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Original Article

## Development of a diagnosis model for coronary artery disease

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### ABSTRACT

**Background:** The purpose of this study was to develop a coronary artery disease (CAD) prediction model that optimally estimates the pre-test probability of CAD for patients suspected of CAD.

**Methods and results:** This retrospective, multi-centre study included 7360 consecutive patients (4678 men,  $57.87 \pm 11.42$  years old; 2682 women,  $61.60 \pm 9.58$  years old) who underwent coronary angiography for evaluation of CAD. A prediction model was fitted for diagnosis of CAD with the help of eight significant risk factors including sex, age, smoking status, diabetes, hypertension, dyslipidaemia, serum creatinine and angina. All potential predictors were significantly associated with the presence of CAD. The prevalence of CAD was significantly higher in men than in women. The clinical model gives a relatively accurate prediction of CAD with an area under the curve (AUC) of 0.74 (95% CI, 0.88–0.96;  $P < 0.001$ ). Addition of angina to the prediction model improves the predictive precision of the model. The optimal cut-off for predicting CAD in this model was 0.79 with a sensitivity of 0.658 and a specificity of 0.709.

**Conclusion:** A prediction model including age, sex, and cardiovascular risk factors allow for an accurate estimation of the pre-test probability of coronary artery disease in Chinese populations. This algorithm may be useful in making decisions relating to the diagnosis of CAD.

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### 1. Introduction

Coronary artery disease (CAD) continues to be the leading cause of death and disability in the Chinese population and worldwide.<sup>1</sup> Early and effective identification and treatment of CAD in high-risk patients are recommended.<sup>2,3</sup> Coronary artery angiography (CAG) is still widely accepted as the gold standard for diagnosing CAD. However, using coronary angiography routinely as a first choice test is not accepted because of the risk of complications, high costs and the unwillingness of many patients to undergo invasive examinations. Several important non-invasive diagnostic tools, such as computed tomography (CT) and magnetic resonance imaging (MRI) scanning, in cardiovascular risk patients are limited and expensive.<sup>4</sup> In the Chinese population, the reliability of probabilities has not been investigated in patients referred to invasive CAG testing.

It is generally acknowledged that CAD is a multifactorial disease in which various major risk factors, such as age, sex, diabetes, smoking, family history and high cholesterol, are involved in disease development and clinical manifestation.<sup>5</sup> CAD progresses slowly and may develop over a patient's whole lifetime, and the

results of alterations in diet, exercise, living conditions, or drugs may not be seen until many years later. Time and economics are crucial for obtaining the correct diagnosis in the early stage of heart disease. In recent years, considerable research has been conducted and large amounts of money have been spent to determine whether it is possible to alter the incidence of heart disease by altering peoples' lifestyles. Diagnosing heart disease, in most cases, depends on a complex combination of clinical and pathological data. Because of this complexity, considerable interest exists among clinical professionals and researchers in the efficient and accurate prediction of heart disease. The costs of invasive and non-invasive diagnostic methods, which are used to identify the presence and severity of CAD, are increasing dramatically. Because of the limited resources available in certain areas of the world, finding low-cost strategies for developing a diagnosis model is essential. Developing a model from routine clinical characteristics for the diagnosis of CAD could help physicians refine their knowledge of the stratification of CAD risk with respect to vague information.

There is a growing awareness of the need to apply statistical techniques to develop evidence-based models for enhanced decision-making. Several studies have focused on predicting the risk of CAD in Asian populations.<sup>6,7</sup> However, few studies have constructed prediction models for CAD in a large cohort of Asian

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patients suspected of CAD who met the diagnostic criteria and underwent coronary angiography. The purpose of this study was to develop a simple diagnostic model that can be used in clinical practice for diagnosis of CAD in the Chinese population.

## 2. Methods

### 2.1. Subject selection

This study was performed as a retrospective, case-control study in the south and north of China (Fourth and First Affiliated Hospital of Chinese Medical University, Zhongda Hospital of Southeast University and the First Affiliated Hospital of Soochow University). A total of 8297 consecutive patients were studied in the Department of Cardiology between 2008 and 2014. All patients in the study were consecutive referrals for coronary angiography because of a clinical suspicion of CAD. The patients had no known prior myocardial infarction according to their medical history or electrocardiographic findings, no presence of heart failure and cardiomyopathy, and no known serious valve diseases, prior percutaneous cardiac catheterizations or coronary artery bypass grafts. Other exclusion criteria were chronic kidney disease, apparent infectious disease, chronic inflammatory disorders, and malignancy. All patients received a general health questionnaire survey. The questionnaire covered demographic background and medical history. This study and the consent process were approved by our local ethics committee (Ethics Committee of The Fourth Affiliated Hospital of Chinese Medical University) and were conducted in accordance with the principles of the Declaration of Helsinki. We adhere to the statement of ethical publishing as it appears in the International Journal of Cardiology.<sup>8</sup>

### 2.2. Data collection

All patients received routine blood sample tests before coronary angiography. The blood samples were drawn after overnight fasting for laboratory tests. All of the laboratory tests were conducted by certified experimental specialists using standard protocols at the hospital's Laboratory Department. We selected biomarkers from the routine health check-up, including low-density lipoprotein (LDL) and serum creatinine. Other data were collected from the patient records and were used as clinical variables. The variables used for predicting CAD or non-CAD were age (years), sex (men/women), type of angina, history of hypertension, smoking history and history of diabetes.

### 2.3. Clinical definitions

The type of angina was classified as typical or atypical. Typical angina was defined as all of the following criteria: (1) characterized by squeezing or crushing, (2) substernal in location, with or without arm/neck radiation, and (3) provoked by stress and promptly relieved by rest and/or nitroglycerine. If two or none of the criteria was present, the symptoms were classified as atypical angina. Hypertension was defined as systolic blood pressure  $\geq 140$  mm Hg and/or diastolic blood pressure  $\geq 90$  mm Hg or use of antihypertensive drugs. Diabetes mellitus was defined as fasting glucose levels of  $\geq 7$  mmol/L or treatment with insulin or oral hypoglycaemic medications.<sup>9</sup> Cigarette smoking was defined as smoking at least one cigarette per day for one or more years.<sup>1,10</sup>

### 2.4. Coronary angiography

All patients suspected of CAD in this study had undergone coronary angiography. Multiple projections were obtained to assess the maximal coronary artery luminal narrowing.

Angiograms were analyzed in each institution by consensus opinion of two experienced interventional cardiologists. Each major coronary vessel, such as the right coronary, left main, left anterior descending and circumflex artery or their major branches, was assessed, and the visual estimation of the percent grades of luminal stenosis was reported. CAD was defined as the presence of at least one major epicardial coronary artery with  $\geq 50\%$  lumen diameter narrowing.

### 2.5. Derivation of the probability algorithms and validation

Logistic regression is a type of regression analysis used for statistically predicting the outcome of a categorical dependent variable from a set of predictor or independent variables.<sup>11</sup> Because many factors are related to the diagnosis of coronary disease, multivariate methods have been extensively applied to the diagnostic evaluation process. The logistic regression equation allows us to easily calculate the predicted probability of an outcome. We used the logistic model to evaluate individual contributions of clinical characteristics to determine the presence of coronary artery stenosis in a large segment of the Chinese population. The maximum likelihood method was applied to derive formulas in this model. The Wald test-statistic was used to test the significance of the logistic regression co-efficient.

The model developed in the training sample was used to predict the probability of severe CAD for each patient in the test sample. The accuracy of the model to separate CAD from non-CAD was assessed by using the means of the area under the receiver operating characteristic (ROC) curve, and Youden's index was applied to establish the optimal cut-off value.

### 2.6. Statistics

All values are reported as the mean  $\pm$  SD (standard deviation). All tests of significance were two-tailed, and statistical significance was defined as  $P < 0.05$ . All statistical analyses and the multivariable logistic regression analysis were performed using Stata/SE software programme, version 12 (STATA Corp).

## 3. Results

### 3.1. Baseline characteristics

Our study collected the data from 7360 consecutive asymptomatic and symptomatic patients (4678 men, 2682 women) with suspected CAD who underwent coronary angiography from the 4 participating centres. A total of 937 patients were excluded from the study because of incomplete or absent data according to our study protocol. Table 1 shows the demographic and clinical characteristics of the various patient groups. The mean age was 59 years, ranging from 19 to 90 years.

A total of 4860 consecutive patients were diagnosed with CAD (at least 1 coronary stenosis  $>50\%$  in the major epicardial arteries), and the remaining 2500 patients with normal coronary arteries were categorized as control subjects. All eight characteristics of the patient population showed statistically significant variation between CAD and non-CAD patients. The prevalence of CAD was significantly higher in men than in women. All variables were significantly different between CAD patients and non-CAD patients. The prevalence of diabetes was substantially higher in CAD patients. Of these characteristics, the incidence of angina, smoking and serum creatinine were higher in males than in females, while age and prevalence of diabetes, LDL and hypertension were higher in females than in males.

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