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ADA Diabetes Risk Test Adaptation in Indonesian Adult Populations: Can It Replace Random Blood Glucose Screening Test?

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Abstract

Aims: The use of non-invasive and easily available assessment tools such as the ADA diabetes risk test is recommended for diabetes screening among general population. This study aims to assess the validity of the ADA diabetes risk test in screening for screening hyperglycemia in Indonesian population. **Methods:** This cross-sectional study conducted at primary health care in Cibeber sub district at Cilegon city, Banten province, Indonesia. Subjects were aged ≥45 years old without a prior diagnosis of diabetes were recruited consecutively. The risk of hyperglycemia was measured using the ADA Diabetes Risk Test. Random capillary blood glucose (RcBG) with a cut-off value >140 mg/dL used as a comparison. **Results:** From a total of 134 subjects, 23.13% of subjects (n = 31) had hyperglycemia. The ADA Diabetes Risk Test gave an area under the ROC curve (AUC) of 0.71 (95% CI: 0.60-0.81) with an optimal cut-off of value ≥5. The sensitivity of the ADA diabetes risk test in diagnosing hyperglycemia was 68% with a false-negative rate (FNR) of 32.26%. Meanwhile, at a cut-off value ≥4, the sensitivity of the ADA Diabetes Risk Test was 93% with an FNR of 9.7%. **Conclusion:** ADA diabetes risk test provides a valuable result as a diabetes screening tool in the Indonesian population, thus promotes intervention strategies for population known to be at risk

Keywords

ADA diabetes risk test, hyperglycemia, Indonesia, screening, adult population

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Introduction

Diabetes mellitus is a global health problem with a rapidly growing impact on the burden of its complications, mortality, and societal costs.[1-3] The condition of diabetes can go undetected for several years.[4] During that time, the complications due to hyperglycemia already occur.[2,3] Undiagnosed diabetes mellitus can increase the risk of complications, use of health care services, and the economic burden due to the disease.[5] According to data from Ministry of Health in 2015 to 2019 showed approximately 8 millions were aged 45 to 49 years old from the total of 270 million Indonesian population.[6] In 2019, about 7.9 million people in Indonesia were unaware of their condition.[5] This number places Indonesia as the fifth highest ranked country with undiagnosed diabetes mellitus in the world.[5] It was estimated that 3 out of 4 people with diabetes in Indonesia (73.9%) do not know their condition.[5] Therefore, it is mandatory to perform early mass detection to reduce the number of people with undiagnosed diabetes mellitus, so that they could get early treatment and reduce the complications.[7] However, we need convenient and inexpensive ways to identify prediabetes or undiagnosed diabetes.

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In 2019, Indonesian Ministry of Health issued a regulation whereby the government is required to perform diabetes screening using a glucometer for citizens aged 15 years or older in a period of at least once per year.[6] It means there are approximately 200 million people who should get screen using this invasive method, and we estimated that the costs required for diabetes screening reach 1.2 trillion rupiahs each year. The Indonesian Society of Endocrinology in 2019 has provided a recommendation to start screening for diabetes in populations aged 45 years or older if they not having any risk factors.[8] The ISE recommends screening by examining the oral glucose tolerance test (OGTT) or if 1 way or another the activity is not possible to do, a screening examination using capillary blood glucose level examination is allowed for a diabetes diagnosis.[8] Capillary blood glucose testing, using portable point of care devices, maybe an alternative and known as the most convenient way to reach large numbers of people.[9] However, in a subpopulation with a low prevalence of diabetes and prediabetic conditions, the results would be insensitive.[10] This kind of invasive examination might increase unnecessary medical expenditure. Therefore, a convenient, less invasive, and effective strategy to screen diabetes is needed. Moreover, RcBG was chosen due to the one of eligible examinations particularly in the primary health care center in Indonesia because it is covered by the government insurance and almost of the center are not equipped with HbA1C test, especially in the rural area.

In a study conducted on the Asian population, the sensitivity of random capillary blood glucose (RcBG) level in diagnosing diabetes was 78.6%, while for diagnosing impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) the sensitivity of RcBG reached 62.8% and 64.7% respectively.[11] Looking at the low sensitivity score and invasive procedures of the RcBG screening test, the American Diabetes Association (ADA) in 2019 recommends screening for prediabetes and type 2 diabetes using validated tools.[12] They recommend using the ADA diabetes risk test to assess diabetes risk in asymptomatic patients.[12] This assessment tool was first developed by Bang et al[13] in 2009 using the results of the NHANES survey in 1999 to 2004. In the original study, the ADA diabetes risk test can diagnose diabetes Mellitus with a sensitivity of 88% in the cut-off value 5.[13] The ADA diabetes risk test can provide suggestion to clinician whether or not to performed diabetes diagnostic procedure in the patients, so that screening of high risk patients might be cost effective. Studies reported that variation in body compositions such as intra-abdominal fat deposition and muscle mass were higher across Asian populations compared to Caucasians. Consequently, contributes in higher predisposition to insulin resistance at later age.[14] However, because the ADA Diabetes risk test was developed based on a Caucasian population whose clinical characteristics and body proportions differ from the Indonesian population, a validity test should perform first before applying this assessment. Therefore this study aims to assess the validity of the ADA diabetes risk test for screening hyperglycemia in Indonesian population aged ≥45 years old.

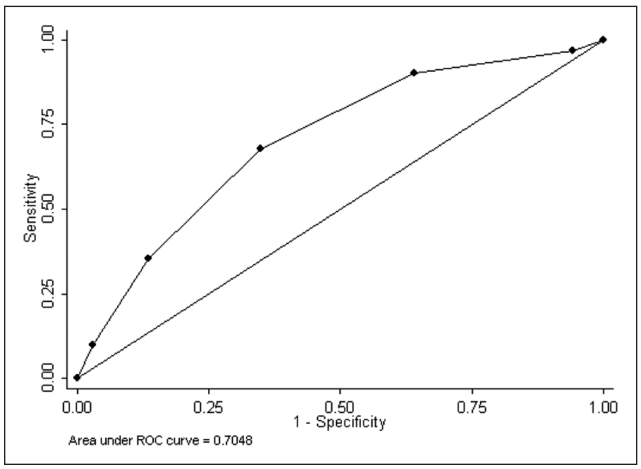

Figure 1. Flow diagram of participants.
Abbreviations: ADA, American Diabetes Association; RBG, random blood glucose.

Methods

This cross-sectional study conducted at primary health care in Cibeber sub-district at Cilegon City, Banten province, Indonesia. The total population was 412 106 people with 21.45% aged 45 years old. The number of people diagnosed with Diabetes in 2010 was 1301. However, the prevalence of prediabetes and undiagnosed diabetes mellitus were not recorded. It is previously known that the prevalence of undiagnosed diabetes mellitus in Indonesia was 4.2% and the prevalence of prediabetes in Indonesia was 10%.[15] Therefore a total number of 110 people needed to be included in this study to measured sensitivity with a confidence interval of 95% and a power of 85%.This is the sample size calculation that used in this study. In order to determine the minimum sample, the single population proportion formula was used in this study.

$$n = \frac{\left(Z_{\left(1-\frac{\alpha}{2}\right)}\right)^2 Sn\left(1-Sn\right)}{d^2\left(1-P\right)}$$

$$n = \frac{\left(1.96\right)^2 0.72\left(1-0.72\right)}{0.10^2\left(1-0.156\right)}$$

N = number of samples
Sn = ADA diabetes risk test sensitivity: 0.40[13]

Table 1. Subject Profile Based on RcBG Levels.

Variable	Hyperglycemia RBG ≥ 140 N = 31 (23.13%)	Normoglycemia N = 103 (76.87%)	Total N = 134
Mean age (years)—mean ± SD	60 ± 11	52 ± 14	53 ± 15
Sex (male)	14 (45.16%)	29 (28.16%)	43 (32.09%)
BMI (kg/m^2)—mean ± SD	24.82 ± 4.39	24.97 ± 3.68	24.97 ± 3.84
Physical activity (no)	29 (93.55%)	95 (92.23%)	124 (92.54%)
Hypertension	16 (51.61%)	34 (33.01%)	50 (37.31%)
Gestational diabetes	0 (0%)	0 (0%)	0 (0%)
Family history of diabetes	7 (22.58%)	9 (8.74%)	16 (11.94%)
RcBG levels (g/dL)—mean ± SD	181 ± 52	102 ± 23	107.5 ± 41

Abbreviations: BMI, body mass index; RcBG, Random capillary blood glucose; SD, standard deviation.

D = precision (0.10, **power = 90%)**
CI: confidence interval 95% ($Z_{(1-\alpha/2)} = 1.96$)
P = Prevalence of hyperglycemia cases in Indonesia[15]
The minimum number of samples needed is **92 people.**

All participant were consented to participate in this study were consecutively selected until the minimum number of samples is met. One hundred seventy-four of eligible subjects were included this study, whose 40 subjects were excluded due to prior history of diabetes. There were 134 subjects were participated in this study assessed for ADA Diabetes Risk Test with response rate 95.01%. This study included all adult subjects aged ≥45 years who was interview for their medical history and examined for blood pressure, waist circumference, and Body Mass Index (BMI). Moreover, the diabetes risk data was collected using the ADA Diabetes risk test in Bahasa by a trained physician. Physical activity was asked using "do you think you do the same/heavier physical activity than people of your age?" question, while gestational diabetes history was asked using "did you ever experience diabetes during pregnancy, or high blood sugar levels which then returns to normal after giving birth?" question. Measurements of weight and height were carried out by trained nurses. All measurements and responses of the ADA diabetes risk test were evaluated by the investigator.

RcBG was measured from all subjects after assessing their diabetes risk. RcBG was selected as a comparison test in this study with the consideration that the examination does not require special preparation and is recommended by the World Health Organization (WHO) and Indonesian Ministry of Health as a method of diabetes screening tool.[6,16] Samples are taken from capillary blood and measurements are carried out using a multi-check NESCO glucometer device (ISO:13485). Subjects with RcBG level ≥140 g/dL were categorized as hyperglycemia and refer to the physician in charge of further hyperglycemia evaluation and treatment.

Data analysis was performed using STATA 12. Descriptive analysis was performed on diabetes risk and RcBG levels. The performance of the ADA Diabetes risk test is assessed by measuring sensitivity, specificity, Negative Predictive Value (NPV), Positive Predictive Value (PPV), overall accuracy, Positive Likelihood Ratio (LR+), and Negative Likelihood Ratio (LR−). The optimal cut-off value is measured by determining the closest distance between the point (0, 1) and the point on the ROC curve (*d*) and determining the farthest vertical distance between the line of equality and the point on the ROC curve (Youden index).

Results

From total of 134 subjects, 23.13% (n = 31) had hyperglycemia (Figure 1). The demographic and diabetes risk profile of the subjects can be seen in Table 1.

The mean ± standard deviation (SD) age in this study was 53 ± 15 years old. Male was predominant in RcBG ≥200 g/dL group (60%), the study population mean body mass index (BMI) was classified as overweight (BMI: 24.97 + 3.84), the majority of subjects who were not perform enough physical activity at 92.54%, majority of the patients with history of hypertension was found in RcBG levels ≥200 g/dL group (60%), the family history of diabetes was present in 11.94% of all subjects. The performance of the ADA Diabetes Risk Test in for screening hyperglycemia in the Indonesian population aged ≥45 years old gives good results with an area under the ROC curve (AUC) of 0.71 (95% CI: 0.60-0.81) (Figure 2). The ADA diabetes risk test score gives the greatest AUC value when a cut-off ≥5 is used (Youden index 0.33 and d 0.48) with an overall accuracy of 66% (Figure 1). At a cut-off of ≥5, the sensitivity of ADA diabetes Risk Test in diagnosing hyperglycemia was 68% with a false negative rate (FNR) of 32.26%. Meanwhile, at a cut-off of ≥4, the

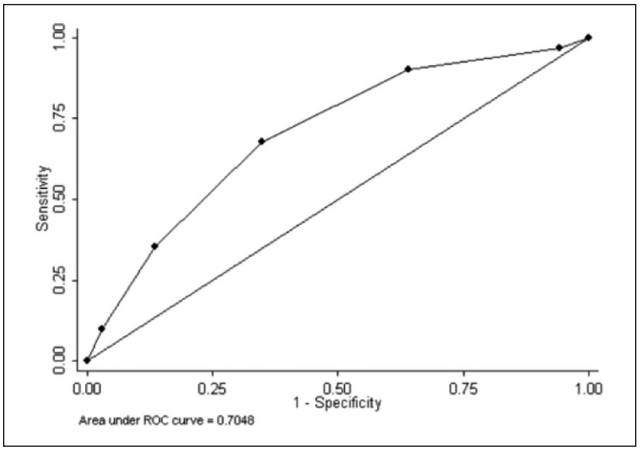

Figure 2. Receiving operation curve of the American Diabetes Association (ADA) diabetes risk test.

ADA sensitivity could increase to 93% with an FNR of 9.7%. The ADA Diabetes Risk Test performance showed in Table 2.

Discussion

This is the first study conducted in Indonesia that assessed the accuracy of the ADA Diabetes Risk Test in populations aged ≥45 years old. The ADA diabetes risk test consists of 7 questions covering age, gender, history of gestational diabetes, family history of diabetes, history of hypertension, physical activity, and measurements of body mass index.[12] The scoring system on the ADA Diabetes risk test is easy to use with a score range of 0 to 11.

Our study showed an AUC value of 0.71 with an optimal cut of value ≥5 based on the Youden index and distance (*d*). Looking at its validity, the ADA Diabetes Risk test provides a sensitivity value of 68% and a specificity of 65% at cut of value = 5 to diagnose hyperglycemia. It means about 68% of the population with hyperglycemia will give an ADA diabetes risk score above 5. Ideally a test would separate those who have the disease from those who do not. Reminding that the main aim of the ADA diabetes risk test use is for diabetes screening, a higher sensitivity needs to consider.[7] If the cut-off value was reduced to 4, the sensitivity value will increase to 93%. Thus, improve the screening of person with risk for hyperglycemia and minimize the number of false-negative test result by 9.7%. As an interpretation of these figures, if the results of this study are applied in the Cilegon city and the number of residents aged 45 years or older reached 105 781 people.[17] Assuming that the prevalence of prediabetes in Indonesia is 10%,[6,15] the possibility that the person does not has hyperglycemia is 97.9% if the results of the ADA Diabetes Risk in a person is below 4. Meanwhile, if the results of the ADA Diabetes Risk in a person is 4 or above, the possibility that the person has hyperglycemia is 13.9%.

In comparison, 2 studies conducted in Asian populations showed good results. The ADA diabetes risk test gives an AUC value of 0.725 in the Chinese population aged 45 years old and above with a sensitivity of 80% and a specificity of 56.7% for a cut-off above 5. The study comparing ADA diabetes risk test with fasting blood sugar level (GDP) ≥7 mmol/L or 2 h post glucose tolerance test ≥11.1 mmol/L.[18] Another study in the Philippine population also showed good results with a sensitivity of 86% and a specificity of 48% for a cut-off of 5 by comparing with fasting plasma glucose levels.[19] This might explain that screening strategy in primary health care have a pivotal role in early diagnosis of Diabetes, particularly in Indonesia.

Limitation of this study include the choice of RcBG as the gold standard or reference test. The use of RcBG as a reference test might affects the results of the sensitivity and specificity of this study. RcBG has large result variability. Therefore, its use is not intended for diagnosing diabetes.

ADA 2019 recommends using a validated tool for screening pre-diabetes and T2DM condition due to the low sensitivity and specificity of random blood glucose. More sources of glucose monitoring inaccuracy such as: strip factors, physical factors, patient factors, and pharmacological factors.[12] However, the results of this study can provide new insights and become an impetus for conducting more studies with an appropriate reference test, for example by checking HbA1C, fasting blood sugar, or blood sugar 2 h post-prandial. Thus, focus on strategies that promote and maintain the primary care working in Diabetes. Further studies to assess the validity and reliability of the ADA Diabetes Risk Test are still needed to confirm these findings.

Conclusion

The ADA diabetes risk test provides good results as a diabetes screening tool in the Indonesian population. This assessment tool is safe, easy to use, non-invasive, cost-free, and provides good validity. By using this assessment tool, the cost savings for diabetes screening will be enormous and should consider as a replacement for an invasive procedure such as RcBG. Further studies to assess the validity and reliability of the ADA Diabetes Risk Test with more research time and larger population, particularly using standard reference test such as fasting blood glucose or AIC are needed to confirm these findings and give more in depth multivariate analysis

Table 2. The Performance of American Diabetes Association (ADA) Diabetes Risk Test.

Cut off	Risk	Hyperglycemia (true positive) N = 31[a]	Normoglycemia (true negative) N = 103[b]	SE	SP	PPV	NPV	LR+	LR−	Overall accuracy
≥5	+	21	36	0.68	0.65	0.37	0.87	1.9	0.50	0.66
	−	10	67							
≥4	+	28	66	0.93	0.36	0.30	0.93	1.4	0.27	0.49
	−	3	37							

Abbreviations: LR+, likelihood ratio positive; LR−, likelihood ratio negative; NPV, negative predictive value; PPV, positive predictive value; SE, sensitivity; SP, specificity.
[a]Random capillary blood glucose level ≥140 g/dL.
[b]Random capillary blood glucose level <140 g/dL.

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Author Contributions

All authors contributed evenly in this study. DSH, MIM, NM, and H contributed to the design and implementation of the research, analysis, results, and the writing of the manuscript.

Declaration of Conflicting Interests

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