International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Disease Burden of Diabetic Kidney Disease in China: A Systematic Literature Review

INPLASY202610023

doi: 10.37766/inplasy2026.1.0023

Received: 7 January 2026

Published: 7 January 2026

Tang, WB; Tan, L; Luo, Y; Zhang, T; Liu, F; Yan, L; Chen, WD.

Corresponding author:
wendong chen

wendong.chen@normin.ca

Author Affiliation:
Xiangya Hospital, Central South University.

ADMINISTRATIVE INFORMATION

Support - Major Scientific Research Projects of National Key Clinical Specialties of Hunan Provincial Health Commission (Z2023136).

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202610023

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 January 2026 and was last updated on 7 January 2026.

INTRODUCTION

Review question / Objective This systematic literature review aims to synthesize evidence from observational studies on the clinical characteristics, metabolic control, disease progression, health-related quality of life, and healthcare resource use and costs among patients with diabetic kidney disease in China, in order to characterize the overall disease burden in this population.

Rationale Diabetic kidney disease (DKD) is a major microvascular complication of diabetes and the leading cause of chronic kidney disease (CKD) and end-stage renal disease (ESRD) in China. The increasing prevalence of diabetes, population ageing, and the high burden of comorbid conditions have contributed to a growing number of patients affected by DKD. Disease progression is associated with worsening renal function, increased risks of cardiovascular events and mortality, deterioration in health-related quality of life (HRQoL), and escalating healthcare resource utilization and costs, particularly in advanced CKD stages and among patients requiring dialysis.

Although a substantial number of observational studies on DKD have been conducted in China, the available evidence remains scattered and heterogeneous. Existing studies often focus on isolated outcomes, such as clinical characteristics, metabolic control, renal outcomes, HRQoL, or healthcare costs, and are frequently limited by regional scope, small sample sizes, or specific disease stages. As a result, there is a lack of an integrated and comprehensive synthesis that characterizes the overall disease burden of DKD in the Chinese population across multiple domains.

A systematic literature review of real-world observational studies is therefore warranted to address this evidence gap. Synthesizing data on patient characteristics, metabolic control, disease progression, HRQoL, and economic burden can provide a clearer and more comprehensive understanding of the multidimensional burden of DKD in China. Such evidence is essential to

support future research, inform clinical practice, and facilitate health policy planning by identifying key unmet needs and areas where improvements in DKD management may have the greatest impact.

Condition being studied Diabetic kidney disease (DKD) is a chronic microvascular complication of diabetes mellitus and represents the most common cause of chronic kidney disease (CKD) and end-stage renal disease (ESRD) worldwide. DKD is characterized by progressive structural and functional kidney damage resulting from long-term hyperglycemia, metabolic dysregulation, hemodynamic changes, and inflammation. Clinically, the condition is typically defined by persistent albuminuria, a decline in estimated glomerular filtration rate (eGFR), or both, in individuals with diabetes, in the absence of alternative primary kidney diseases.

The progression of DKD is commonly classified according to CKD stages based on eGFR, ranging from early-stage disease with preserved renal function to advanced stages requiring renal replacement therapy, including dialysis or kidney transplantation. As DKD advances, patients face increasing risks of cardiovascular disease, infections, disability, and premature mortality. In addition to clinical complications, DKD is associated with substantial impairments in health-related quality of life, driven by symptom burden, treatment complexity, and reduced functional capacity, particularly among patients with advanced CKD or ESRD.

In China, DKD has emerged as a major public health challenge due to the rapidly growing prevalence of diabetes, population ageing, and the high burden of comorbid conditions such as hypertension and dyslipidemia. Management of DKD involves long-term glycemic control, blood pressure and lipid management, and renal-protective therapies aimed at slowing disease progression. Despite advances in clinical management, many patients continue to experience progressive renal decline, leading to significant healthcare resource utilization and economic burden. These features make DKD a critical condition of interest for systematic evaluation of its clinical, humanistic, and economic burden in the Chinese population.

METHODS

Search strategy A comprehensive and systematic literature search was conducted to identify relevant observational studies reporting the disease burden of diabetic kidney disease (DKD) in China. Both English-language and Chinese-language electronic databases were searched to ensure broad coverage of published evidence.

The English-language databases included MEDLINE (via PubMed), Embase, and Web of Science. The Chinese-language databases included China National Knowledge Infrastructure (CNKI), Wanfang Data, and VIP Database. The search period covered studies published from January 2019 to March 2024, reflecting contemporary real-world evidence and current clinical practice in China.

The search strategy combined controlled vocabulary terms (e.g., MeSH and Emtree terms, where applicable) and free-text keywords related to three core concepts: (1) diabetic kidney disease, (2) China or Chinese population, and (3) observational or real-world study designs. Key search terms included, but were not limited to, “diabetic kidney disease,” “diabetic nephropathy,” “diabetes-related kidney disease,” “chronic kidney disease,” “China,” “Chinese,” “observational study,” “real-world,” “cohort,” “cross-sectional,” and “registry.” Database-specific search syntax was adapted for each database.

Reference lists of included articles and relevant reviews were also manually screened to identify additional eligible studies that may not have been captured through electronic database searches. All retrieved records were imported into reference management software, and duplicate records were removed prior to study screening.

The detailed search strategies and database-specific search strings are documented separately to ensure transparency and reproducibility.

Participant or population The population of interest for this systematic literature review includes adult patients (aged ≥18 years) diagnosed with diabetic kidney disease (DKD) in China. DKD is defined according to the diagnostic criteria used in the original studies, typically characterized by persistent albuminuria, reduced estimated glomerular filtration rate (eGFR), or both, occurring in individuals with diabetes mellitus and in the absence of alternative primary kidney diseases.

The review will include patients across all stages of chronic kidney disease (CKD stages I–V), ranging from early-stage DKD with preserved renal function to advanced disease requiring renal replacement therapy, including dialysis. Both outpatient and inpatient populations will be considered. Studies enrolling patients from any healthcare setting (e.g., tertiary hospitals, secondary hospitals, or community-based settings) within mainland China will be eligible.

No restrictions will be applied with respect to sex, ethnicity, or socioeconomic status. Studies including mixed populations will be eligible if data

for patients with DKD can be clearly identified or extracted. Pediatric populations, non-human studies, and studies conducted outside mainland China will be excluded. This review will focus on real-world patient populations reported in observational studies.

Intervention The exposure of interest is diabetic kidney disease (DKD) under real-world clinical management and its natural disease course. This review does not evaluate the effects of specific therapeutic interventions. Instead, it focuses on the burden associated with DKD as observed in routine clinical practice.

Comparator No comparator or control group is required for this review. Comparisons between different CKD stages or patient subgroups, when reported in the original studies, will be summarized descriptively.

Study designs to be included Observational real-world studies, including cross-sectional studies, retrospective cohort studies, prospective cohort studies, and registry-based studies conducted in China.Only original studies reporting patient-level data will be included. Interventional studies, randomized controlled trials, case reports, case series, reviews, editorials, guidelines, expert consensus statements, and animal or in vitro studies will be excluded.Observational real-world studies, including cross-sectional studies, retrospective cohort studies, prospective cohort studies, and registry-based studies conducted i.

Eligibility criteria Population: Adult patients (aged ≥18 years) diagnosed with diabetic kidney disease (DKD) in mainland China.
Study type: Original observational real-world studies with a minimum sample size of ≥20 patients.
Outcomes: Studies reporting at least one of the following outcomes will be eligible: patient characteristics, metabolic control indicators, disease progression (including CKD progression, ESRD, or mortality), health-related quality of life (HRQoL), healthcare resource utilization, direct medical costs, or indirect costs.
Exclusion criteria: Interventional clinical trials, randomized controlled trials, case reports or case series, reviews, meta-analyses, editorials, commentaries, clinical guidelines, expert consensus statements, non-human studies, and studies conducted outside mainland China.

Information sources The literature search will be conducted using multiple electronic bibliographic databases in both English and Chinese. English-language databases will include MEDLINE (via PubMed), Embase, and Web of Science. Chinese-language databases will include China National Knowledge Infrastructure (CNKI), Wanfang Data, and VIP Database. The search will cover studies published from January 2019 to March 2024.
In addition, reference lists of all included studies and relevant review articles will be manually screened to identify potentially eligible publications not captured by the electronic searches. No trial registries will be searched, as this review focuses on published observational real-world studies. Grey literature, including conference abstracts, dissertations, and unpublished reports, will not be included. Corresponding authors will not be contacted for additional data.

Main outcome(s) The primary outcomes of this review are the clinical, humanistic, and economic burden of diabetic kidney disease (DKD) among adult patients in mainland China. Clinical outcomes include patient demographic and clinical characteristics, metabolic control indicators (e.g., HbA1c, blood pressure, lipid levels), chronic kidney disease (CKD) stage distribution, and disease progression outcomes such as the incidence of end-stage renal disease (ESRD) and all-cause mortality, reported over the follow-up periods available in the included studies. Humanistic outcomes include health-related quality of life measured primarily by EQ-5D utility scores. Economic outcomes include healthcare resource utilization and direct medical costs. Effect measures include pooled means, proportions, incidence rates, and utility values synthesized using single-arm meta-analyses where applicable.

Additional outcome(s) Additional outcomes include diabetes-related complications, comorbidities, indirect costs, length of hospital stay, outpatient visits, hospitalization frequency, and productivity loss where reported. Outcomes may also be stratified by CKD stage when data are available.

Data management All eligible studies will undergo full-text review, and data will be extracted using a standardized data extraction form developed in Microsoft Excel. Extracted data will include study characteristics, patient demographics, clinical indicators, outcomes of interest, and follow-up duration.
Data consistency will be checked by two independent reviewers. Discrepancies will be resolved through discussion or consultation with a senior investigator. All extracted variables will be standardized to ensure consistency in definitions and measurement units across studies. Cost data

will be adjusted to 2025 Chinese Yuan (CNY) using official inflation indices.

Quality assessment / Risk of bias analysis Formal risk of bias assessment tools were not applied in this review.
Study quality and potential sources of bias were evaluated descriptively based on study characteristics and reporting quality during the data extraction and synthesis process. Key methodological aspects considered included study design, sample size, population representativeness, diagnostic criteria for diabetic kidney disease, definition and measurement of outcomes, follow-up duration, and completeness of outcome reporting.

Potential biases such as selection bias, information bias, and reporting bias were qualitatively considered when interpreting pooled estimates, particularly given the predominance of observational and cross-sectional study designs. The overall strength and limitations of the evidence were discussed in light of heterogeneity across studies and variations in outcome reporting.

Strategy of data synthesis A quantitative synthesis will be conducted when at least two studies report the same outcome using comparable definitions. Single-arm meta-analyses will be performed using random-effects models to generate pooled estimates of clinical, humanistic, and economic outcomes.
Heterogeneity will be assessed using the I^2 statistic, with values greater than 50% indicating substantial heterogeneity. When quantitative synthesis is not feasible due to limited data or heterogeneity, findings will be summarized descriptively.
For outcomes reported as medians and interquartile ranges, values will be converted to means and standard deviations using established statistical methods. All analyses will be conducted using R software.

Subgroup analysis Subgroup analyses will be conducted when sufficient data are available, primarily stratified by chronic kidney disease (CKD) stage.
Additional subgroup analyses may be performed based on study characteristics or patient health states, including early versus advanced CKD, dialysis status, and outcome type (clinical, humanistic, or economic), to explore potential sources of heterogeneity.

Sensitivity analysis No formal sensitivity analyses are planned.

Given the descriptive nature of this systematic review and the use of single-arm meta-analyses to summarize disease burden outcomes, heterogeneity will be explored using the I^2 statistic, and findings will be interpreted cautiously in light of between-study variability.

Language restriction Studies published in English or Chinese will be eligible for inclusion. No additional language restrictions will be applied.

Country(ies) involved China.

Other relevant information This systematic review will be conducted and reported in accordance with the PRISMA 2020 guidelines.
All analyses will be based on previously published data, and therefore ethical approval is not required. Any deviations from the registered protocol, if necessary, will be transparently reported in the final publication.

Keywords Diabetic kidney disease; China; metabolic control; quality of life; healthcare costs; ESRD.

Dissemination plans The results of this systematic review will be submitted for publication in a peer-reviewed international journal and presented at relevant academic conferences. The findings are expected to inform clinicians, researchers, and health policy makers about the clinical, humanistic, and economic burden of diabetic kidney disease in China.

Contributions of each author
Author 1 - Wenbin Tang - The author participated in conceiving the research plan and guided the writing of the research proposal and the manuscript.
Email: tangwenbin@csu.edu.cn
Author 2 - Liang Tan - The author participated in guiding the literature search, study selection, and data extraction processes, as well as conducting data analysis and evidence synthesis using the extracted data.
Email: l.tan@norminchina.com
Author 3 - Yang Luo - The author participated in literature search, study selection, and data extraction.
Email: 2294706786@qq.com
Author 4 - Ting Zhang - The author participated in literature search, study selection, and data extraction.
Email: 934984608@qq.com
Author 5 - Fang Liu - The author participated in literature search, study selection, and data extraction.

Email: xyliufang@csu.edu.cn
Author 6 - Li Yan - The author participated in data analysis and evidence synthesis.
Email: l.yan@norminchina.com
Author 7 - Wendong Chen - The author participated in conceiving the research plan and guided the writing of the research proposal and the manuscript.
Email: wendong.chen@normin.ca