Nomogram Prediction Model and Validation Study for Risk of Diabetic Kidney Disease in Patients with Type 2 Diabetes Mellitus: Postprint

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Abstract

Background Diabetic nephropathy (DN) is a common complication in patients with diabetes mellitus. Its risk prediction and validation facilitate early identification of high-risk patients and implementation of interventions to prevent or delay the progression of renal disease.

Objective To analyze the risk factors influencing DN development in patients with type 2 diabetes mellitus (T2DM), and to construct and validate a predictive model for DN risk in T2DM patients.

Methods A total of 5810 T2DM patients hospitalized at the First Affiliated Hospital of Xinjiang Medical University from January 2016 to January 2021 were selected as study subjects. Patients were divided into a DN group (481 cases) and a non-DN group (5329 cases) based on the presence or absence of concurrent DN. Among them, 481 DN patients were matched 1:1 with controls by sex and age ($±$2 years). The matched 962 T2DM patients were randomly divided into a training group (n=641) and a validation group (n=321) at a 2:1 ratio. Baseline data were collected, including clinical characteristics, laboratory test results, and other relevant data. LASSO regression was employed for optimal variable selection, and a nomogram predictive model was developed using multivariate logistic regression analysis. The discriminative ability, calibration, and clinical utility of the predictive model were evaluated using receiver operating characteristic (ROC) curve, Hosmer-Lemeshow calibration curve, and decision curve analysis (DCA), respectively.

Results Comparisons between the DN and non-DN groups showed statistically significant differences in sex, age, BMI, diabetes duration, white blood cell count (WBC), total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), serum creatinine (Scr), hypertension, systolic blood

pressure (SBP), diastolic blood pressure (DBP), glycated hemoglobin (HbA1c), apolipoprotein B (ApoB), 24-hour urinary total protein (Up), and qualitative urinary protein (Upn) (P<0.05). Using LASSO regression analysis, five predictive variables associated with DN risk in T2DM patients were selected. Combined with multivariate logistic regression analysis, the results indicated that diabetes duration, TC, Scr, hypertension, and Upn were risk factors for DN in T2DM patients (P<0.05). The area under the ROC curve (AUC) for DN risk in the training group was 0.866 (95% CI=0.839-0.894), and the AUC in the validation group was 0.849 (95% CI=0.804-0.889). The Hosmer-Lemeshow goodness-of-fit test for the calibration curve showed good fit (training group P=0.748; validation group P=0.986). DCA demonstrated that using the nomogram predictive model to predict DN risk in T2DM patients was more beneficial when the patient's threshold probability was 0.15-0.95.

Conclusion This study found that diabetes duration, TC, Scr, hypertension, and Upn may be risk factors for DN in T2DM patients. A nomogram predictive model incorporating these five risk factors was established, which can be used to predict the risk of DN in T2DM patients.

Full Text

A Nomogram Prediction Model and Validation Study on the Risk of Diabetic Nephropathy in Type 2 Diabetes Patients

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Abstract

Background: Diabetic nephropathy (DN) is a common complication of diabetes. Predicting and validating its risk can help identify high-risk patients in advance and implement interventions to avoid or delay disease progression. **Objective:** To analyze risk factors affecting DN complication in type 2 diabetes mellitus (T2DM) patients, construct a risk prediction model for DN in T2DM patients, and validate it. **Methods:** A total of 5,810 T2DM patients hospitalized at the First Affiliated Hospital of Xinjiang Medical University from January 2016 to January 2021 were selected as study subjects and divided into a DN group (n=481) and non-DN group (n=5,329) based on DN complication. A 1:1 case-control matching was performed for 481 DN patients by gender and

age ($±$2 years). The matched 962 T2DM patients were randomly divided into a training group (n=641) and validation group (n=321) at a 2:1 ratio. Basic patient data including clinical characteristics, laboratory test results, and other relevant data were collected. LASSO regression was applied to optimize variable screening, and a nomogram prediction model was developed using multivariate logistic regression analysis. Model discrimination, calibration, and clinical validity were evaluated using receiver operating characteristic (ROC) curve, calibration curve (Hosmer-Lemeshow test), and decision curve analysis (DCA), respectively. **Results:** Significant differences were observed between DN and non-DN groups in gender, age, BMI, diabetes duration, white blood cell count (WBC), total cholesterol (TC), triacylglycerol (TG), low-density lipoprotein cholesterol (LDL-C), serum creatinine (Scr), hypertension, systolic blood pressure (SBP), diastolic blood pressure (DBP), glycosylated hemoglobin (HbA1c), apolipoprotein B (ApoB), 24-hour urinary micro total protein (Up), and qualitative urinary protein (Upn) ($P<0.05$). Five predictor variables associated with DN risk in T2DM patients were screened using LASSO regression. Combined with multivariate logistic regression analysis, diabetes duration, TC, Scr, hypertension, and Upn were identified as risk factors for DN complication in T2DM patients ($P<0.05$). The area under the ROC curve (AUC) for DN risk was 0.866 (95%CI=0.839-0.894) in the training group and 0.849 (95%CI=0.804-0.889) in the validation group. The calibration curve showed good Hosmer-Lemeshow fit (training group $P=0.748$; validation group $P=0.986$). DCA demonstrated that using the nomogram prediction model was more beneficial for predicting DN risk in T2DM patients when the threshold probability ranged from 0.15 to 0.95. **Conclusion:** This study identified diabetes duration, TC, Scr, hypertension, and Upn as risk factors for DN complication in T2DM patients. A nomogram prediction model containing these five risk factors was established, which can be used to predict DN risk in T2DM patients.

Keywords: Diabetes mellitus, type 2; Diabetic nephropathies; Risk factors; Nomogram; Prediction model; Decision curve analysis

1. Introduction

Diabetic nephropathy (DN) is one of the most important complications in patients with type 2 diabetes mellitus (T2DM). According to the International Diabetes Federation, the global prevalence of diabetes is projected to increase to 10.2% (approximately 578 million people) by 2030 and to 10.9% (approximately 700 million people) by 2045, with about 30%-40% of diabetic patients potentially developing DN. Due to complex metabolic disturbances, DN can cause renal damage or functional loss, creating substantial burdens on patients' lives and finances. Therefore, early screening for DN and prevention in high-risk patients is of great significance and represents an important global public health objective.

Appropriate interventions for DN patients can effectively reduce or delay disease onset, particularly when implemented in the early stages. This study employed multiple preprocessing methods to clean medical data, used LASSO regression to screen potential predictive features for T2DM nephropathy, and constructed a nomogram prediction model through multivariate logistic regression analysis to identify DN risk factors. The model's predictive performance and clinical utility were validated using the area under the receiver operating characteristic curve (AUC), calibration curve (Hosmer-Lemeshow test), and decision curve analysis (DCA), providing a reference basis for early diagnosis and prevention of DN.

2. Materials and Methods

2.1 Study Subjects

Clinical data from 5,810 T2DM patients hospitalized at the First Affiliated Hospital of Xinjiang Medical University between January 2016 and June 2021 were collected and retrospectively analyzed. Inclusion criteria were: (1) confirmed T2DM diagnosis; (2) age $ $18 years; (3) ability to communicate independently without mental or psychological disorders; and (4) signed informed consent. Exclusion criteria included: (1) incomplete data or records; (2) type 1 diabetes, gestational diabetes, or other special types of diabetes; (3) renal damage due to urinary tract infection, acute kidney injury, renal tumors, or other causes; and (4) history of malignant tumors, psychiatric disorders, or severe renal or hepatic dysfunction. This study was approved by the Ethics Committee of the First Affiliated Hospital of Xinjiang Medical University (Approval No.: K202108-24).

2.2 Diagnostic Criteria

T2DM diagnosis was based on the "China Guidelines for the Prevention and Treatment of Type 2 Diabetes (2010 Edition)." DN was diagnosed when at least two out of three urinary albumin results obtained over 3-6 months reached or exceeded the critical value, with other influencing factors such as infection excluded. Patients were divided into a DN group (n=481) and non-DN group (n=5,329) based on DN complication status.

2.3 Data Collection

General information included age, gender, BMI, hypertension status, diastolic blood pressure (DBP), systolic blood pressure (SBP), and diabetes duration. After 8-12 hours of fasting, 3 mL of elbow venous blood was collected the following morning and centrifuged at 3,000 r/min (radius 22 cm) for 10 minutes to obtain serum samples. Clinical measurements included white blood cell count (WBC), serum creatinine (Scr), total cholesterol (TC), triacylglycerol (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), apolipoprotein A1 (ApoA1), apolipoprotein B (ApoB), 24-hour urinary micro total protein (Up), qualitative urinary protein (Upn), and glycosy-

lated hemoglobin (HbA1c), performed using a BECKMAN DxC800 automatic biochemical analyzer. Upn standards were defined as: negative (-) for urinary protein <0.1 g/L, (+) for 0.2-0.9 g/L, (++) for 1.0-2.0 g/L, and (+++) for >2.0 g/L.

2.4 Statistical Analysis

Data were analyzed using SPSS 26.0 and R 4.1.3 software. Normally distributed continuous variables were expressed as mean±standard deviation ($\bar{x}\pm s$) and compared between groups using independent samples t-tests. Non-normally distributed continuous variables were presented as median (interquartile range) [M(QR)] and compared using rank-sum tests. Categorical data were expressed as percentages and compared using ^{2} tests. The 481 DN patients were matched 1:1 by gender and age ($\pm$2 years). The matched 962 patients were randomly divided into training (n=641) and validation (n=321) groups at a 2:1 ratio. Using DN as the outcome variable, LASSO regression identified independent risk factors, which were then incorporated into a multivariate logistic regression analysis to construct a nomogram prediction model. Model performance was evaluated using AUC, ROC curve analysis, calibration curve (Hosmer-Lemeshow goodness-of-fit test), and DCA. DCA evaluates clinical effectiveness by considering patient and clinician preferences, making it more aligned with real clinical decision-making needs. Statistical significance was set at $P<0.05$.

3. Results

3.1 General Characteristics

Among the 5,810 T2DM patients, 3,671 (63.2%) were male and 2,139 (36.8%) were female, with a mean age of 57.2$\pm$12.1 years. Significant differences between DN and non-DN groups were observed in gender, age, BMI, diabetes duration, WBC, TC, TG, LDL-C, Scr, hypertension prevalence, SBP, DBP, HbA1c, ApoB, Up, and Upn ($P<0.05$). No significant differences were found in HDL-C or ApoA1 levels ($P>0.05$) .

3.2 Variable Screening

LASSO regression analysis was used to screen for predictor variables with non-zero coefficients among 18 variables [Figure 1: see original paper]. Vertical lines were drawn at the minimum λ value (λ=0.005) and at 1 SE of the minimum (λ=0.035). The optimal value was selected at the minimum 10-fold cross-validation error plus 1 SE, yielding five predictor variables with non-zero coefficients: diabetes duration, TC, Scr, hypertension, and Upn.

3.3 Multivariate Logistic Regression Analysis and Nomogram Construction

3.3.1 Multivariate Logistic Regression Analysis Using DN complication as the dependent variable (no=0, yes=1) and the five LASSO-selected variables as independent variables—diabetes duration (actual value), TC (actual value), Scr (actual value), hypertension (no=0, yes=1), and Upn (-=0, +=1, ++=2, +++=3)—a conditional multivariate logistic regression prediction model was constructed. All five variables were significant risk factors for DN complication in T2DM patients ($P<0.05$). Specifically, hypertensive patients had 2.174 times higher risk of developing DN than non-hypertensive patients (95%CI=1.517-3.137, $P<0.001$) .

3.3.2 Nomogram Construction A nomogram was constructed based on the analysis results [Figure 2: see original paper]. The total score is obtained by summing the points for each variable, and a vertical line drawn downward from the total score indicates the estimated probability of DN complication in T2DM patients. For example, using median values for diabetes duration (P50=10 years), TC (P50=4.14 mmol/L), and Scr (P50=74 mol/L), with Upn (++) and hypertension present, the total score is 128 points, corresponding to an 85% risk of DN complication.

3.4 Model Validation

ROC curve analysis evaluated the model's discrimination ability. The AUC was 0.866 (95%CI=0.839-0.894) in the training group [Figure 3: see original paper]A and 0.849 (95%CI=0.804-0.889) in the validation group [Figure 3: see original paper]B. Calibration was assessed using the Hosmer-Lemeshow goodness-of-fit test, showing $P=0.748$ for the training group [Figure 4: see original paper]A and $P=0.986$ for the validation group [Figure 4: see original paper]B (both $P>0.05$), indicating good calibration.

3.5 Clinical Application

DCA was used to evaluate the model's clinical validity [Figure 5: see original paper]. The results showed that when the threshold probability for patients or clinicians ranged from 0.15 to 0.95, using this nomogram to predict DN risk was more beneficial than intervening in all patients. Assuming a prediction probability of 60% (high-risk threshold=0.6) for diagnosing and treating DN, approximately 50 out of 100 patients using this nomogram would benefit (net benefit=0.5) without harming others.

4. Discussion

This study used LASSO regression and multivariate logistic regression to identify risk factors for DN complication in T2DM patients and construct a prediction model. Five predictors were selected: diabetes duration, TC, Scr, hy-

pertension, and Upn. The nomogram based on these independent risk factors demonstrated good discrimination, with AUCs of 0.866 (95%CI=0.839-0.894) and 0.849 (95%CI=0.804-0.889) in the training and validation groups, respectively. Calibration curves showed good agreement between predicted and actual probabilities, and DCA indicated clinical utility across a wide threshold range (0.15-0.95).

LASSO regression improves model stability by penalizing coefficients and shrinking less important variable coefficients to zero, making it suitable for predictive modeling regardless of outcome variable type. The nomogram visualizes the clinical prediction model, allowing users to directly read predicted outcome probabilities from the chart. Numerous studies have used machine learning algorithms to improve nomogram prediction models for survival prediction in breast cancer, colon cancer, and other diseases.

Model validation employed AUC and DCA. Our model's AUC of 0.866 in the training group and 0.849 in the validation group compares favorably with similar studies. Xi et al. constructed a DN risk prediction model with 10 indicators (including gender, age, hypertension, Scr, diabetes duration, BMI, and urinary nitrogen) achieving an AUC of 0.813 (95%CI=0.778-0.848). Our model, using similar but fewer indicators (excluding gender and age), demonstrated relatively better performance. Compared with Shi et al.'s model (AUC=0.807, 95%CI=0.784-0.830), our model also showed superior efficacy. Additionally, our results based on laboratory variables were similar to those of Hou et al. (AUC=0.852, 95%CI=0.822-0.882) and Hui et al. (AUC=0.862, 95%CI=0.834-0.890). The Hosmer-Lemeshow test indicated good model fit (training group P=0.748; validation group P=0.986), and DCA demonstrated net benefit across threshold probabilities of 0.15-0.95.

The prediction model suggests that T2DM patients with longer diabetes duration should receive early interventions including blood pressure control, lipid reduction, low-salt diet, and renal function improvement to decrease DN risk. Studies have shown that diabetes duration is closely related to DN development, with T2DM patients of over 10 years gradually progressing to massive proteinuria and higher DN risk. Hypertension was identified as a DN risk factor, consistent with Bashir et al.'s findings. Tian et al. found that SBP in the DN group was significantly higher than in the non-DN group, as elevated blood pressure increases renal perfusion, damages microvascular endothelial cells, and accelerates renal microvascular lesions, significantly increasing DN risk in T2DM patients. Research has also shown that urinary protein and microalbumin are significantly higher in DN patients. When renal function is severely impaired, large molecular proteins leak into urine, causing high urinary protein levels. Our results similarly identified Upn as a DN risk factor. According to the "China Guidelines for the Prevention and Treatment of Type 2 Diabetes (2020 Edition)," blood pressure control on top of routine glycemic control can delay DN progression. These findings suggest that hypertension accelerates urinary protein excretion in DN, indicating that controlling blood pressure around 125/75

mmHg in T2DM patients with hypertension can delay DN onset and progression.

Total cholesterol plays a crucial role throughout the development and prognosis of nephropathy. Our study found TC positively correlated with DN risk (OR=1.260, 95%CI=1.109-1.439). Zhou et al. observed that as diabetic renal damage worsened, Scr and TC levels gradually increased (P<0.01). This occurs because TC alters glomerular basement membrane phospholipid composition or changes glucose metabolism, increasing basement membrane permeability and causing renal damage. Scr is closely associated with DN development and is a key indicator for assessing renal function and diagnosing DN. Our study also found Scr positively correlated with DN risk (OR=1.008, 95%CI=1.004-1.013). Research indicates that Scr levels rise when glomerular filtration function is severely impaired.

This study has several limitations. First, the prediction model did not consider potential factors such as daily living environment and dietary habits of T2DM patients, which may introduce information bias or selection bias and cause deviations from true results. Second, this was a retrospective, cross-sectional, single-center study without external validation to further assess the model's predictive performance. Future research will utilize database samples for external validation and further validate the model using large-sample, multicenter data from different regions to improve its predictive accuracy and generalizability.

In conclusion, this study identified diabetes duration, TC, Scr, hypertension, and Upn as risk factors for DN complication in T2DM patients. The established nomogram prediction model demonstrates good predictive ability and clinical utility, providing clinicians with decision-making support for early and effective diagnosis. The key to DN treatment lies in controlling diabetes progression through low-salt diet, blood pressure and lipid control, smoking cessation, alcohol abstinence, and regular medical examinations to prevent further renal damage and reduce DN occurrence.

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Author Contributions: HAN Junjie conceptualized the study and drafted the manuscript. WU Di performed data cleaning, statistical analysis, and clinical prediction model construction. CHEN Zhisheng collected the data. XIAO Yang proposed variable screening methods, performed data preprocessing, and revised the manuscript. SEN Gan designed the study, supervised subject selection, and took responsibility for the overall manuscript. All authors read and approved the final manuscript.

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Note: Figure translations are in progress. See original paper for figures.