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A predictive model for diabetic foot ulcer recurrence risk: A scoping review

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Abstract: *To systematically integrate the construction and application status, predictors and performance of diabetic foot recurrence risk prediction models in China and abroad. The Chinese and English databases were retrieved, and retrieval time from database establishment to April 1, 2024. Data was extracted and summarized for analysis. According to Prediction model Risk Of Bias Assessment Tool, the risk of bias was evaluated from four aspects with research objects, predictor, outcome and analysis of the models established. 14 papers were finally included, with more studies in China, and the research subjects were mainly diabetic foot patients who were already in the healing state at the time of inclusion in the study. The model construction methods were Logistic regression model, Cox regression model, and machine learning. The model presentation was dominated by the risk calculation formula based on the regression coefficients of each factor. And the three most frequent predictors were previous ulcer site, previous ulcer duration, and smoking history. The predictive efficacy of the included models is good, but the overall bias risk of the study is higher. In order to construct models with good predictive performance and operationalization, machine learning can be applied to construct risk prediction models in the future with extensive external validation.*

Keywords: *diabetic foot; recurrence; prediction model; risk assessment; scoping review*

1. Introduction

Diabetic foot ulcers (DFUs) are one of the common complications of diabetes mellitus (DM) and are the most serious complications[1]. The lifetime incidence of DFUs ranges from 15% to 25% in the diabetic population[2,3]. Due to the high mortality and amputation rates, DFUs have long been a serious public health challenge[4]. In a follow-up study by Winkley, the 18-month recurrence rate of diabetic foot (DF) patients was 43.2%[5]. 70% of patients with DFUs had recurrent lesions within 5 years of treatment [6]. Some studies have reported that the risk of ulcer recurrence increases with increasing healing time, with approximately 60% of patients developing recurrent ulcers in the 3rd year and 90% in the 10th year after ulcer healing [7]. The high recurrence rate of DFUs results in patients' long-term foot care costs will be significantly increased [6], and will increase anxiety and depression due to recurrent episodes, which will lead to lower treatment adherence and seriously affect patients' quality of life [8]. And timely prediction of the risk of ulcer recurrence enables early identification of those at high risk of diabetic foot ulcer recurrence and the development of targeted interventions to help patients avoid ulcer recurrence. In recent years, there has been a significant increase in studies of prediction models for diabetic foot ulcer recurrence risk, but there is heterogeneity in the applicable targets and predictors of prediction models in each study. This study provides a scope review of the construction and application status, predictors and performance of relevant prediction models in China and abroad, and analyzes the current problems of relevant studies in this field, with a view to providing lessons for clinical care and future research.

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2. Information and methods

2.1 Purpose and Problems

1) What studies of DFUs recurrence risk prediction models exist?2)What predictors are typically involved in the models?3)What are the current modeling approaches for DFUs recurrence risk prediction models? What is the performance? 4) What are the shortcomings of the current studies and what are the implications for future related studies?

2.2 Literature search

The databases searched were PubMed, the Cochrane Library, EMbase, CINAHL, Web of Science, China Biology Medicine Database, CNKI, and Wanfang Database, and the time limit for the search was from the establishment of the database to April 1, 2024, and the search was conducted by combining the subject terms and the free terms.Chinese search terms include“prediction model”“risk prediction”“Predictors”“Risk Factors”“Forecasting tool”“risk score”“risk assessment”“risk prediction model”“Risk Factors”“Diabetic Foot”“Diabetic foot patients”“Diabetic ulcers”“Diabetic ulcer patients” “DF ” “Diabetic foot infection”“Diabetic foot”“'Diabetic foot(df)”“recurrence”“relapse”“relapse again” “reproduction” “Reproduce”,English search terms include “recurrence” “relapse” “Recurrences” “Recrudescence” “Recrudescences”“Relapses”“Risk Factors”“Forecasting tool”“prediction model” “prediction tool”“prognostic model”“risk prediction”“risk assessment”“risk score”“risk prediction model” “predict*”“model*”“Diabetic Foot”“Foot ulceration”“Foot, Diabetic”“Diabetic Feet”“Feet, Diabetic” “Foot Ulcer, Diabetic”“diabetic foot ulcer”“DFu”“foot ulcer”.Taking the PubMed database as an example, the search strategy is as follows:(((((((recurrence*[MeSH Terms]) OR (relapse[Title/Abstract])) OR (Recurrences[Title/Abstract])) OR (Recrudescence[Title/Abstract])) OR (Recrudescences[Title/Abstract])) OR (Relapses[Title/Abstract])) AND (((Risk Factors[MeSH Terms]) OR (Forecasting tool[Title/Abstract])) OR (((((((((prediction model[Title/Abstract]) OR (prediction tool[Title/Abstract])) OR (prognostic model[Title/Abstract])) OR (risk prediction[Title/Abstract])) OR (risk assessment[Title/Abstract])) OR (risk score[Title/Abstract])) OR (risk prediction model[Title/Abstract])) OR (predict*[Title/Abstract])) OR (model*[Title/Abstract])))) AND ((Diabetic Foot[MeSH Terms]) OR (((((((Foot ulceration[Title/Abstract]) OR (Foot, Diabetic[Title/Abstract])) OR (Diabetic Feet[Title/Abstract])) OR (Feet, Diabetic[Title/Abstract])) OR (Foot Ulcer, Diabetic[Title/Abstract])) OR (diabetic foot ulcer[Title/Abstract])) OR (DFu[Title/Abstract])) OR (foot ulcer[Title/Abstract]))).

2.3 Literature inclusion and exclusion criteria

Inclusion criteria: (1) Research content focused on constructing or validating a risk assessment tool for diabetic foot ulcer recurrence; (2) Chinese and English literature; (3) Original studies (cohort studies, case-control studies, cross-sectional studies, etc.), guidelines, expert consensus, etc.

Exclusion criteria: (1) Conference abstracts; (2) unable to obtain the full text; (3) content or method of the prediction model not specified.

2.4 Literature screening

The titles of the retrieved literature were imported into EndNote X9 software to remove duplicate literature. Two researchers independently screened the title and abstract according to the inclusion and exclusion criteria, and then read the full text for review. When there is controversy in the screening of literature, discuss with the third researcher and ultimately determine the literature that meets the criteria.

2.5 Quality evaluation

Two researchers independently assessed the quality of the included literature using the Prediction model Risk Of Bias Assessment Tool (PROBAST) [9], which is dedicated to predictive model research. In case of disagreement, an agreement was reached after consulting with a third researcher.

2.5.1 Risk of bias assessment

Using the risk of bias assessment tool PROBAST, the assessment covered 4 aspects of the research

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object, predictors, outcomes and statistical analysis.

2.5.2 Applicability assessment

The applicability assessment included three domains: research object, predictors and outcomes, and the judgment process was similar to the risk of bias.

2.6 Data extraction and analysis

Two researchers independently extracted data from the included literature, and discussed with the third researcher in case of disagreement. The extracted information includes the author, publication year, country, research object, research design, model construction and / or validation methods, model predictors, display methods and performance, etc., and a summary analysis is carried out.

3. Result

3.1 Literature screening process and results

The preliminary search yielded 1249 documents, 890 in English and 359 in Chinese. After duplicate checking and reading the title, abstract and full text, 14 documents were finally included. 14 literature were published in the years 2014-2024, including 11 in China and 3 in the Netherlands. The literature screening process and results are shown in Figure 1, and the basic characteristics of the included literature are shown in Table 1.

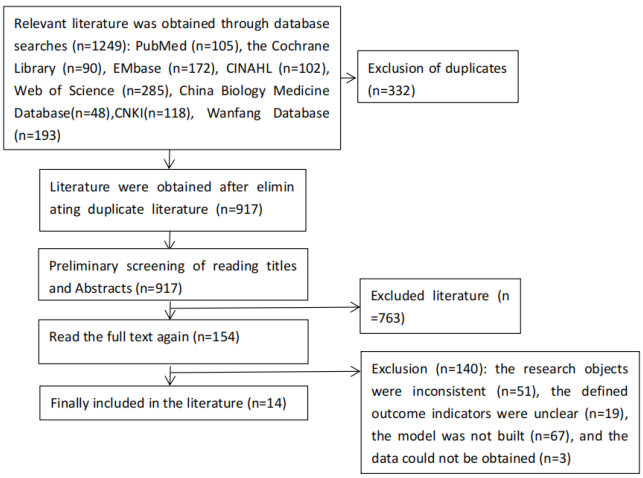

Figure 1: Literature screening process and results

Table 1: Basic characteristics of the included literature

Inclusion of literature	Time	Country	Research object	Sample size		Model building method	Ulcer recurrence rate (%)
				Model building	Model validation		
Roelof Waaijman[10]	2014	Netherlands	Patients with healed plantar ulcers	171	/	Logistic regression model	41.52
Meijun Wang[11]	2022	China	Patients with Wagner stage 1 and above (30 < patients < 90)	1027	306	Logistic regression model	Unreported
Wouter B aan de Stegge[12]	2020	Netherlands	Patients with a history of plantar ulcer	171	Unreported	Logistic regression model	41.52
Wouter B aan de Stegge[13]	2021	Netherlands	Patients with a history of foot ulcers	304	Unreported	Logistic regression model	41.45
Guo Qingjiao[14]	2023	China	Patients with Wagner stage 1 or older (>18 years old) had healed ulcer at the time of enrollment	101	Unreported	Logistic regression model	28.71
Lai Jianjun[15]	2024	China	Patients with Wagner grade 1-3 had healed ulcer at the time of enrollment	172	/	Cox regression model	29.65
Wei Lei[16]	2023	China	Patients with Wagner grade 1-2 had healed ulcer at the time of enrollment	226	/	Cox regression model	20.80
Xia Lei[17]	2023	China	Wagner grade 1-5 and the foot	375	131	Logistic regression	26.13

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			ulcer wound was cured at discharge			model	
Hu Minghua[18]	2023	China	Diabetic foot patients with healed ulcers	113	/	Logistic regression model	31.86
Tang Yannan[19]	2022	China	New foot lesions (≥ 18 years old) first appeared after DF healing	718	308	Logistic regression model	20.33
Wang Hong[20]	2023	China	For patients with Wagner grade 1 or above, the ulcer was cured at the time of enrollment	70	/	Logistic regression model	40.00
LYU Jing[21]	2022	China	For patients with Wagner grade 1 or above, the ulcer was cured at the time of enrollment	465	/	Logistic regression model	26.88
ZHANG Juan[22]	2023	China	Diabetic foot patients	292	98	Logistic regression model、BPNN and SVM model	29.74
WANG Yinrong[23]	2023	China	Patients with Wagner grade 1-5 (≥ 18 years old)	247	Unreported	Cox regression model	27.94

3.2 Risk of bias and applicability evaluation results

The risk of bias was evaluated according to PROBAST for the 4 aspects of research object, predictors, outcomes, and analyses established by the model, and the applicability was evaluated for the 3 aspects of research object, predictors, and outcomes. The overall risk of bias was high and applicability was good in the 14 included literature, and the detailed evaluation results are shown in Table 2.

Table 2: Evaluation of risk of bias and applicability of the included literature

Inclusion of literature	Risk of bias				Applicability			Totally	
	research object	predictor	outcome	analyse	research object	predictor	outcome	Risk of bias	Applicability
Roelof Waaijman[10]	low	low	low	high	Good	Good	Good	high	Good
Meijun Wang[11]	low	low	high	high	Good	Good	Good	high	Good
Wouter B aan de Stegge[12]	low	low	low	high	Good	Good	Good	high	Good
Wouter B aan de Stegge[13]	high	high	low	high	Good	Good	Good	high	Good
Guo Qingjiao[14]	high	high	low	high	Good	Good	Good	high	Good
Lai Jianjun[15]	low	low	low	high	Good	Good	Good	high	Good
Wei Lei[16]	low	unclear	low	high	Good	Good	Good	high	Good
Xia Lei[17]	high	high	low	high	Good	Good	Good	high	Good
Hu Minghua[18]	low	low	low	high	Good	Good	Good	high	Good
Tang Yannan[19]	high	high	low	high	Good	Good	Good	high	Good
Wang Hong[20]	low	low	low	high	Good	Good	Good	high	Good
LYU Jing[21]	low	low	low	high	Good	Good	Good	high	Good
ZHANG Juan[22]	low	low	low	high	Good	Good	Good	high	Good
WANG Yinrong[23]	low	low	low	high	Good	Good	Good	high	Good

3.3 Construction and validation of a predictive model for diabetic foot ulcer recurrence risk

3.3.1 Model construction basics

The modeling study population was patients with diabetic foot ulcers, with a sample size of 70-1027 cases. The methods of model construction can be categorized into 3 types, including 11 studies using Logistic regression to construct models [10-14,17-22], 3 studies using Cox regression to construct models [15,16,23], and 1 study using machine learning algorithms [22].

3.3.2 Model prediction content and presentation

The number of predictors included in the study is 3-15, and the model display can be divided into three categories, namely, risk calculation formula, nomogram, and the combination of risk calculation

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formula and nomogram. Among them, there are many studies on the risk calculation formula based on the regression coefficient of each factor. See Table 3 for the detailed model predictors and display methods. According to the summary of the results, the most frequent occurrence of model predictors in the included studies were previous ulcer site, previous ulcer duration, smoking history, diabetic peripheral neuropathy, amputation, foot lesion degree, HbA1c, deformity, gender, diabetes duration, age, BMI, infection, C-reactive protein

Table 3: Model predictors and presentation.

Inclusion of literature	Model predictors	Model presentation
Roelof Waaijman[10]	Model 1: Severe foot deformity, minor foot lesions, cumulative duration of foot ulcers, and peak barefoot pressure. Model 2: Peak in-shoe pressure at the site of previous ulcers, peak barefoot pressure, and cumulative duration of foot ulcers.	Risk calculation formula
Meijun Wang[11]	Model 1: gender, diabetes duration, previous DFU, ulcer location, smoker, amputation history and foot deformity. Model 2: gender, DFU, duration of diabetes, ulcer site, smoking history, amputation history, foot deformity, use of statins, antiplatelet drugs, systolic blood pressure, BMI. Model 3: gender, diabetes duration, previous DFU, ulcer site, smoking, amputation history, foot deformity, use of statins, antiplatelet drugs, systolic blood pressure, BMI, low-density lipoprotein cholesterol, HbA1c, fibrinogen and 24-hour urinary protein.	nomogram
Wouter B aan de Stegge[12]	Model 1: Peak plantar pressure, minor foot lesions, duration of previous ulcers, living alone, number of steps per day. Model 2: Minor foot lesions, previous ulcer duration, previous ulcer location.	Risk calculation formula
Wouter B aan de Stegge[13]	Model 1: Age, grade of peripheral neuropathy, number of months since last ulcer healed, extent of foot lesions, foot temperature monitoring, use of walker or not. Model 2: Age, site of previous ulcer, number of months since last ulcer healed, degree of foot pathology, use of walker, history of alcohol consumption, and receipt of medical care for the foot.	Risk calculation formula
Guo Qingjiao[14]	HbA1C > 7.5%, plantar ulcers, diabetic peripheral neuropathy, diabetic peripheral vasculopathy, smoking, osteomyelitis, amputation/toe amputation, and multidrug-resistant bacterial infections.	Risk calculation formula
Lai Jianjun[15]	Coronary heart disease, ulcer depth score, subcutaneous sinus tract or latent wound score.	nomogram
Wei Lei[16]	Gender, age, body mass index (BMI), ulcer location, WIfI grade, high-sensitivity C-reactive protein (hs CRP).	nomogram
Xia Lei[17]	Wagner grade, vascular disease, osteomyelitis, multidrug-resistant infection, callose, amputation history.	nomogram+Risk calculation formula
Hu Minghua[18]	Gender, smoking history, Wagner grade, blood glucose control, plantar ulcer, peripheral neuropathy, peripheral vascular disease, diabetic nephropathy, osteomyelitis, amputation history, deformity, multidrug-resistant infection.	Risk calculation formula
Tang Yannan[19]	Coronary heart disease, diabetic nephropathy, plantar lesions, amputation, vascular intervention, HbA1c (%), C-reactive protein, ankle brachial index, hypoglycemic drugs, smoking, foot care behavior.	Nomogram + Risk calculation formula
Wang Hong[20]	Wagner grade, HbA1c (%), peripheral neuropathy, infection	Risk calculation formula
LYU Jing[21]	Smoking, abnormal skin color of feet, corpus callosum, diabetic peripheral neuropathy, and coronary heart disease	Risk calculation formula
ZHANG Juan[22]	BMI, diabetes duration, smoking history, foot ulcer grade, HbA1c (%), ulcer location on the sole of the foot, foot self-management behavior, and DFU risk perception level	no information
WANG Yinrong[23]	Age, HbA1c (%), C-reactive protein, diabetic peripheral neuropathy, ankle brachial index	no information

3.3.3 Model validation and performance

A total of 14 studies and 21 models were included. Among them, five models [10,15,16,21] did not report the validation method, four models [11,17] used internal validation and external validation, 11 models used internal validation [12-14,19-23], and one model used external validation [18]. In terms of model performance, 14 models [11-13,17,19-22] applied Hosmer lemeshow goodness of fit test, and some of them reported P values, which all showed $P > 0.05$, indicating that the difference between the predicted value of the model and the actual observation value was not obvious, and the model calibration was good. 18 models reported the area under the receiver operating characteristic curve (AUC) to show the discrimination of the models, and the AUC was 0.660~0.937, which showed that the overall model discrimination was good; One model [23] reported the c-index to show the discrimination of the model, and the C was 0.796. The results showed that the discrimination of the model was good. Some of the models reported the sensitivity and specificity, which ranged from 72% to 99%, and the specificity ranged from 50% to 92.73%, suggesting that the models have good judgment ability. The details of model validation and performance are shown in Table 4.

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Table 4: Model validation and performance

Inclusion of literature	Validation Methods	AUC/C	calibration method	sensitivity(%)	Specificity(%)
Roelof Waaijman[10]	Unreported	Unreported	Unreported	Model 1:81.000 Model 2:76.000	Model 1:50.000 Model 2:51.000
Meijun Wang[11]	Internal validation + external validation	Model 1:0.833 Model 2:0.849 Model 3:0.860	Hosmer-Lemeshow goodness-of-fit test	Model 1:73.500 Model 2:74.300 Model 3:76.100	Model 1:87.000 Model 2:80.300 Model 3:85.500
Wouter B aan de Stegge[12]	Internal validation	Model 1:0.680 Model 2:0.760	Hosmer-Lemeshow goodness-of-fit test	Unreported	Unreported
Wouter B aan de Stegge[13]	Internal validation	Model 1:0.690 Model 2:0.660	Hosmer-Lemeshow goodness-of-fit test	Unreported	Unreported
Guo Qingjiao[14]	Internal validation	0.810	Unreported	72.000	86.000
Lai Jianjun[15]	Unreported	0.832	Unreported	74.500	82.400
Wei Lei[16]	Unreported	0.906	Unreported	Unreported	Unreported
Xia Lei[17]	Internal validation+external validation	0.890	Hosmer-Lemeshow goodness-of-fit test	Unreported	Unreported
Hu Minghua[18]	external validation	0.874	Unreported	94.400	62.300
Tang Yannan[19]	Internal validation	0.844	Hosmer-Lemeshow goodness-of-fit test	79.400	75.900
Wang Hong[20]	Internal validation	0.812	Hosmer-Lemeshow goodness-of-fit test	74.290	92.730
LYU Jing[21]	Unreported	0.855	Hosmer-Lemeshow goodness-of-fit test	0.928	0.665
ZHANG Juan[22]	Internal validation	Model 1:0.843 Model 2:0.937 Model 3:0.820	Hosmer-Lemeshow goodness-of-fit test	Model 1:Unreported Model 2:0.990 Model 3:Unreported	Model 1:Unreported Model 2:0.870 Model 3:Unreported
WANG Yinrong[23]	Internal validation	0.796	Unreported	Unreported	Unreported

4. Discussion

In recent years, risk prediction modeling about diseases has received more and more attention from scholars in various countries [24], and risk prediction modeling is a kind of statistical assessment based on the multi-risk factors of a disease, using mathematical formulas to calculate the probability of a certain event occurring in the future of a patient [25].The aim is to improve patient health outcomes by helping healthcare organizations and personnel to identify early significant risks that may occur and to take proactive measures to reduce the likelihood and impact of risk events[26].In response to the important clinical condition of diabetic foot ulcer recurrence, an increasing number of scholars have begun to construct risk prediction models for this type of disease, and the risk prediction models included in this study first began in 2014 and proliferated between 2020 and 2024.In the models included in the study in descending order of frequency of occurrence of risk predictors were: site of previous ulcers, duration of previous ulcers, history of smoking, diabetic peripheral neuropathy, amputation, extent of foot lesions, HbA1C, deformities, gender, age, duration of diabetes, BMI, infections, and c-reactive protein. However, most of the included studies used Logistic regression model as well as Cox regression model for the screening of predictors, this method requires that the independent variables and the dependent variable satisfy a linear relationship and does not allow the existence of multiple covariance between the independent variables; whereas the machine learning algorithms have no requirements for the independence and linear relationship between the variables, and the scope of application is much wider [27].Therefore, it is suggested that machine learning could be used in the future to screen risk predictors regarding diabetic foot ulcer recurrence, with a view to exploring risk factors for ulcer recurrence that have not been identified in previous models.

And among the included studies, only four studies [11-13,22] reported on the treatment of missing values in the data, and most of the studies lacked detailed reporting on the appropriateness of the treatment of complex issues (e.g., missing values, outliers, etc.) in the data, which may increase the risk of bias at the analysis stage and result in less accurate prediction models. In the construction phase of the model, most of the studies used traditional methods to construct the model, and only one study used machine learning for model construction, and its study found that the model constructed using machine learning worked optimally. Based on this, this study suggests that the construction of risk prediction models using machine learning algorithms can be carried out in the future to make the models more accurate and generalizable. In terms of model performance assessment, only one study [11] reported three aspects of model differentiation, calibration, and Clinicalusefulness, and most of the studies

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lacked assessment of Clinicalusefulness. While only considering the differentiation and calibration is not a complete evaluation of the use value of the predictive model, therefore, it is recommended that researchers refer to TRIPOD to report on the predictive model[28] in order to improve the transparency of the process of constructing the predictive model, and to facilitate the researchers' assessment of the model. In the validation stage of the model, each model can not get relatively accurate prediction performance because internal validation is often used in the validation. Compared with internal validation, external validation further improves the quality of research results and makes the prediction model more credible. Therefore, this study suggests that external validation of large samples can be carried out in the future to screen out models with more accurate predictors.

5. Strengths and limitations of this study

This study systematically retrieved the database and extracted the information in detail, but there are still some limitations: (1) this study only included the literature published in Chinese and English, which may be missing; (2) Most of the prediction models have not been externally validated, and have not yet been found in clinical application, so the generalizability of the prediction model needs to be verified; (3) Most of the models are built by Asians, and their global applicability remains to be tested.

6. Conclusion

A total of 21 risk prediction models were included in this study, which reviewed the basic features of the models and analyzed the parts of the current model building that can still be further optimized. It is recommended that future prospective studies be used to obtain data and expand the sample size, and that machine learning be used to construct risk prediction models, along with extensive external validation, with a view to making the models more generalizable.

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