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Machine Learning-Based Risk Predictive Models for Diabetic Kidney Disease in Type 2 Diabetes Mellitus Patients: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 September 2024 and was last updated on 9 September 2024.

INTRODUCTION

Review question / Objective Machine learning (ML) models are being increasingly employed to predict the risk of developing and progressing diabetic kidney disease (DKD) in patients with type 2 diabetes mellitus (T2DM). However, the performance of these models still varies. Therefore, we conducted a systematic review and meta-analysis to summarize and evaluate the performance and clinical applicability of these risk predictive models and to identify key research gaps.

Condition being studied Diabetic kidney disease (DKD) is characterized by diabetes-induced alterations in kidney function and structure, representing one of the most prevalent and significant microvascular complications of type 2 diabetes mellitus (T2DM). It is a leading cause of end-stage renal disease (ESRD). Approximately 20% to 40% of individuals with diabetes will eventually develop DKD. The presence and severity of DKD can significantly increase the risk of adverse health outcomes and premature mortality in patients with T2DM. Consequently, DKD has emerged as a critical global public health challenge. According to the 2022 report by the International Diabetes Federation (IDF), 537 million individuals worldwide are currently living with diabetes, with over 90% of these cases attributable to T2DM, which has become the predominant form of diabetes. The incidence of T2DM continues to rise annually, contributing to the increasing prevalence of DKD. Clinically, the diagnosis of DKD is based on elevated 24-hour urinary albumin excretion rates and reduced glomerular filtration rates. However, due to the insidious onset of DKD, by the time a diagnosis is made, the kidneys may have already suffered irreversible damage. Therefore, developing a risk prediction model for the progression of T2DM to DKD is crucial for early screening and identification of DKD risk and high-risk individuals. followed by timely intervention, are essential for enhancing the preventive capabilities against DKD. This proactive

approach not only enables timely preventive interventions but also contributes to significant reductions in healthcare costs while improving long-term health outcomes.

Clinical prediction models estimate the probability that a study subject currently has a certain disease or will experience a particular outcome in the future by using multifactorial models. Traditional DKD risk prediction models primarily rely on linear regression models based on demographic, clinical, and lifestyle factors. These methods typically predict the DKD risk in T2DM patients by calculating a weighted sum of multiple known risk factors. However, traditional methods have significant limitations in capturing complex nonlinear relationships and interactions among multidimensional risk factors, leading to suboptimal predictive performance. In recent years, with the rapid advancement of scientific and artificial intelligence technologies, machine learning (ML) has increasingly become an essential tool in medical research. ML techniques can automatically learn from large and complex datasets to develop predictive models that relate input data to output data, demonstrating superior performance compared to traditional statistical methods. In predictive models for the DKD risk in T2DM patients, ML has showcased its unique advantages in handling large-scale, multidimensional datasets.

However, considering the diversity of ML algorithms, the initial differences in dataset characteristics, and the variations in sample sizes, the heterogeneity among studies cannot be overlooked. Moreover, although ML has garnered significant attention within the medical field, its robustness in clinical practice remains uncertain, and its widespread adoption and application are somewhat constrained. Therefore, in this systematic review and meta-analysis, we aimed to comprehensively integrate and evaluate the performance and clinical applicability of published ML-based models for predicting the DKD risk in T2DM patients. And hope to provide more reliable reference for clinical practice.

METHODS

Participant or population The participants were diagnosed with T2DM, with no eligibility restrictions based on gender, age, ethnicity, or geographical location. Studies focusing on other types of diabetes were excluded from this review.

Intervention Studies were included if they explicitly specified the application of clinical prediction models based on machine learning algorithms in T2DM patients. This included all relevant synonyms and methodologies related to ML, such as "supervised machine learning", "unsupervised machine learning", "deep learning", "neural networks" and "support vector machines". Consequently, studies that did not employ machine learning algorithms or those where ML was applied in nonclinical settings were excluded.

Comparator We included studies that compared ML methods with other ML approaches, traditional statistical analyses, clinical scoring tools, and manual diagnoses with or without clinical scoring tools. Studies that solely used traditional statistical prediction tools or relied exclusively on unaided clinical performance were excluded.

Study designs to be included cohort studies, case-cohort studies, case-control studies and nested case-control studies.

Eligibility criteria The primary outcome indicator is the risk of developing DKD in T2DM patients. Included studies must report model performance metrics, specifically area under the receiver operating characteristic curve (AUC).We excluded studies in the form of review articles, meta-analysis, case reports, conference abstracts, guidelines, editorials, commentaries, expert opinions, letters, and animal studies. Additionally, studies employing simple algorithms instead of machine learning were excluded. We also excluded studies that merely analyzed influencing factors without constructing a machine learning risk mode. Furthermore, studies that used machine learning exclusively for image recognition without developing a predictive model were excluded. In case where multiple studies used the same or overlapping patient datasets, only the most recent study was included.

Information sources We aimed to compile predictive models for the DKD risk in T2DM patients based on ML algorithms, with the goal of evaluating their performance. With the assistance of information specialists, we conducted a comprehensive search across the following databases: PubMed, Embase, Cochrane Library, and Web of Science Core Collection. We included all relevant English-language publications up to April 18, 2024. Both controlled vocabulary terms (MeSH terms in Embase and PubMed) and free-text terms were employed using Boolean operators.

Main outcome(s) Our primary outcome measure is a meta-analysis of the performance of risk prediction models forDKD in T2DM patients that utilize machine learning algorithms, with the

performance evaluation metric primarily focused on Area Under the Curve （AUC）.

Quality assessment / Risk of bias analysis We assessed the risk of bias in the prediction models using the Prediction Model Risk of Bias Assessment Tool (PROBAST), which is specifically designed for studies involving multivariable prediction models for individual prognosis or diagnosis. This tool assesses four domains: participants, predictors, outcomes, and statistical analysis.

Strategy of data synthesis We conducted a meta-analysis, pooling the AUC values and their 95% CIs from individual studies, and performed stratified analyses based on study design, model type, and other relevant factors. If the AUC did not report a 95% CI or standard error (SE), we estimated the SE and 95% CI using the Hanley and McNeil formula. Given the high heterogeneity among the included studies due to variations in study design, ML models, predictive factors, and parameters, we used the DerSimonian and Laird random-effects model to pool the AUCs in the meta-analysis and presented the results in a forest plot. Additionally, we assessed the degree of heterogeneity between studies using the Cochrane Q test and I^2 statistic to determine the suitability of a fixed-effects model (P 25%). All statistical analyses were conducted using STATA version 18. Statistical significance was defined as a P-value less than 0.05, with a threshold of 0.10 for heterogeneity testing.

Subgroup analysis To identify potential sources of heterogeneity, we will conducte subgroup analyses based on study type and prediction model type using the internal validation datasets.

Sensitivity analysis To validate the stability and reliability of the meta-analysis results, we conducted a sensitivity analysis by sequentially excluding each included study to assess the robustness of the results.

Country(ies) involved China.

Keywords machine learning, predictive model, type 2 diabetes mellitus, diabetic kidneydisease.

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