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Evaluation of a risk factor scoring model in screening for undiagnosed diabetes in China population*

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Abstract: Objective: To develop a risk scoring model for screening for undiagnosed type 2 diabetes in Chinese population. Methods: A total of 5348 subjects from two districts of Jinan City, Shandong Province, China were enrolled. Group A (2985) included individuals from east of the city and Group B (2363) from west of the city. Screening questionnaires and a standard oral glucose tolerance test (OGTT) were completed by all subjects. Based on the stepwise logistic regression analysis of Group A, variables were selected to establish the risk scoring model. The validity and effectiveness of this model were evaluated in Group B. Results: Based on stepwise logistic regression analysis performed with data of Group A, variables including age, body mass index (BMI), waist-to-hip ratio (WHR), systolic pressure, diastolic pressure, heart rate, family history of diabetes, and history of high glucose were accepted into the risk scoring model. The risk for having diabetes increased along with aggregate scores. When Youden index was closest to 1, the optimal cutoff value was set up at 51. At this point, the diabetes risk scoring model could identify diabetes patients with a sensitivity of 83.3% and a specificity of 66.5%, making the positive predictive value 12.83% and negative predictive value 98.53%. We compared our model with the Finnish and Danish model and concluded that our model has superior validity in Chinese population. Conclusions: Our diabetes risk scoring model has satisfactory sensitivity and specificity for identifying undiagnosed diabetes in our population, which might be a simple and practical tool suitable for massive diabetes screening.

Key words: Diabetes mellitus, Screening, Questionnaire, Risk factor score
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1 Introduction

The prevalence of type 2 diabetes mellitus (T2DM) has increased rapidly worldwide, particularly in developing countries such as China. According to a new study, it is estimated that 92.4 million adults aged 20 and older are diabetic in China; 60.7% of patients in this group remain undiagnosed (Yang *et al*., 2010). Previous studies also showed that the onset of T2DM is often insidious and may remain undiagnosed for many years until significant complications develop (Ruige *et al*., 1997; Park *et al*., 2002). Early diagnosis and treatment, therefore, are very important to prevent severe diabetic complications. It is generally accepted that the blood glucose measurements or glucose tolerance tests are the most reliable tests to identify the undiagnosed patients, but cannot be used for screening purposes in the general population due to high cost.

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Several risk scoring models have been proposed to identify subjects at high risk for diabetes, which proved to be practical and effective, and most of them were developed in Caucasian populations (Lawrence *et al*., 2001; Smith *et al*., 2003; Rathmann *et al*., 2005; Bergmann *et al*., 2007), with only a few in Asians (Ko *et al*., 2010; Gao *et al*., 2010). The present study attempts to develop a risk scoring model to screen T2DM in Chinese population.

2 Materials and methods

2.1 Subjects

A total of 5404 individuals with Han nationality, aged between 35 and 74, were approached in two districts of Jinan City, Shandong Province in eastern China. Among them, 40 were excluded due to known history of diabetes and 16 refused to participate. That left 5348 participants in the study. They were further divided into two groups by their geographic locations: Group A (2985 individuals from the east part of the city) and Group B (2363 individuals from the west part of the city). Their baseline characteristics were shown in Table 1.

An informed consent was given by each participant before the survey started. Protocols were in accordance with the Helsinki declaration and were approved by the Ethnics Committee of Shandong University. A screening questionnaire with medical history and health behavior information was completed by each participant, including treatment of hypertension and/or dyslipidemia, daily consumption of vegetables, whether the work requires a lot of sitting or activities, whether the level of physical activity was 4 h per week or more, et cetera. Some simple and easy-to-obtain potential risk factors were also selected, which included measurements of weight (in light indoor clothes), height (without shoes), waist circumference (at a level midway between the lowest rib and the iliac crest), hip circumference (the maximal horizontal circumference between the waist and thigh), and seated blood pressure (measured twice with at least 5 min apart by a trained nurse from the right arm after the individual resting for 10 min in seated position and took the average). Body mass index (BMI) was calculated as body weight (kg) divided by squared height (m^2). Waist-to-hip ratio (WHR) was equal to waist circumference (cm) divided by hip circumference (cm). Information about smoking and alcohol intakes was also obtained. All subjects underwent a standard 75 g oral glucose tolerance test (75 g OGTT). Diagnosis of diabetes was made according to the World Health Organization (WHO) 1999 diagnostic criteria. Individuals with fasting plasma glucose (FPG) level ≥7.0 mmol/L or 2-h post-load plasma glucose (P2hPG) level ≥11.1 mmol/L were identified as positive screening and referred to hospital for additional tests. If repeat FPG or P2hPG was still at or above the previously mentioned criteria, the individual was diagnosed with diabetes. Participants with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) were considered non-diabetic.

2.2 Establishment of a diabetes risk scoring model

A diabetes risk scoring model was developed based on data of Group A. With diabetes as the dependent variable, all the potential risk factors included in the questionnaire and clinical examinations were put in stepwise logistic regression and β-coefficients were calculated to detect risk factors. P value <0.05 was considered statistically significant. Each independent variable was assigned with a score value as 10 times of its coefficient (β). Diabetes risk score was the sum of those scores. It is assumed that the probability of diabetes increases as the diabetes risk score accumulates.

Table 1 Baseline characteristics of the participants

Group	Number		Age[#] (year)	BMI[#] (kg/m^2)	BP[#] (mmHg)	WHR[#]	Smoking (%)	Physical activity (%)
	Male	Female						
A	1125	1860	54.41±7.83	25.28±3.00	138±19/83±12	0.85±0.06	23.84	78.49
B	936	1427	55.62±7.41	24.57±3.11	140±20/86±13	0.86±0.07	25.67	77.44
Total	2061	3287	55.23±7.49	24.88±3.09	139±20/85±13	0.85±0.07	24.68	78.00
P^*	0.15		0.21	0.33	0.11	0.45	0.10	0.34

[#] Data are expressed as $\bar{x} \pm s$. [*] P value compared the data in Group A with that in Group B; Those characteristics did not show any significant differences among the three groups with all the P values >0.05

2.3 Evaluation of the diabetes risk scoring model

The diabetes risk scoring model developed in Group A was validated in the participants of Group B. The sensitivity (S), specificity (S'), and Youden index were calculated. Youden index was equal to $S+S'-1$, ranging from −1 to1. It indicated the validity of the diagnostic technique. The closer it is to 1, the better the diagnostic technique is. The optimal cutoff point was determined by the maximum values of the Youden index. The predictive performance of the risk score was evaluated with the area under the curve (AUC) in a receiver operating characteristics (ROC) curve. The sensitivity was plotted on the Y-axis, and the false-positive rate ($1-S'$) was plotted on the X-axis (Fig. 1). A steeper upward portion of the ROC curve and a lager AUC indicate a more discriminative test. The higher the AUC, the nearer the optimal cut-off point to the peak of the curve. The effectiveness of diagnosis was better when the AUC was closer to 1.

2.4 Statistical analysis

Statistical analysis was performed with SPSS software (Version 11.5). Stepwise logistic regression analysis was carried out using diabetes as dependent variable, with age, sex, smoking, physical activity, BMI, WHR, systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse, family history of diabetes mellitus, and known hyperglycemia as independent variables. χ^2-test was used for rate comparisons. Analysis of variance was used for comparisons of normal distribution data. ROC curves were plotted, and larger AUC reflected a higher accuracy of the test, with the optimal cut-off point at the peak of the curve.

3 Results

3.1 Establishment of the diabetes risk scoring model

The data from Group A were analyzed by stepwise logistic regression analysis with diabetes as the dependent variable and the known risk factors of diabetes, including hypertension, dyslipidemia, activities, BMI, WHR, etc., as potential independent variables. By stepwise logistic regression analysis, variables with P value <0.05 were selected and defined as risk factors for the risk scoring model. The selected variables included age, BMI, WHR, SBP, DBP, heart rate, family history of diabetes, and history of hyperglycemia (Table 2). Each variable was assigned with a score calculated as 10 times of its β-coefficient in the stepwise logistic regression models. The maximum score value was 124.

Table 2 Risk factors of diabetes and their scores in Group A

Independent variable	β	OR	95% CI	P	Score
Age					
45–54 years	1.48	4.41	2.39–8.14	0.00	15
55–64 years	1.92	6.83	3.43–13.61	0.00	19
≥65 years	2.07	7.95	2.92–21.69	0.00	21
BMI					
24.00–27.99 kg/m^2	1.31	3.70	1.83–7.49	0.00	13
≥28.00 kg/m^2	2.41	11.08	4.94–24.89	0.00	24
WHR[1]	1.02	2.78	1.59–4.85	0.00	10
SBP[2]	0.63	1.87	1.07–3.26	0.03	6
DBP[3]	0.55	1.74	1.05–2.88	0.03	6
Heart rate[4]	1.17	3.24	1.98–5.29	0.00	12
Family history of DM[5]	1.69	5.41	3.48–8.40	0.00	17
History of hyperglycemia[6]	2.80	16.52	9.00–30.30	0.00	28

[1] WHR: male ≥0.90, female ≥0.85; [2] SBP: ≥140 mmHg; [3] DBP ≥90 mmHg; [4] Heart rate ≥90 beats/min; [5] Family history of diabetes mellitus (DM): either parents or siblings have diabetes; [6] History of hyperglycemia: ever been told have hyperglycemia or latent diabetes, including gestational diabetes

3.2 Evaluation of the diabetes risk scoring model by the data from Group B

The accumulative scores and diabetes prevalence rates of the individuals in Group B were calculated with the model developed in Group A (Table 3). The odds ratio (OR) indicated the incremental times of diabetes prevalence rate. Then Youden index was calculated for every score range and it was achieved when the accumulative score reached 51. With this score value, the diabetes risk scoring model had the best validity. It could identify diabetes patients with a sensitivity of 83.3% and a specificity of 66.5%, the positive predictive value was 12.83%, and the negative predictive value was 98.53% (Fig. 1).

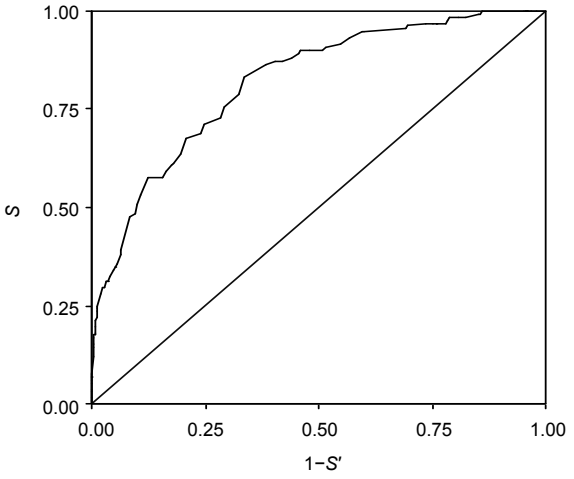

Fig. 1 Receiver operating characteristics (ROC) curves showing the performance of the diabetes risk score in predicting diabetes

Diagonal segments are produced by ties. The area under the curve (AUC) was 0.82 (95% CI: 0.78–0.86). When the cut-off point of diabetes risk score was ≥51, the sensitivity (*S*) was 83.3%, specificity (*S*′) was 66.5%, positive predictive value was 12.83%, and negative predictive value was 98.53%

Table 3 Diabetes prevalence rate of the individuals in Group B

Score	Number of people	Number of diabetics*	Prevalence rate (%)	OR
0–25	396	2	0.51	1.00
26–51	1138	26	2.28	4.61
52–77	725	65	8.97	19.40
78–124	104	39	37.50	118.20

* The individuals who were not yet diagnosed as diabetes mellitus before. χ^2=259.44, P<0.05

Sensitivity, specificity, positive and negative predictive values, as well as AUC in the ROC curve were compared. There were no significant differences between the two groups with all P>0.05 (Table 4).

3.3 Comparisons of the three different diabetes risk scoring models

Our risk scoring model showed differences from other models used in western countries in many aspects (Table 5). In Finnish screening model, the most important factor for developing T2DM was history

Table 4 Comparisons of the sensitivity, specificity, Youden index, positive and negative predictive values, and AUC between the two groups

Group	Sensitivity (%)	Specificity (%)	Youden index	Predictive value (%)		AUC
				Positive	Negative	
A	82.1	65.6	0.477	12.62	98.21	0.80
B	83.3	66.5	0.498	12.83	98.53	0.82

There were no significant differences between the two groups with all P>0.05

Table 5 Comparisons of three different models of diabetes risk score questionnaires

Source	Variables	Performance
Finnish model	Age (45–54 and 55–64 years old), BMI (25–30 and ≥30 kg/m^2), waist circumference (men 94 to <102, women 80 to <88; men ≥102, women ≥88), history of antihypertensive drug treatment, high blood glucose, physical activity, daily consumption of fruits, berries, or vegetables.	The cut-off point ≥9 with sensitivity of 77%, specificity of 66%, and AUC of 0.80 in original population. The sensitivity was 45%, specificity 86%, and AUC 0.76 when the model was applied to our total participants.
Danish model	Age (45, 50, and 55–60 years old), sex (male and female), BMI (25–29 and 30 kg/m^2), known hypertension, physical activity at leisure time, family history of diabetes.	The cut-off point ≥31 with sensitivity of 76%, specificity of 72%, and AUC of 0.80 in original population. The sensitivity was 51%, specificity 76%, and AUC 0.71 when the model was applied to our total participants.
Our model	Age (45–54, 55–64, and ≥65 years old), BMI (24–28 and ≥28 kg/m^2), WHR (male ≥0.9 and female ≥0.85), SBP (≥140 mmHg), DBP (≥90 mmHg), heart rate (≥90 beats/min), family history of diabetes mellitus, history of hyperglycemia.	The cut-off point ≥51 with sensitivity of 83%, specificity of 66%, and AUC of 0.82 in original population.

of hyperglycemia followed by obesity and age. It is consistent with our study. While in Danish model, the most important factor for development of T2DM was age, followed by obesity, then hypertension. When the two screening models (Finnish and Danish diabetes risk scores) were applied to the total participants of our study, we found that the AUC of Finnish model was 0.76 (95% confidence interval (CI): 0.71–0.81), and that of Danish model was 0.71 (95% CI: 0.65–0.76, P=0.00), both of which had lower validity than originally described (Table 5). The AUC of our risk scoring model was 0.82 (95% CI: 0.78–0.86) (Fig. 1).

4 Discussion

Previous studies have shown that 30%–50% T2DM patients have at least one microvascular or macrovascular complication at the time of diagnosis (Harris, 1993). Individuals with previously undiagnosed diabetes also have a higher risk for cardiovascular disease when compared with normal glucose-tolerant individuals (Fuller *et al*., 1980; Williams *et al*., 1995; Midthjell *et al*., 1999; Claudi *et al*., 2000). Therefore, it is of great importance to develop a practical screening method for early detection of the disease.

Several risk scoring models for screening diabetes have been developed (Lindström and Tuomilehto, 2003; Glümer *et al*., 2004; Thomas *et al*., 2006; Schulze *et al*., 2007). However, scoring models developed in western countries might yield low validity when applied to Chinese population. The low validity could be caused by differences in lifestyles and dietary habits, and possibly genetic marks in different ethnic groups (Dong *et al*., 2009). The above assumption was proved in our present study. Moreover, we also demonstrated different relative power of each risk factor in our model when compared with previous models (Table 5). The reasons are that we use different definitions in some risk factors; for example, the definition of overweight is BMI≥24 kg/m^2, and obesity BMI≥28 kg/m^2 in China, while it is ≥25 kg/m^2 for overweight and ≥30 kg/m^2 for obesity in western countries. When using their standards to evaluate our study population, the scores were lower and deviations occurred. Besides, Chinese diabetes patients have certain unique characteristics, such as lower BMI (Hong *et al*., 2007), more prominent defect in first-phase insulin secretion (Jia *et al*., 2007), and different dietary habit such as eat more carbohydrates and less fat. Those differences may account for the low validity when applying western models to Chinese population.

In our study, one of the risk factors was blood pressure, including SBP, DBP, and pulse, but not the "history of antihypertensive drug treatment" as reported previously (Glümer *et al*., 2004). This change was purposefully made due to the following: in China, many people do not know that they have hypertension until they have overt symptoms; on the other hand, some people know they have hypertension but refuse any treatment, in respect that health insurance or medicare is not as popular as it is in developed countries.

Eight variables were found to be independent risk factors for diabetes in our model. They are age, BMI, WHR, SBP, DBP, heart rate, family history of diabetes, and history of hyperglycemia. The most powerful risk factor was the history of hyperglycemia including gestational diabetes. The second important risk factor was obesity. The optimal risk score was determined when the accumulative score reached 51. With this score value, our model identified 83.3% of previously undiagnosed T2DM patients, with a specificity of 66.5%; furthermore, the positive predictive value was 12.83% and the negative predictive values was as high as 98.53%.

Family history of diabetes, which reflects the genetic predisposition for the disease, is known to be an important marker for increased risk of diabetes (Ma *et al*., 2008). Its role was less important than history of hyperglycemia, obesity, and age in our study, underscoring the role of environment and lifestyle in development of T2DM. If those risk factors were properly controlled, individuals with high genetic susceptibility can be prevented from developing diabetes.

With this model, automatic calculation of risk scores in the health website becomes possible for people to undergo diabetes self-assessment (Baan *et al*., 1999). Therefore, our study provides an easy and practical tool to screen undiagnosed diabetes in Chinese population and can be divided into two steps. In the first step, people receive the risk score automatically after filling the questionnaires. If the scores are

smaller than 51, the individuals are at less risk of suffering diabetes. If the scores are over 51, the individuals are suggested to undergo a standard OGTT. In this way, many unnecessary blood tests can be saved.

In summary, our diabetes risk scoring model is a simple, inexpensive and relative reliable method to detect diabetes patients in Chinese population. A larger sample size might be needed to make some modification to this model in order to reduce its false-negative predictive value. Other limitations include the lacking of an external validation of the scoring model, and the model will need further evaluation before it can be applied to populations of other Chinese nationalities.

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