Progression to ESRD Among White, Black and Hispanic Diabetic Kidney Disease Patients: Real-World Evidence from Multiple Linked Claims Databases

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CHRONOS

Disclosures: Seth Kuranz is an employee of Forian, Inc.

Background & Objectives

Diabetes is a common cause of progression from chronic kidney disease (CKD) to end-stage renal disease (ESRD). Progression to ESRD among racial/ethnic groups with diabetic kidney disease (DKD) is not well characterized.[1]

This analysis compares rates of progression to ESRD between White, Black, and Hispanic DKD patients and describes the impact of using linked claims to conduct analyses and to evaluate the use of multiple real-world data (RWD) sources.

Methods

Design: Adult patients with newly diagnosed CKD and a history of diabetes (i.e., DKD patients) were identified in CHRONOS, Forian's linked claims and social determinants of health (SDoH) database. White, Black, and Hispanic DKD patients were followed for up to three years after the first CKD diagnosis (index).

Setting: The primary analysis using closed claims data and secondary analysis using combined closed and open claims data identified DKD patients in the US, stratified by race/ethnicity. All patients met the inclusion/exclusion criteria in **Figure 1.**

Outcome: Progression to ESRD within the three years following index was defined by a claim for stage 5 (S5) CKD or ESRD, dialysis, or kidney transplant. Outcomes were defined by ICD-10-CM diagnoses or CPT/HCPCS/ICD-10-PCS procedure codes.

Statistical Analysis: Patient characteristics and progression to ESRD are described for White, Black, and Hispanic DKD patients. Patients who did not progress were censored at the date of disenrollment from a health plan or at year three of follow-up. Kaplan-Meier curves describe progression-free probabilities over follow-up, and hazard ratios (HRs) and 95% confidence intervals from Cox Proportional Hazards models compare rates of progression between White (reference), Black, and Hispanic patients, adjusting for demographics, baseline characteristics, and SDoH. The secondary analysis repeated the primary analysis in a cohort of patients where open claims supplemented the inclusion/exclusion criteria and outcome definitions. Summary-level, probabilistic quantitative bias analysis (QBA) examined outcome misclassification in the closed claims based upon the unadjusted risk ratios (RRs) and 95% confidence intervals (CIs), given their alignment with adjusted HRs, with QBA inputs taken direction from the combined closed and open claims data.[2]

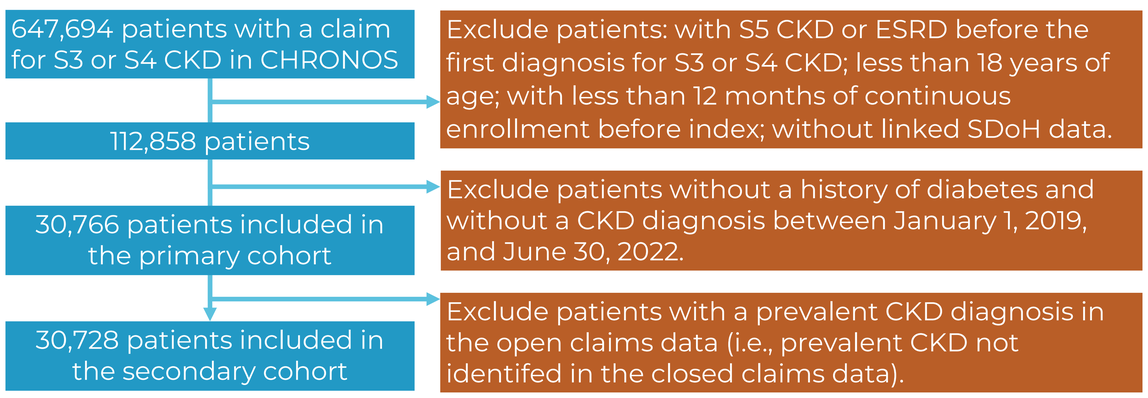

Figure 1. Attrition Criteria

Conclusions

This analysis found Black and Hispanic patients were more likely to progress to ESRD than White patients. The secondary analysis showed changes in the event-free survival results with only small increases in the HRs. QBA confirmed outcome misclassification resulted in an attenuation of relative measures of association and highlights the need to more accurately reflect confidence levels in RWE studies.

Results

Patient and study characteristics for the primary and secondary cohorts are described in **Table 1.** In the primary analysis, progression occurred in 5.8%, 8.6%, and 10.1% of White, Black, and Hispanic patients, respectively, with an additional 287, 106, and 81 outcomes observed in the secondary analysis. The additional outcomes were attributed to claims with dialysis or transplant procedures (**Table 1**).

Table 1. Patient and Study Characteristics

	Primary Cohort			Secondary Cohort		
	White	Black	Hispanic	White	Black	Hispanic
Total (n)	23,097	4,895	2,774	23,072	4,886	2,770
Follow-up days (mean, SD)	511 (356)	501 (356)	475 (350)	512 (356)	502 (356)	476 (350)
Age (mean, SD)	61 (8)	58 (9)	58 (9)	61 (8)	58 (9)	58 (9)
Female (%)	45.6	54.1	46.1	45.6	54.2	46.2
CCI (mean, SD)	1.2 (1.7)	1.1 (1.5)	1.1 (1.6)	1.2 (1.7)	1.1 (1.5)	1.1 (1.6)
Progression (%)	5.8	8.6	10.1	7..0	10.8	13.0
ESRD Diagnosis (%)	4.6	7.3	8.7	4.6	7.2	8.6
Dialysis (%)	3.6	5.9	6.6	4.8	8.0	9.2
Transplant (%)	0.5	0.8	1.2	0.7	1.1	1.7

Abbreviations: CCI, Charlson Comorbidity Index; ESRD, End-Stage Renal Disease; SD, Standard Deviation
Notes: ESRD, Dialysis, and Transplants are not mutually exclusive. The first instance of any of the three events defining Progression in the outcomes analysis.

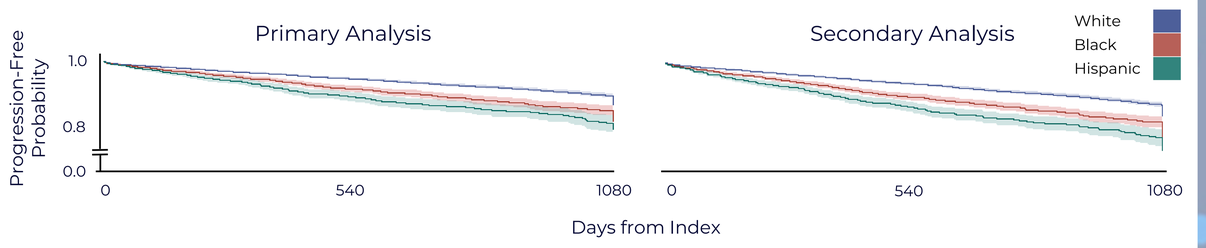

Figure 2. Kaplan-Meier Curves for Primary and Secondary Analysis

Three-year progression-free probabilities of 0.87, 0.82, and 0.79 were observed among White, Black, and Hispanic patients in the primary analysis, respectively. These probabilities decreased to 0.84, 0.77, and 0.73 with the inclusion of open claims data in the secondary analysis (**Figure 2**). Compared to White patients, Black [HR: 1.3 (1.2-1.5)] and Hispanic [HR: 1.6 (1.4-1.8)] patients were more likely to progress in the primary analysis. Black [HR: 1.4 (1.2-1.5)] and Hispanic [HR: 1.7 (1.5-1.9)] patients were similarly more likely to progress in the secondary analysis.

Figure 3. Unadjusted RRs and QBA Results

A QBA utilized beta distributions with a mean sensitivity (SE) of 0.80 and specificity of 0.99 based on values from the observed closed and open claims data for all racial/ethnic groups. A SE distribution with mean 0.40 was also examined to represent a greater degree of outcome misclassification. In all cases, correcting for outcome misclassification resulted in a RR that was further from the null than the observed RR with substantially wider confidence intervals. The QBA RRs align with the observed HRs from the secondary analysis (**Figure 3**).

References: [1] Hounkpatin et al. (2020). Ethnic minority disparities in progression and mortality of pre-dialysis chronic kidney disease: A systematic scoping review. BMC Nephrology, 21(1), 217. [2] Fox et al. (2023). SAS and R code for probabilistic quantitative bias analysis for misclassified binary variables and binary unmeasured confounders. International Journal of Epidemiology..

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