

## Original Article

# Development of a self-assessment score for metabolic syndrome risk in non-obese Korean adults

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**Background and Objectives:** There is a need for simple risk scores that identify individuals at high risk for metabolic syndrome (MetS). Therefore, this study was performed to develop and validate a self-assessment score for MetS risk in non-obese Korean adults. **Methods and Study Design:** Data from the fourth Korea National Health and Nutrition Examination Survey (KNHANES IV), 2007-2009 were used to develop a MetS risk score. We included a total of 5,508 non-obese participants aged 19-64 years who were free of a self-reported diagnosis of diabetes, hyperlipidemia, hypertension, stroke, angina, or cancer. Multivariable logistic regression model coefficients were used to assign each variable category a score. The validity of the score was assessed in an independent population survey performed in 2010 and 2011, KNHANES V (n=3,892). **Results:** Age, BMI, physical activity, smoking, alcohol consumption, dairy consumption, dietary habit of eating less salty and food insecurity were selected as categorical variables. The MetS risk score value varied from 0 to 13, and a cut-point MetS risk score of  $\geq 7$  was selected based on the highest Youden index. The cut-point provided a sensitivity of 81%, specificity of 61%, positive predictive value of 14%, and negative predictive value of 98%, with an area under the curve (AUC) of 0.78. Consistent results were obtained in the validation data sets. **Conclusions:** This simple risk score may be used to identify individuals at high risk for MetS without laboratory tests among non-obese Korean adults. Further studies are needed to verify the usefulness and feasibility of this score in various settings.

**Key Words:** metabolic syndrome, risk score, lifestyle factors, dietary intake, Korean population

## INTRODUCTION

The metabolic syndrome (MetS) is a major escalating public-health and clinical challenge worldwide.<sup>1</sup> MetS is characterized by accumulation of visceral fat, dyslipidemias, i.e., low HDL and high plasma triglycerides (TG), increased blood pressure, and high concentrations of fasting plasma glucose.<sup>2</sup> MetS can be viewed as a precursor condition, which may increase the risk of type 2 diabetes,<sup>3,4</sup> cardiovascular diseases<sup>5</sup> and some cancers.<sup>6</sup> Accumulating evidence suggest that the majority of MetS can be preventable if he/she changes their unhealthy lifestyles.

An increasing trend of MetS also has been observed in Asian countries. In Korea, the age-adjusted prevalence of MetS increased significantly from 24.9% in 1998 to 31.3% in 2007. Among the five components of MetS, dyslipidemia and abdominal obesity were major factors in increasing the prevalence of MetS in Koreans for the past 10 years.<sup>7</sup> At the same time, there has also been a rapid increase of colorectal cancer incidence and mortality,<sup>8</sup> which may be related to an increase of MetS in Korean adults over the past decade.<sup>9,10</sup> The recent meta-analysis of prospective cohort studies reported that both men and women had about 1.3 times greater risk of developing colorectal cancer in the presence of MetS compared with those in the absence of MetS.<sup>6</sup> Since lifestyle interventions that can modify the risk of MetS can be used as an important strategy to prevent and control the MetS, there

is a need to develop a MetS risk score questionnaire that can be useful for identifying high risk subjects who need health behaviour changes. Several risk score questionnaires for type 2 diabetes have been developed in different populations including Korean adults,<sup>11-13</sup> but a simple risk score for MetS has not been developed in Korean adults.

Therefore, in this study, to provide a reliable and practical tool that easily screens individuals at high risk for MetS, we developed and validated a self-assessment score for MetS in Korean adults using simple anthropometric and lifestyle factors without laboratory tests. Since obesity itself is a very strong risk factor for MetS in the Korean population, we limited our subjects to non-obese adults (BMI <25 kg/m<sup>2</sup>). Early identification and control of MetS is of great importance from a clinical and public health perspective, which could potentially reduce the incidence and mortality of several chronic diseases.

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## MATERIALS AND METHODS

### *Data source and study subjects*

This study was based on data from the Korea National Health and Nutrition Examination Survey (KNHANES), which is the nationally representative dietary and health examination surveys of non-institutionalized Korean civilians (<http://knhanes.cdc.go.kr>).<sup>14</sup> The KNHANES has been implemented annually to assess health related behaviours, health conditions, and nutritional states of the Koreans. Each survey data consists of independent sets of individuals from the Korean population. The KNHANES used a stratified, multistage, probability sampling design based on geographical areas, gender, and age-groups. Details of the cross-sectional data in the KNHANES have been previously described.<sup>8</sup>

Data from the 4<sup>th</sup> KNHANES 2007-2009 were used to develop a risk score model for MetS in Korean adults, and data from the 5<sup>th</sup> KNHANES 2010-2011 were used to validate the risk score. For the model development, we included 20,899 subjects who completed the health interview, health examination, and nutrition survey among the 24,871 participants from the 4<sup>th</sup> KNHANES 2007 (n=4,594), 2008 (n=9,744), and 2009 (n=10,533). Subjects were sequentially excluded from this study if they were aged <19 or ≥65 years (n=9,345), were obese (BMI ≥25) (n=3,625), had a self-reported diagnosis of hypertension, hyperlipidemia, diabetes, stroke, myocardial infarction, angina pectoris, or cancer (n=1,273), were pregnant (n=66), had missing information on laboratory measurements (e.g., fasting serum glucose, TG, HDL-cholesterol, systolic or diastolic blood pressure) (n=147), had no fasting (<8 h) status at blood test (n=230), and had extreme energy intake (≤500 or >6000 kcal/d) (n=45). Among the 6,168 participants, those with missing data on alcohol consumption (n=605), moderate physical activity (n=35), and smoking status (n=34) were excluded. Among the 5,555 participants, those with missing data on food intake-related variables (dairy consumption [n=34], dietary habit of eating less salty [n=3], and food insecurity [n=13]) were further excluded. As a result, 5508 participants were included in the full model development. For the validation study of the developed risk score, we used independent data from the 5<sup>th</sup> KNHANES 2010 (n=8,958) and 2011 (n=8,518). The validation data sets went through the same exclusion criteria as the KNHANES 2007-2009, which included 3,892 participants after the exclusion. The Institutional Review Board (IRB) of Korea Centers for Disease Control and Prevention (KCDC) provided formal ethics approval for the KNHANES data sets, and written informed consent was obtained from each subject.

### *Assessment of metabolic syndrome*

Blood samples were collected after having fasted for at least 8 hours, and measurements of fasting serum glucose, TG, and HDL-cholesterol concentrations were performed by laboratory staff. Waist circumference was measured to the nearest 0.1 cm, at the narrowest point between the lower borders of the rib cage and the iliac crest. Blood pressure was measured by health professionals three times after the participants had rested for a period of 5 minutes in a stable state. The average of the last two read-

ings for systolic blood pressure (SBP) and diastolic blood pressure (DBP) was used for data analysis.

We defined MetS according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria.<sup>15</sup> The abdominal obesity criterion was modified using the WHO Asian-Pacific values.<sup>16</sup> Under these definitions, a person has been considered to have MetS if at least three of the following criteria are present: 1) waist circumference ≥90 cm for men and ≥80 cm for women; 2) TG ≥150 mg/dL; 3) fasting serum glucose ≥100 mg/dL; 4) HDL cholesterol <40 mg/dL for men and <50 mg/dL for women; and 5) SBP ≥130 mmHg or DBP ≥85 mmHg.

### *Assessment of lifestyle factors and other covariates*

Using a self-administered questionnaire, participants were asked to report the frequency and the amount of alcohol drinking yearly, and we calculated the weekly servings of alcoholic beverages, which were determined by multiplying the frequency of alcohol drinking by the amount of alcoholic beverage servings consumed. Smoking status was classified as non-smoker, past or current smoker. Dietary intake including dairy (milk and yogurt) consumption was assessed using frequencies on the 63-item food frequency questionnaire. Participants were asked to indicate how frequently they consumed the specified foods over the previous year with 10 categories ranging from almost none to 3 times per day. In addition, information on eating habits and food insecurity were also asked. Height and weight were assessed and recorded by the medical teams performing the health examination. BMI was calculated as weight divided by height<sup>2</sup> (kg/m<sup>2</sup>).

### *Statistical analyses*

Descriptive statistics in participants according to their clinical and lifestyle factors are summarized in Table 1. Continuous variables are expressed as means ± SEs, and categorical variables are indicated as percentages. The differences between participants with and without MetS in the characteristics were described using the Student's t-test and the  $\chi^2$  test depending on the type of variables.

For model development, we carried out multivariable logistic regression analyses by including variables considered to be potentially associated with MetS, based on the scientific evidence from previous epidemiological studies. Since the aim of this study was to create a simple risk score that can be used easily by individuals themselves, we included only parameters that are easy to assess without any laboratory measurements. The logistic regression analyses were performed using the SURVEYLOGISTIC procedure of SAS software (version 9.2; SAS Institute, Cary, NC). Coefficients ( $\beta$ ) of the multivariable logistic regression model were used to assign a score value for each variable, and the score values were then added up to a total score for each individual. We calculated standard validation measures such as sensitivity (probability that the test is positive for subjects with MetS), specificity (probability that the test is negative for subjects without MetS), positive predictive value (PPV; probability that subjects with a positive test truly have MetS), negative predictive value (NPV; probability that subjects with a negative test are truly MetS-free), and the

**Table 1.** Characteristics of non-obese Korean adult participants with and without MetS in KNHANES 2007 and 2009

Characteristics	No MetS (N=5,070)	MetS (N=438)	<i>p</i> value
Age, † y	36.2±0.22	44.5±0.59	<0.001
Men, %	46.5	59.1	<0.001
BMI, † kg/m <sup>2</sup>	21.6±0.03	23.2±0.08	<0.001
MetS risk components†			
Waist circumference, cm			
Men	78.5±0.18	84.4±0.44	<0.001
Women	72.5±0.17	81.0±0.47	<0.001
HDL-cholesterol, mg/dL			
Men	47.3±0.32	38.0±0.54	<0.001
Women	52.6±0.28	42.0±0.56	<0.001
Fasting glucose, mg/dL	89.5±0.18	107±1.49	<0.001
Systolic blood pressure, mmHg	108±0.24	121±0.84	<0.001
Diastolic blood pressure, mmHg	71.8±0.19	81.9±0.59	<0.001
Triglycerides, mg/dL	97.5±1.05	233±9.92	<0.001
Past or current smoking, %	44.9	59.3	<0.001
Alcohol drinking (≥1 drink/day), %	25.4	39.9	<0.001
Dairy consumption (<once per day), %	66.2	77.4	<0.001
Food insecurity (yes), %	4.98	8.58	0.003
Moderate physical activity (<twice per week), %	64.5	69.8	0.062
Dietary habit of eating less salty (no), %	67.2	71.8	0.067

MetS: metabolic syndrome; KNHANES: Korea National Health and Nutrition Examination Survey.

†Values are means±SEs.

area under the receiver operating characteristic curve (AUC). The AUC is commonly reported as a summary measure to evaluate the discriminatory accuracy of diagnostic or screening markers, which gives the probability that the predicted risk for a subject with MetS is higher than that for a subject without MetS. The AUC of 1.0 represents perfect discrimination, while the AUC of 0.5 reflects a random guess. To determine the optimal cut point for high risk of MetS, we selected the score that had the highest value of Youden-index (= sensitivity + specificity- 1).<sup>9</sup> In addition, the developed MetS risk score was validated using independent data sets, KNHANES 2010-2011. A *p* value <0.05 was considered statistically significant.

## RESULTS

The characteristics of non-obese Korean adult participants in the KNHANES 2007-2009 are presented according to MetS status in Table 1. Of the 5,508 participants, 438 subjects were classified to have MetS. Compared with participants without MetS, those with MetS tended to be older, be men, and have higher BMI. For the life-style-related variables, the subjects with MetS seemed to have unhealthy personal behaviours compared with those without MetS. The subjects with MetS tended to be past or current smokers, be alcohol drinkers, be less physically active, have low dairy consumption, and were less likely to have dietary habits of eating less salty. For the food insecurity variable, subjects with MetS were more likely to experience insufficient food intake due to economic difficulty than those without MetS. For the MetS risk components, we confirmed that fasting serum glucose and TG concentrations, blood pressure, and waist circumfer-

ence were higher, but serum HDL concentrations were lower in subjects with MetS, compared with those without MetS.

The multivariable logistic regression models using the development data sets are presented in Table 2. A total of 5,555 subjects with complete data were included in the concise model, and of these individuals, 439 subjects had MetS. For the full model, 5,508 subjects including 438 MetS cases were included. The concise model includes variables which are well-known risk factors for MetS including increased age, increased BMI, higher alcohol consumption, more smoking, and less physical activity only, and all of the five variables were statistically significant. The full model also included food intake-related variables such as higher food insecurity, higher dairy consumption, and more dietary habit of eating less salty, all of which were significant determinants of MetS as well. In the full model, however, the variable of smoking status, which was significant in the concise model, was no longer statistically significant, but the smoking variable was still included in the full model to emphasize the importance of non-smoking in the prevention of MetS. In the univariable model, gender was a significant determinant of MetS risk; the OR for men vs. women was 1.67 (95% CI 1.33-2.08), but when the gender variable was included in the multivariable models, the significance disappeared and did not change the coefficients of the other independent variable substantially. Therefore, we did not include gender in the MetS risk score model.

The MetS risk score values were estimated based on the  $\beta$ -coefficients of the full model, as follows: for  $\beta=0.01-0.6$ , the score was 1; for  $\beta=0.61-1.2$ , the score was 2; for  $\beta=1.21-1.8$ , the score was 3; and for  $\beta >1.8$ , the

**Table 2.** Multivariable logistic regression models of related factors for MetS among non-obese Korean adults<sup>†</sup>

	Concise model: n=5,555 (439 of whom had MetS)		Full model <sup>§</sup> : n=5,508 (438 of whom had MetS)		Score <sup>‡</sup>
	OR (95% CI)	β-coefficient	OR (95% CI)	β-coefficient	
Intercept	—	-5.147	—	-5.519	
Age (years)					
19 to <35	1.00 (ref)		1.00 (ref)		
35 to <45	2.51 (1.78-3.53)	0.919	2.46 (1.74-3.47)	0.899	2
45 to <65	4.49 (3.23-6.24)	1.502	4.49 (3.22-6.27)	1.502	3
BMI (kg/m <sup>2</sup> )					
<21	1.00 (ref)		1.00 (ref)		
21 to <23	2.33 (1.52-3.57)	0.846	2.32 (1.52-3.55)	0.841	2
23 to <24	5.44 (3.53-8.38)	1.694	5.43 (3.53-8.36)	1.692	3
24 to <25	8.23 (5.49-12.3)	2.108	8.20 (5.47-12.3)	2.104	4
Alcohol consumption					
<1 drink/d	1.00 (ref)		1.00 (ref)		
≥1 drink/d	1.58 (1.22-2.05)	0.457	1.57 (1.21-2.05)	0.453	1
Moderate physical activity					
≥twice/week	1.00 (ref)		1.00 (ref)		
<twice/week	1.48 (1.14-1.92)	0.391	1.45 (1.12-1.89)	0.374	1
Smoking status					
Never	1.00 (ref)		1.00 (ref)		
Past/current smoking	1.32 (1.03-1.68)	0.274	1.24 (0.96-1.61)	0.218	1
Food insecurity					
No			1.00 (ref)		
Yes			1.63 (1.05-2.51)	0.487	1
Dietary habit of eating less salty					
Yes			1.00 (ref)		
No			1.33 (1.04-1.71)	0.286	1
Dairy consumption					
≥once/day			1.00 (ref)		
<once/day			1.32 (1.01-1.75)	0.278	1
Area under the ROC curve		0.773		0.776	0.766

MetS: metabolic syndrome; ref: reference.

<sup>†</sup>Only subjects with no missing data on the risk factors were included into the specific model.

<sup>‡</sup>The score values were estimated based on the β coefficients of the multivariable logistic regression model and are provided for the full model.

<sup>§</sup>The full model includes food intake-related variables in addition to the variables included in the concise model.

score was 4. The total MetS risk score was calculated as the sum of the individual scores and the maximum total score for this risk model was 13. The eight risk factors jointly yielded an AUC of 0.776 in the full model based on the development data sets. Figure 1 shows a sample of a self-assessment questionnaire that can be used by non-obese Korean adults to screen for MetS risk.

A cut-point MetS risk score of ≥7 was selected as it results in the highest value for the Youden index to indicate an individual at high risk for MetS. In the development data sets, the cut-point yielded a sensitivity of 81%, specificity of 61%, PPV of 14%, and NPV of 98%, with an AUC of 0.78. Relatively similar results were observed when we applied this score to the KNHANES 2010-2011 validation data sets. For the independent data sets, the cut-point of ≥7 yielded a sensitivity of 78%, specificity of 71%, PPV of 14%, and NPV of 98%, with an AUC of 0.80. Table 3 presents the prevalence of MetS by the four MetS risk score categories in the development and validation data sets. The mean prevalence of MetS in the development data sets was 0.85, 4.21, 9.22, and 20.7% in individuals with total risk score of ≤4, 5-6, 7-8, and ≥9, re-

spectively. Similar results were observed in the validation data sets (i.e., 0.83, 3.18, 10.3, and 20.3%). The risk of MetS was remarkably elevated in the two highest categories in both model development and validation data sets.

## DISCUSSION

We developed and validated a self-assessment score to identify high-risk subjects for MetS in Korean non-obese adults. The risk score model included age, BMI, physical activity, smoking, alcohol consumption, dairy consumption, dietary habit of eating less salty and food insecurity as determinants for MetS risk. We aimed to develop a simple MetS risk score questionnaire to screen individuals at high risk for MetS without laboratory tests, and the variables in our risk model emphasize the importance of lifestyle interventions that can modify the risk of MetS.

Although there was no published data on undiagnosed MetS in Korea, one study from Italy showed that 16.4-28% of people with MetS were not aware of their illness, and the prevalence of undiagnosed MetS was 5.2-8.9% in normal-BMI individuals.<sup>17</sup> As MetS is associated with increased risk of type 2 diabetes,<sup>3,4</sup> cardiovascular dis-

Question		Answer (score)	Your score
1	Your age category	<35 y (0 point) 35 to 44 y (2 points) 45 to <65 y (3 points)	
2	Your BMI (kg/m <sup>2</sup> )	<21 (0 point) 21 to <23 (2 points) 23 to <24 (3 points) 24 to <25 (4 points)	
3	Do you drink alcohol on a daily basis (≥1 drink per day)?	No (0 point) Yes (1 point)	
4	Have you ever been smoking (in the past or currently)	No (0 point) Yes (1 point)	
5	Have you ever experienced insufficient food in a household due to economic difficulty?	No (0 point) Yes (1 point)	
6	Do you get moderate-intensity of physical activity often (≥twice per week)?	Yes (0 point) No (1 point)	
7	Do you avoid salty foods and try to eat a low sodium diet?	Yes (0 point) No (1 point)	
8	Do you consume dairy products on a daily basis (≥once per day)?	Yes (0 point) No (1 point)	
Calculate total score by adding all points from questions 1-8. (If the total score is ≥7, you are at high risk for MetS, so see your doctor for laboratory test)		<b>Total Score is</b> _____	

**Figure 1.** Self-assessment questionnaire for MetS risk in non-obese Korean adults.

ease<sup>5</sup> and several cancers,<sup>6</sup> the early detection of people with undiagnosed MetS and early treatment of MetS might be important for reducing the burden of many diseases. If this simple and easy risk assessment score could efficiently identify high-risk individuals and help them change their unhealthy lifestyles for prevention and treatment of MetS, it would be greatly helpful to promote public health and improve the quality of life of individuals in Korea.

The number of people with MetS increases rapidly every year,<sup>7</sup> but no screening tool of MetS has been provided in the Korean population so far. It is important to establish different risk models of MetS for different ethnic groups, because some criteria such as waist circumference are different according to ethnicity, and the prevalence of MetS of Asians is higher than that of whites considering body size.<sup>18</sup> There were several published risk models based on Asian ethnic groups,<sup>19-21</sup> but all of the models required biomarkers through blood tests. To the best of our knowledge, this is the first study to develop a simple risk score of MetS using eight answerable questions for the identification of high-risk individuals in the Korean population. In addition, validation assessments confirmed that our risk score performed well in the prediction of MetS in the independent data sets.

Our risk model is based on scientific evidence from recent investigations. This model includes adjustable factor such as BMI,<sup>22-24</sup> smoking,<sup>25-27</sup> physical activity,<sup>28,29</sup> alcohol consumption,<sup>26,27,30</sup> dairy consumption,<sup>31</sup> sodium intake<sup>32</sup> and food security.<sup>33</sup> A four-year follow-up study from Taiwan showed that people with overweight BMI (23≤BMI<25) were more than twice as likely to have MetS risk compared with those who had optimal BMI (18≤BMI<23) in both men and women.<sup>24</sup> A recent meta-analysis reported that heavy drinkers (>35 g/d of alcohol) had an 84% higher risk of MetS compared with non-drinkers.<sup>30</sup> Two observational studies from cohort<sup>26</sup> and cross-sectional studies<sup>27</sup> also suggested that smoking cessation and the restriction of alcohol consumption may be good interventions to reduce the prevalence of MetS. One study from Taiwan confirmed that a moderate and high level of physical activity significantly reduced the risk of MetS.<sup>28</sup> With regard to food consumption, several studies reported that high dairy consumption<sup>31</sup> and low sodium intake<sup>32</sup> are associated with reduced risk of MetS. In addition, results from the National Health and Nutrition Examination Survey showed that people with marginal and very low food security had an increased risk of MetS by 80% and 65%.<sup>33</sup>

Our self-assessment score is unique in that it considers

**Table 3.** The MetS risk by the risk score among non-obese Korean adults in the development data sets (KNHANES 2007-2009) and validation data sets (KNHANES 2010-2011)

Score	Model development data sets (KNHANES 2007-2009)			Model validation data sets (KNHANES 2010-2011)		
	Subjects n	MetS risk		Subjects n	MetS risk	
		n	%		n	%
0-4	1602	18	0.85	1481	10	0.83
5-6	1481	70	4.21	1095	45	3.18
7-8	1490	146	9.22	914	97	10.3
≥9	935	204	20.7	402	80	20.3

MetS: metabolic syndrome; KNHANES: Korea National Health and Nutrition Examination Survey.

diet-related risk factors in addition to lifestyle factors. Several potential mechanisms can explain the association between dietary factors and MetS. Calcium in dairy products may help reduce obesity by reducing fat absorption and lipogenesis or promoting lipolysis through increased excretion of bile acids and regulation of serum calcium levels.<sup>2,34</sup> Dairy proteins such as casein and whey protein also may decrease blood pressure by mediating renin-angiotensin system through the inhibition of angiotensin-converting enzyme.<sup>2,34</sup> Although the downstream mechanism about the effect of sodium intake on MetS is not fully understood, previous studies have suggested that insulin resistance,<sup>35</sup> hypertension<sup>36</sup> and obesity<sup>37</sup> are associated with salt sensitivity, which responds to changes in dietary sodium intake. For food insecurity, it has been shown in several studies that a positive association exists with hypertension,<sup>38</sup> dyslipidemia<sup>39</sup> and diabetes.<sup>40</sup>

This risk model for MetS is simple to use because it does not need any blood tests to acquire a MetS risk score. Thus, people can easily derive their own risk score for MetS by themselves, and they also can be aware of various risk factors for MetS through reading the questionnaire and filling in the MetS risk score. If they get a high score and recognize risk factors for MetS, they should have a blood test for diagnosis of MetS in the hospital or try to modify their lifestyles including diet, exercise, smoking, and alcohol drinking for prevention and treatment of MetS. For food insecurity, some policies and programs should be conducted to provide nutrition support to members of households with food insecurity.

The present study has some limitations, which could be resolved by additional research. The results of this risk score should be interpreted with caution because it was derived from a national cross-sectional study, which is difficult to draw causal or directional inferences from our findings. However, we excluded subjects with a self-reported diagnosis of hypertension, hyperlipidemia, diabetes, and other chronic diseases to eliminate possible reverse causation. Nevertheless, there is still a possibility that the risk model might be unable to accurately predict the risk of future development of MetS. Further studies based on prospective studies with a long duration of follow-up will be necessary in the Korean population. For the validation tests of our risk score, we confirmed that it was valid in the independent data sets, but additional external validation is needed.

Our simple self-assessment score for MetS risk has been developed to screen individuals at high risk of MetS and increase the recognition of modifiable healthy lifestyles for prevention of MetS in the Korean population. We believe that this easy, simple and inexpensive risk assessment tool is an alternative approach at the screening phase, because this can be used without laboratory tests in communities and clinical situations. Further studies are warranted to verify the usefulness and eligibility of our risk tool and improve the accuracy of this score in various settings.

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#### AUTHOR DISCLOSURES

No conflict of interest in this study.

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