diabetic retinopathy in the Chinese population

Yan Wen, Qing Wang

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Abstract

BACKGROUND

Glycated hemoglobin A1c (HbA1c) is considered the most suitable for diabetes mellitus diagnosis due to its accuracy and convenience. However, the effect of HbA1c on diabetic retinopathy (DR) in the Han and Korean populations in Jilin, China, remains inconclusive.

AIM

To determine the best cut-off of HbA1c for diagnosing DR among the Chinese.

METHODS

This cross-sectional study included 1933 participants from the Yanbian area of Jilin Province, China. Trained investigators employed a questionnaire-based survey, physical examination, laboratory tests, and fundus photography for the investigation. The best cut-off value for HbA1c was established *via* the receiver operating characteristic curve. The factors associated with HbA1c-associated risk factors were determined *via* linear regression.

RESULTS

The analysis included 887 eligible Chinese Han and Korean participants, 591 of whom were assigned randomly to the training set and 296 to the validation set. The prevalence of DR was 3.27% in the total population. HbA1c of 6.2% was the best cut-off value in the training set, while it was 5.9% in the validation set. In both Chinese Han and Korean populations, an HbA1c level of 6.2% was the best cut-off value. The optimal cut-off values of fasting blood glucose (FBG) ≥ 7 mmol/L and < 7 mmol/L were 8.1% and 6.2% respectively in Han populations, while those in Korean populations were 6.9% and 5.3%, respectively. Age, body mass index, and FBG were determined as the risk factors impacting HbA1c levels.

CONCLUSION

HbA1c may serve as a useful diagnostic indicator for DR. An HbA1c level of 6.2%

may be an appropriate cut-off value for DR detection in the Chinese population.

Key Words: Diabetic retinopathy; Glycated hemoglobin A1c; Cut-off value; Age; Body mass index; Fasting blood glucose

Core Tip: This cross-sectional analysis of data from 887 participants in Yanbian area of China from March to April 2017 determined the best glycated hemoglobin A1c (HbA1c) cut-off point for the diagnosis of diabetic retinopathy (DR) among the Chinese population. This study implies that HbA1c is a practical diagnostic marker for DR, and an HbA1c level of 6.2% may be an appropriate cut-off value for DR detection in the Chinese population.

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INTRODUCTION

Diabetes mellitus has significantly impacted global health and medical expenses in recent decades, reaching pandemic proportions[1]. By 2030, projections indicate that it will impact 643 million people[2]. Diabetic retinopathy (DR), the most common microvascular consequence of diabetes, is the primary lead to blindness and is expected to influence 191 million people globally by 2030[3]. DR is usually asymptomatic in its initial stages, progresses gradually over years, and symptoms may not manifest until it reaches an advanced stage, which might hinder timely treatment and lead to poor therapeutic outcomes[4]. Hence, early detection of DR is imperative to promptly implement therapeutic interventions and prevent visual loss.

Diabetes duration, blood pressure control, and glucose control have a significant correlation with DR and are the primary risk factors affecting its severity[5]. Glucose control plays a key role in the progression of DR, accounting for about 11% of DR risk. The relationship between glucose control and DR is established through glycated hemoglobin A1c (HbA1c), fasting blood glucose (FBG), and 2-h plasma glucose (2 h-PG). HbA1c is the gold standard for evaluating glycaemic control. HbA1c is considered the most suitable for DR diagnosis due to its accuracy and convenience[6-8]. However, the effect of HbA1c on DR in the Chinese population remains inconclusive. This study aimed to explore the diagnostic significance of HbA1c in DR and measure the best HbA1c threshold for detecting DR in a Chinese population.

MATERIALS AND METHODS

Study subjects and data acquisition

This cross-sectional study was conducted in Jilin Province, China, from March to April 2017. Two neighborhood committees in the Yanbian area were randomly selected to enlist the residents aged 18-85 years. Three days before the study, investigators visited the house to schedule a field investigation and obtained written informed consent with the assistance of the local staff. The field investigation conducted by the trained investigators included a questionnaire-based survey (including name, sex, age, nationality, medical history, medication history, occupation, and income), physical examination (including weight, height, waist circumference, pulse rate, blood pressure), laboratory measurement program (including FBG, 2 h-PG, and HbA1c), blood lipids (including total cholesterol, low- and high-density lipoprotein, triglyceride), renal function (including creatinine, urea nitrogen, and uric acid), routine blood examination parameters (including white and red blood cell count, hemoglobin, and blood platelet count), and fundus photography. Investigators conducted face-to-face questionnaire-based surveys and recorded them. Physical examinations were performed using standard methods. Fasting blood was collected in the morning fasting for at least 10 h. Laboratory tests, except for HbA1c, were conducted using the AU58000 automatic biochemistry analyzer (Beckman Coulter Inc., CA, United States). HbA1c was measured using the D-10™ Hemoglobin Testing System (Bio-Rad Laboratories Inc., CA, United States). Two digital fundus photographs were captured for each eye using a Canon CR-2 AF nonmydriatic digital fundus camera (Canon, Tokyo, Japan). The images were graded by two professional ophthalmologists in a double-blind manner. A total of 1933 participants were enrolled. Participants who were older adults, frail, had restricted mobility, suffered from severe liver and kidney diseases, or had incomplete data were excluded. Finally, 887 participants were involved in the data analysis and were grouped into a training set and a validation set according to a ratio of 2:1 at random.

Definition

The Early Treatment Diabetic Retinopathy Study (ETDRS) scale was utilized for DR diagnosis[9]. The presence of DR in

the participant and its grading were determined based on the eye with the higher score. Herein, the specific level of DR was defined by an ETDRS letter score of ≥ 31 (mild nonproliferative DR or more severe DR).

Statistical analysis

The R software (version 4.1.2) was applied to statistical analysis. Counting data was described as frequency number and percentage, and experimental data was presented as mean ± SD. Data corresponding to a normal distribution was compared using variance analysis, while data fitting a non-normal distribution was compared by Mann-Whitney *U* test. The best HbA1c cut-off value was determined by the receiver operating characteristic (ROC) curve. Factors related to HbA1c were determined *via* linear regression. A P value < 0.05 was deemed statistically significant.

RESULTS

Baseline characteristics of participants

A total of 887 eligible participants representing the Chinese Han and Korean populations were involved in the analysis, of which 591 were grouped randomly into the training set and 296 were allocated to the validation set. The proportion of the population representing Chinese Korean nationality accounted for 67.68% of the population in the training set and 63.85% in the validation set, respectively. In the total population, the prevalence of DR was 3.27%. The baseline characteristics of the participants are displayed in Table 1. No significant differences regarding demographic information, physical examination, or lab test results were found between the two sets.

Optimal HbA1c cut-off value

The ROC curve was utilized to measure the optimal HbA1c cut-off value for diagnosing DR, and the area under the ROC curve (AUC) was applied to assess its diagnostic efficacy. In the training set, the AUC was 0.731 [95% confidence interval (CI): 0.682-0.773], and an HbA1c of 6.2% was the optimal cut-off value with a specificity of 82.5% and a sensitivity of 60.5% (Figure 1A). The AUC for the validation set was 0.770 (95%CI: 0.679-0.861), and an optimal HbA1c cut-off value of 5.9% was determined, corresponding to a specificity of 73.9% and a sensitivity of 76.9% (Figure 1B). The best cut-off value for both the Chinese Han and Korean populations was HbA1c of 6.2%, which had a high specificity (81.2% and 84.9%, respectively) and a relatively low sensitivity (60.0% and 50.0%, respectively). The corresponding AUC was 0.721 and 0.685, respectively (Supplementary Figure 1).

Age, body mass index (BMI), and FBG were determined to be significant risk factors associated with HbA1c (Table 2). An HbA1c level of 6.3% was the best cut-off value in the older adults (Supplementary Table 1, AUC: 0.694, sensitivity: 62.4%, specificity: 78.9%), whereas in the young people, it was 5.9% (AUC: 0.752, sensitivity: 66.7%, specificity: 82.4%). An HbA1c level of 6.2% was the best cut-off value in the overweight and obese individuals (AUC: 0.702, sensitivity: 68.5%, specificity: 79.7%), while it was 6.0% in the healthy participants (AUC: 0.738, sensitivity: 72.6%, specificity: 88.6%).

DISCUSSION

Diabetes and its complications present a serious global health problem, and China is its primary epicenter[2]. The present study proposes using an HbA1c cut-off value of 6.2% to detect DR in the Chinese population. HbA1c is an internationally utilized indicator to assess glycemic control over extended periods, reflecting the average blood glucose level over the previous three months. The association between the glucose level and diabetic complications, especially DR, is fundamental to diabetes diagnosis. The American Diabetes Association recommends using HbA1c for diabetes diagnosis [10]. As HbA1c levels rise, the occurrence of DR significantly increases[11]. Conversely, lowering HbA1c levels is correlated with a lower risk of DR. The risk of developing DR decreases by approximately 37% for every 1% reduction in HbA1c, indicating that strict control over HbA1c could lower the risk of DR development[12].

Ethnicity is correlated with variations in HbA1c diagnostic performance and thresholds, suggesting that the best HbA1c cut-off value should be modified to account for local conditions[13]. For Asians, the HbA1c cut-off value for diagnosing DR is equivalent. The best HbA1c diagnostic threshold for DR was reported to be 6.2% in the Korean population [14]. The Hisayama Study concluded that an HbA1c level of 6.1% was the best cut-off level for detecting the presence of DR in the Japanese population[15]. However, various studies conducted in different areas of China revealed diverse HbA1c cut-off points, inconsistent with our results. A study in Beijing revealed that HbA1c of 6.4% was the best cut-off value for identifying DR in a Chinese population[16]. Another study in Dalian city, Liaoning Province, proposed that HbA1c of 6.5% was effective for detecting DR with high accuracy[17]. These differences may be attributed to the varied demographic characteristics and diagnostic criteria utilized in the respective studies.

Age, BMI, and FBG were identified as the risk factors influencing HbA1c cut-off values. An increased BMI and advancing age were associated with a higher HbA1c cut-off value. Aging is associated with an elevation in HbA1c levels. Furthermore, age is correlated with the rising prevalence of overweight and obesity[18-20], a correlation that could potentially be attributed to the increased HbA1c levels. These findings indicated that age may be a factor in establishing the HbA1c cut-off value among different groups of people.

The study has several limitations. Because this experiment was a cross-sectional design, the causal link between HbA1c and DR could not be established. The sample size was limited, making it extremely crucial to exercise caution when extrapolating the results to other populations. In the future, large-scale, multicenter prospective studies are recom-

Table 1 Basic characteristics and physical parameters data of participants in the training set and validation set

	Training set (*n* = 591)	Validation set (*n* = 296)	*P* value
Chinese Korean population, *n* (%)	400 (67.68)	189 (63.85)	0.2832
Female, *n* (%)	387 (65.48)	186 (62.84)	0.4759
Age (yr)	55.82 ± 11.41	54.81 ± 11.24	0.1913
BMI (kg/m^2)	25.38 ± 3.84	25.66 ± 4.03	0.5643
Waist circumference (cm)	80.17 ± 9.77	80.88 ± 9.84	0.4620
Systolic blood pressure (mmHg)	136.67 ± 21.83	137.62 ± 20.48	0.4574
Diastolic blood pressure (mmHg)	80.56 ± 12.59	80.57 ± 12.26	0.4661
Beats per minute	80.58 ± 11.85	80.54 ± 13.04	0.9233
FBG (mmol/L)	6.20 ± 1.62	6.14 ± 1.65	0.1461
2 h-PG (mmol/L)	7.59 ± 3.02	7.58 ± 3.62	0.7261
HbA1c (%)	5.83 ± 1.06	5.81 ± 1.07	0.7282
White blood cell count (10^9/L)	5.73 ± 1.47	5.89 ± 1.69	0.2423
Red blood cell count (10^{12}/L)	4.71 ± 0.45	4.74 ± 0.48	0.7093
Blood platelet count (10^9/L)	225.47 ± 57.29	227.50 ± 57.49	0.6463
Hemoglobin (g/L)	144.99 ± 16.27	145.81 ± 15.45	0.7393
Total cholesterol (mmol/L)	5.28 ± 1.05	5.29 ± 1.17	0.9639
Triglyceride (mmol/L)	1.76 ± 1.41	1.79 ± 1.44	0.8220
Low-density lipoprotein (mmol/L)	3.02 ± 0.83	3.04 ± 0.88	0.8941
High-density lipoprotein (mmol/L)	1.49 ± 0.37	1.49 ± 0.32	0.8240
Creatinine (μmol/L)	57.88 ± 15.08	57.87 ± 15.02	0.8231
Urea nitrogen (mmol/L)	5.03 ± 1.42	4.96 ± 1.33	0.6231
Uric acid (μmol/L)	280.60 ± 82.06	284.96 ± 81.33	0.6276

BMI: Body mass index; FBG: Fasting blood glucose; 2 h-PG: 2-h plasma glucose; HbA1c: Glycated hemoglobin A1c.

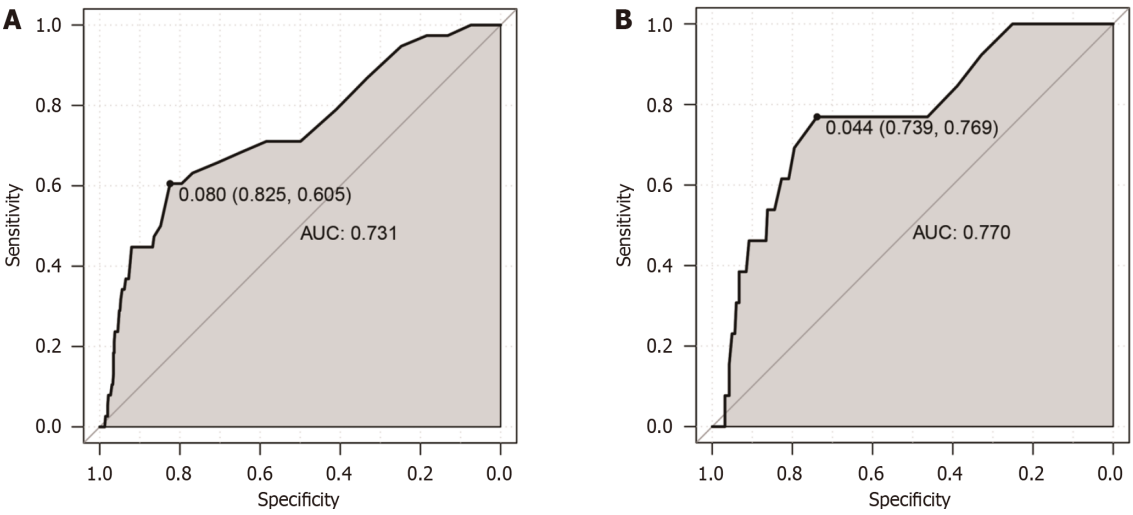

Figure 1 Receiver operating characteristic curve of glycated hemoglobin A1c for diabetic retinopathy diagnosis in the training and validation set. A: In the training set; B: In the validation set. AUC: Area under the receiver operating characteristic curve.

Table 2 Factors associated with glycated hemoglobin A1c

	Coefficient	SE	*P* value
Age (yr)	0.350	0.0017	0.0042
BMI (kg/m^2)	0.283	0.0643	< 0.0001
FBG (mmol/L)	0.547	0.0121	< 0.0001

BMI: Body mass index; FBG: Fasting blood glucose.

mended.

CONCLUSION

HbA1c is a useful diagnostic marker for DR, and an HbA1c level of 6.2% may be an appropriate cut-off value for DR detection in the Chinese population.

FOOTNOTES

Author contributions: Wen Y made significant contributions in the acquisition of data or in the analysis and interpretation of data; Wang Q was responsible for the overall conception of the manuscript and revised the important parts of the manuscript; and all the authors read and approved the final manuscript.

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