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Evaluation of two screening methods for undiagnosed diabetes in China: An cost-effectiveness study

Yanlei Zhang[a], *Jianping Sun*[b], *Zengchang Pang*[b,*], *Weiguo Gao*[a], *Harri Sintonen*[a], *Anil Kapur*[c], *Qing Qiao*[a]

[a] *Department of Public Health, Hjelt Institute, University of Helsinki, Helsinki, Finland*
[b] *Qingdao Municipal Centre for Disease Control and Prevention, Qingdao, China*
[c] *World Diabetes Foundation, Gentofte, Denmark*

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ABSTRACT

Aims: To evaluate the performance and cost-effectiveness of two screening methods to identify undiagnosed diabetes at primary care settings among a Chinese population.
Methods: Two screening methods using a fasting capillary glucose (FCG) test or a Chinese diabetes risk score (DRS) at primary care settings followed by diagnostic tests were compared. The performance of FCG and DRS was evaluated by using receiver operating characteristic (ROC) curve analysis. The main economic outcome measures were the total cost of screening per 1000 persons, proportion of undiagnosed diabetes detected, and cost per undiagnosed diabetes identified from the societal perspective.
Results: Among all participants, 14.6% (1349/9232) had undiagnosed diabetes defined by fasting plasma glucose ≥7.0 mmol/l and/or 2 h plasma glucose ≥11.1 mmol/l and/or hemoglobin A1c ≥6.5%. At the optimal cutoff point of 6.1 mmol/l for FCG and 14 for DRS, the sensitivity was 65.1% and 65.8%, and specificity was 72.4% and 55.2%, respectively. The area under the ROC curve was 75.3% for FCG and 63.7% for DRS ($P < 0.001$). Based on the input costs, the total cost of screening 1000 persons was ¥64,000 ($9143) for FCG and ¥81,000 ($11,571) for DRS. The average cost per case identified was ¥674 ($96) for FCG at cutoff point of 6.1 mmol/l and ¥844 ($121) for DRS at score of 14. The incremental cost per case identified was ¥17,000 ($2429) for DRS compared to FCG. The dominance relations between strategies remained with the changed in sensitivity analysis.
Conclusions: As a first-line screening tool for undiagnosed diabetes, the FCG test performed better than the DRS in primary care settings in China. The non-invasive and layperson-oriented DRS was feasible and detected more cases but more expensive. No strategy has strong dominance that was both more effective and less costly. The favorable strategy will depend on if the purpose of the screening program is to identify more cases or to have lower cost per case.

* *Corresponding author at*: Shandong Road 175, Sifang District, Qingdao, Shandong, CN 266033, China. Tel.: +86 532 85661026; fax: +86 532 85661026.
E-mail address: zengchang.pang@gmail.com (Z.C Pang).
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1. Introduction

Type 2 diabetes is a serious and costly disease, imposing a heavy economic burden on Chinese health care system. Because of its asymptomatic nature, public low awareness, invasive screening tests and limited opportunities of screening, the proportion of undiagnosed diabetes in China is high, about 50–80% of the diabetes population [1–3].

In the light of evidence that diabetes and its complications are preventable [4], early screening of high risk population for identifying undiagnosed type 2 diabetes is crucial to ensure early intervention. In recent decade, various screening protocols have been developed and implemented in different screening programs. A capillary blood glucose test and a risk assessment questionnaire appear to be simple and reliable for identifying undiagnosed type 2 diabetes in China [5,6], India [7,8] and many other countries [9,10]. However, these two screening methods have not been fully evaluated in China. The purpose of this study is to evaluate the performance and cost-effectiveness of the two screening methods in identifying undiagnosed diabetes, as determined by OGTTs and/or HbA1c test, in primary care settings among a Chinese population.

2. Research design and methods

2.1. Study population

Two population-based cross-sectional diabetes surveys were conducted in 2006 and 2009 of Qingdao, China. A total of 13,712 subjects (6100 in 2006 cohort and 7612 in 2009 cohort, age 35–74) were recruited using stratified random sampling procedure among 3 urban and 3 rural areas, and 10,466 (5355 and 5111) subjects participated the surveys, with response rates of 87.8% and 67.1% respectively. The two surveys followed the same study procedure except the questionnaire on physical activity was slightly different. Demographic information, history of previous diabetes or other disease, and family history of diabetes were recorded with a standardized questionnaire during an interview on the survey sites. Weight, height and waist circumference were measured by a trained doctor or nurse. Newly diagnosed diabetes was defined as fasting plasma glucose (FPG) $\geq$7.0 mmol/l and/or 2 h plasma glucose (2 h PG) $\geq$11.1 mmol/l, and/or hemoglobin A1c (HbA1c) $\geq$6.5%. Any of these diagnostic tests if positive confirmed a diagnosis of undiagnosed diabetes. Non-diabetic was defined as FPG < 7.0 mmol/l and 2hPG < 11.1 mmol/l and HbA1c < 6.5% [11]. Thus, 9232 individuals who previously unknown to have diabetes, can be classified either as having diabetes or being non-diabetic based on the above diagnostic criteria and underwent both two screening tests, were included in the further data analysis.

2.2. Screening methods

The FCG and DRS as first-line screening methods were conducted in their respective survey sites of the primary care settings. All the study subjects first completed a DRS questionnaire that included three categorical variables of age, waist circumference and family history of diabetes [6]. After an overnight fast, capillary blood glucose test was done between 07.00 and 09.30 hour using a Bayer Ascensia BRIO blood glucose monitoring system that was calibrated to give capillary plasma/serum glucose equivalent results (Bayer Healthcare Company, Shanghai, China). All participants with positive screening results were consequently referred to the secondary or tertiary hospital to undergo diagnostic tests. To define the positive screening case, the optimal cutoff value was used at base case analysis, which was the one closest to the y intercept (0, 1) of the ROC curve, and it is at this point that the sum of the sensitivity and specificity is maximal. C-statistics were used to compare the area under the ROC curve (AUC).

2.3. The total cost, effectiveness and the cost per undiagnosed diabetes identified

We estimated the total cost associated with the screening program from the societal perspective, which covered both direct and indirect cost. Direct cost included laboratory tests, physician's time and other material cost (e.g. cost of strips, capital cost of glucose machines, needles, printing DRS). Indirect cost included the subjects off work to participate the screening and money/time spent for transportation to a health care provider.

At first-line screening, we estimated that it took about 1/3 h (20 min) for community/village doctors or nurses to measure the weight, height and waist circumference, and to double check the self-administrated questionnaire or did capillary blood glucose test.

The cost of laboratory diagnostic tests in tertiary hospital was based on Norms of Medical Service Items Pricing of China [12] and local medical service price. The price of HbA1c test ranged from ¥40 to ¥70 in different hospitals in Qingdao. We assumed that HbA1 test cost ¥70 and all the screening positive individuals did both OGTT and HbA1c test and spent 3 h to diagnose diabetes at base case analysis. The labor cost of patients and physician was estimated based on national statistics of average physician salaries [13] and also taking into account the local payment level. We estimated the salaries of community/village doctor were ¥12 per hour and doctor in tertiary hospital was ¥15 per hour. The labor cost of screenees was estimated ¥15 per hour for urban participants and ¥10 per hour for rural participants. Since about 40% and 60% of the participants were from urban and rural areas, the average labor cost was estimated as ¥12 per hour.

Transportation cost between residential areas to a tertiary hospital varied depending on the distance and average cost was estimated and used in the data analysis.

All costs were expressed in Chinese Yuan (¥), by using the exchange rate of \$1 ≈ ¥7 represented the level for the year 2007/2008. Since we only consider one-time screening, no discounting was carried out.

The total cost (TC) of screening all individuals were described as

$$\mathrm{TC} = \text{all subjects} \times \text{screening costs} + \text{screening positive subjects} \times \text{diagnostic costs}$$

$$\text{TC per 1000 persons} = \frac{\mathrm{TC}}{\text{all subjects}} \times 1000 \quad (1)$$