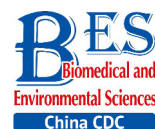


Original Article



Development and Validation of a Model for Predicting Diabetic Nephropathy in Chinese People *

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Abstract

Objective To develop a risk model for predicting later development of diabetic nephropathy (DN) in Chinese people with type 2 diabetes mellitus (T2DM) and evaluate its performance with independent validation.

Methods We used data collected from the project 'Comprehensive Research on the Prevention and Control of Diabetes', which was a community-based study conducted by the Jiangsu Center for Disease Control and Prevention in 2013. A total of 11,771 eligible participants were included in our study. The endpoint was a clear diagnosis of DN. Data was divided into two components: a training set for model development and a test set for validation. The Cox proportional hazard regression was used for survival analysis in men and women. The model's performance was evaluated by discrimination and calibration.

Results The incidence (cases per 10,000 person-years) of DN was 9.95 (95% CI; 8.66-11.43) in women and 11.28 (95% CI; 9.77-13.03) in men. Factors including diagnosis age, location, body mass index, high-density-lipoprotein cholesterol, creatinine, hypertension, dyslipidemia, retinopathy, diet control, and physical activity were significant in the final model. The model showed high discrimination and good calibration.

Conclusion The risk model for predicting DN in people with T2DM can be used in clinical practice for improving the quality of risk management and intervention.

Key words: Type 2 diabetes mellitus; Diabetic nephropathy; Risk factors; Model development and validation

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INTRODUCTION

Diabetic nephropathy is a major complication of type 2 diabetes. Characteristics of diabetic nephropathy include: an elevated urinary albumin excretion rate and blood pressure, as well as a decline in renal

function^[1-4]. In a previous study, more than 95% of renal diseases were observed in people with diabetes^[5-6]. However, the prevalence of renal disease in patients with type 2 diabetes mellitus (T2DM) was previously not acknowledged^[7]. Recent evidence has suggested that DN is becoming the leading cause of end-stage renal disease (ESRD) in

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diabetic patients. Furthermore, diabetes plays a major role in the development of cardiovascular events, which can in turn aggravate renal dysfunction^[8-10]. Several studies conducted in other countries have identified risk factors and subsequently developed risk equations for predicting DN among people with T2DM^[2,11-13]. However, due to the complex pathogenesis of DN and the variation among people from different countries, the results may not be directly applicable. In China, researchers from Shanghai and Beijing have studied the prevalence and risk factors of chronic kidney disease (CKD) in Chinese people with T2DM^[14]. In 2006, the Hong Kong Diabetes Registry developed risk equations for predicting ESRD in clinical settings^[15]. However, those studies were limited to the determination of prevalence through examination of end stage renal dysfunction in clinical participants or in those with renal disease at baseline. Therefore, the main objective of the current study was to evaluate both incidence and associated risk factors of DN in people with T2DM. Using this, we aimed to develop a model for risk prediction of DN among patients with T2DM.

METHODS

Study Design and Data Source

We used data from the baseline dataset of the project, 'Comprehensive Research on the Prevention and Control of the Diabetes (CRPCD)'. The CRPCD project is a large community-based, ongoing study aimed at exploring an applicable technology for comprehensive intervention in people with T2DM (Details of the project can be found in Tables S1-S2 in Supplementary materials in www.besjournal.com). The primary outcome was the patients' first diagnosis of diabetic nephropathy, after the diagnosis of T2DM. Baseline date referred to the date of diagnosis of T2DM. A clinical diagnosis of DN was made on the basis of persistent albuminuria, diabetic retinopathy, and the absence of any clinical or laboratory evidence of other kidney or urinary tract disease^[11]. Information about DN events was obtained, following a comprehensive medical record review, physical examination, or questionnaire survey. Participants were retrospectively followed from baseline until the day of the survey (December 31, 2013) or first occurrence of final events. Patients with missing information, necessary for the diagnosis of DN, or who had already been diagnosed with nephropathy before the baseline assessment were

excluded. We also excluded individuals above the age of 80, and those below the age of 30.

In the end, 11,771 participants were recruited, with 5,705 participants (including 45 patients with DN) from Huai'an city. These were treated as the training set. A total of 6,066 participants (including 32 patients with DN) were from Suzhou city and these were treated as the test set. Information from the two groups was used for model development and evaluation respectively.

Description of Variables

Information on demographics, lifestyle, and disease history was derived from the questionnaires administered. Smoking status during the follow-up period was ascertained through self-reporting. Baseline values of physical examination and laboratory tests were obtained from the medical records of participants or through self-reporting. The actual age was recorded as age of participant at the time of the study, whilst the date of diagnosis of the disease was obtained from the medical records. Smoking status was categorized as 'yes' and 'no' in response to the question 'Have you ever smoked 100 cigarettes in the past?' Physical activity levels by taking the product of the metabolic equivalent (MET) and the amount of time used for each activity. Physical activity was then categorized into low (MET < 31.22) and high (MET > 31.22). Duration of T2DM was defined as the time interval between the date of diagnosis and time of survey. Family history of diseases was recorded on the basis of any of the family members having the disease. Dietary habits were obtained from the questionnaire. Participants with diet control referred to those modifying their dietary habits according to doctors' advice. Antidiabetic treatment included oral hypoglycemic agent or insulin administration. Patients who took their medication as prescribed were classified as demonstrating 'good compliance' while patients who did not take drugs according to the prescription were classified as demonstrating 'poor compliance.' All variables were time varied.

Statistical Analysis

After confirming that the assumption of proportionality of hazards was met, we used the Cox proportional hazards regression model to estimate the parameters separately for men and women. Covariates in the baseline model included age at diagnosis, location, culture degree, smoking status, body mass index (BMI), creatinine, high-density

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