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BRIEF COMMUNICATION

Sociodemographic disparities in sodium-glucose cotransporter-2 inhibitor use among US kidney transplant recipients: An observational study of real-world pharmacy records

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Abstract

Background: Recent clinical trials demonstrate benefits of sodium-glucose cotransporter-2 inhibitors (SGLT2i) in patients with chronic kidney disease, but data on use in kidney transplant (KTx) recipients are limited.

Methods: We examined a novel database linking SRTR registry data for KTx recipients (2000–2021) with outpatient fill records from a large pharmaceutical claims warehouse (2015–2021). Adult (≥18 years) KTx recipients treated with SGLT2i were compared to those who received other noninsulin diabetes medications without SGLT2i. Characteristics associated with SGLT2i use were quantified by multivariable logistic regression (adjusted odds ratio, $_{95\%LCL}$aOR$_{95\%UCL}$).

Results: Among 18 988 KTx recipients treated with noninsulin diabetes agents in the study period, 2224 filled an SGLT2i. Mean time from KTx to prescription was 6.7 years for SGLT2i versus 4.7 years for non-SGLT2i medications. SGLT2i use was more common in Asian adults (aOR, $_{1.09}1.31_{1.58}$) and those aged > 30–59 years (compared with 18–30 years) or with BMI > 35 kg/m^2 (aOR, $_{1.19}1.41_{1.67}$), and trended higher with self-pay status. SGLT2i use was lower among KTx recipients who were women (aOR, $_{.79}.87_{.96}$), Black (aOR, $_{.77}.88_{1.00}$) and other (aOR, $_{.52}.75_{1.07}$) race, publicly insured (aOR, $_{.82}.92_{1.03}$), or with less than college education (aOR, $_{.78}.87_{.96}$), and trended lower in those age 75 years and older. SGLT2i use in KTx patients increased dramatically in 2019–2021 (aOR, $_{5.01}5.63_{6.33}$ vs. prior years).

Conclusion: SGLT2i use is increasing in KTx recipients but varies with factors including race, education, and insurance. While ongoing study is needed to define risks and benefits of SGLT2i use in KTx patients, attention should also focus on reducing treatment disparities related to sociodemographic traits.

KEYWORDS
diabetes, disparities, kidney transplantation, pharmacoepidemiology, sodium-glucose cotransporter-2 inhibitor

1 | INTRODUCTION

Sodium-glucose cotransporter-2 (SGLT2) inhibitors compose a relatively new class of antiglycemic agents which inhibit glucose reabsorption at the renal proximal tubular cells, thereby increasing urinary glucose excretion. Although the glucose-lowering effect of SGLT2 inhibitors is small (hemoglobin A_{1c} reduction by .5%−1%), multiple clinical trials have demonstrated mortality and cardiorenal protective benefits of SGLT2 inhibitors in patients with type 2 diabetes mellitus (T2DM).[1,2] Recently, revised guidelines from the American Diabetes Association now recommend SGLT2 inhibitors as one of the possible first-line pharmacologic interventions to consider in T2DM patients with established or high risk of atherosclerotic cardiovascular disease, heart failure, or chronic kidney disease (CKD).[3] Moreover, based on the ample evidence suggesting that SGLT2 inhibitors slow CKD progression regardless of diabetes status,[4,5] these agents have rapidly become the standard of care for patients with native kidney disease.

There is an increasing interest in the use of SGLT2 inhibitors in kidney transplant (KTx) recipients, although there are concerns regarding associated risk of dehydration and urinary tract infections.[6] Based on the limited evidence from prospective or retrospective case series, a small randomized control trial, and their meta-analysis,[7–11] SGLT2 inhibitors appear to be well-tolerated and efficient in weight loss and glycemic control without increasing the risk of hypoglycemia or other significant adverse events in the KTx population,[12] and potentially useful in reducing mortality and preserving graft function.[13] In addition, increased serum magnesium levels with SGLT2 inhibitors[6,8] may add another benefit in KTx recipients with hypomagnesemia, which reportedly contributes to mortality risk.[14]

To what extent SGLT2 inhibitors are being used in real-world settings among the KTx population is unknown. We examined the prescription patterns of SGLT2 inhibitors among KTx recipients to identify utilization patterns of these potentially beneficial agents.

2 | METHODS

Detailed methods are provided in Item S1. This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere.[15] The Health Resources and Services Administration (HRSA), US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

In brief, we examined a novel database linking SRTR data for KTx recipients (2000–2021) with outpatient fill records from a large pharmaceutical claims warehouse (2015–2021) in the United States. Adult (≥18 years) diabetic KTx recipients treated with SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin) were compared with those who received other noninsulin diabetes medications without SGLT2 inhibitors (Table S1). Patient characteristics of those who received SGLT2 inhibitors after transplant compared with those who received other noninsulin diabetes agents were compared by χ^2 analysis. Adjusted associations of baseline characteristics with SGLT2 inhibitor use after transplant were quantified by multivariable logistic regression (adjusted odds ratio, ${}_{95\%LCL}aOR_{95\%UCL}$ [LCL, lower confidence limit; UCL, upper confidence limit]). Changes in SGLT2 inhibitor fill rates over years of the study were computed as fills per duration of pharmacy record eligibility contributed by the cohort within the calander year, and annualized per 100-patient-years exposure time.

3 | RESULTS

Among 18 988 KTx recipients treated with noninsulin diabetes agents in the study period, 2224 (11.7%) filled an SGLT2 inhibitor prescription. Among them, 50% received empagliflozin; 25%, canagliflozin; 23%, dapagliflozin; and 1.6%, ertugliflozin. Mean time from KTx to SGLT2 inhibitor prescription was 6.7 years, while the mean time to non–SGLT2 inhibitor fill was 4.7 years.

Compared with patients who received non–SGLT2 inhibitor agents, those who received an SGLT2 inhibitor after transplant were more commonly men, Asian, college-educated, and privately insured or with self-pay status (Table 1). Patients who received SGLT2 inhibitors had higher body mass index (BMI), and more commonly had diabetes as cause of end-stage kidney disease or pretransplant diabetes mellitus (Table 1). SGLT2 inhibitor use was less common among patients who were Black or publicly insured.

SGLT2 inhibitor use was more common in adults who were middle-aged (compared with age 18–30 years, aORs in age 31–44: ${}_{.96}1.28_{1.71}$; age 45-59: ${}_{.99}1.31_{1.74}$), were Asian (aOR, ${}_{1.09}1.31_{1.58}$), and had higher BMI (compared with BMI 18.5 to < 30, aOR for BMI > 30 to 35 kg/m^2: ${}_{.99}1.15_{1.33}$; BMI > 35: ${}_{1.19}1.41_{1.67}$) and trended higher with self-pay status (Figure 1). SGLT2 inhibitor use was lower in patients who were age ≥ 75 years (aOR, ${}_{.37}.68_{1.23}$), women (aOR, ${}_{.79}.87_{.96}$), Black (aOR, ${}_{.77}.88_{1.00}$), or other race and ethnicity (aOR, ${}_{.52}.75_{1.07}$), were underweight (compared with BMI 18.5 to < 30, aOR for BMI < 18.5 kg/m^2: ${}_{.20}.42_{.88}$), publicly insured (aOR, ${}_{.82}.92_{1.03}$), or who had less than college education (aOR, ${}_{.78}.87_{.96}$). SGLT2 inhibitor use in KTx patients increased dramatically in 2019–2021 compared with 2015–2018 (aOR, ${}_{5.01}5.63_{6.33}$) (Figure 1). The longitudinal change of the prescription numbers over time is shown in Figure 2.

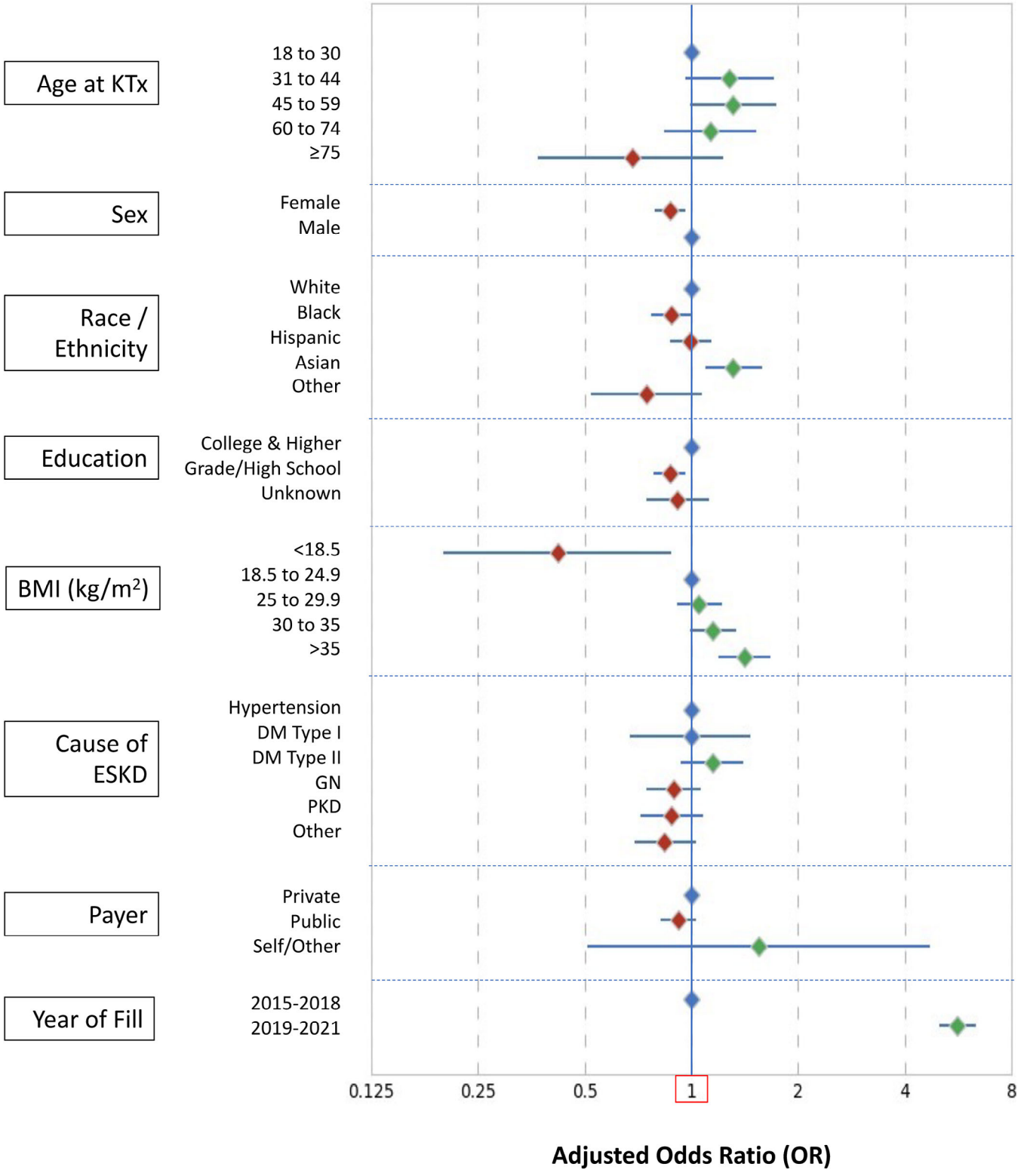

FIGURE 1 Demographic and clinical correlates of SGTL2 inhibitor use versus other noninsulin diabetes agents among US kidney transplant recipients by multivariate logistic regression. Adjusted Odds Ratios are displayed using log10 scale. Significant relationships ($p < .05$) displayed. BMI, body mass index; DM, diabetes mellitus; ESKD, end-stage kidney disease; GN, glomerulonephritis; KTx, kidney transplant; PKD, polycystic kidney disease.

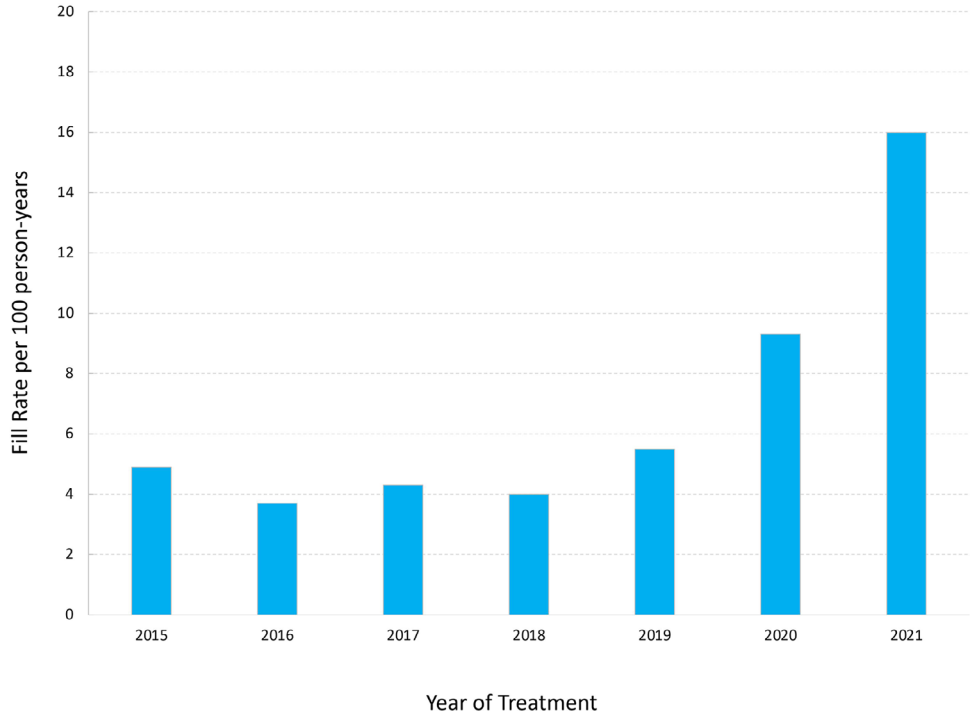

FIGURE 2 Longitudinal trend of the SGLT2 inhibitor fill rate by each year of study. Y axis shows the fill rate within each calendar year per duration of pharmacy record eligibility contributed by the cohort, and annualized per 100-patient years exposure time.

In secondary analysis, results were similarly stratified by baseline diabetes status (Figure S1).

4 | DISCUSSION

We examined real-world pharmacy fill records to study SGLT2 inhibitor use among KTx recipients with diabetes mellitus. We found that SGLT2 inhibitor use is increasing in this population but varies with factors including race and ethnicity, education, and insurance. We observed a significant growth in SGLT2 inhibitor use in KTx recipients in 2019–2021. We chose 2019 as the time point to divide treatment eras based on the history of SGLT2 inhibitor use in the United States. Canagliflozin was the first medication in the SGLT2 inhibitor class to be approved by the US Food and Drug Administration in 2013. Since then, several other SGLT2 inhibitors have also been approved and are available for clinical use. Following the breakthrough cardiovascular outcomes trial, EMPA-REG OUTCOME, in 2015[1] and the subsequent expansion of empagliflozin's label to include cardiovascular risk reduction in T2DM, annual prescriptions of SGLT2 inhibitors dispensed in the United States in 2016 increased by 28% for all prescribers and by 44% for nephrologists, as compared with the previous year.[16] The annual prescription increase was modest in 2017 (+5% for all, +17% for nephrologists) and 2018 (+9% for all, +15% for nephrologists), while it again further increased in 2019 (+15% for all, +41% for nephrologists),[16] when results from the CREDENCE trial showed improved renal outcomes in CKD with canagliflozin[17] and the DAPA-HF trial showed superiority of dapagliflozin to placebo at preventing cardiovascular deaths and heart failure events among patients with heart failure irrespective of diabetes status.[18] Although KTx recipients were excluded from these landmark clinical trials, the paradigm shift in the management of native kidney disease attracted the interest of the transplant nephrology community in the off-label use of SGLT2 inhibitors in the KTx population. Notably, SGLT2 inhibitors carry the potential risks of volume depletion and urinary tract infection, both of which are especially important considerations in the management of KTx recipients. An initial small, randomized controlled trial of SGLT2 inhibitors in KTx patients with posttransplant diabetes mellitus ($N = 49$) in 2019 concluded that SGLT2 inhibitors appeared to be safe and useful for glycemic control.[10] Since then, several case series and observational studies have suggested beneficial effects of SGLT2 inhibitors, not only on hyperglycemia management but also on reduction of body weight, blood pressure, proteinuria, and serum uric acid, as well as improvement in hypomagnesemia without increasing adverse events.[8,13,19]

Disparities in health outcomes persist among people with diabetes by race, ethnicity, income, occupation, and sex and tend to be associated with differences in access to effective treatments.[20] Lack of treatment access due to income or insurance coverage are often identified as key determinants in studies of disparities in prescription drug coverage and medication use in the United States.[21] Such limitations are notably manifest in the context of the latest classes of glucose-lowering agents, given their high price. One study found a robust association between the possession of commercial insurance, as compared with Medicare, and an increase in SGLT2 inhibitor use.[22] Such a finding suggests that out-of-pocket costs are likely one of the largest

TABLE 1 Distributions of clinical traits of kidney transplant recipients according to SGLT2 inhibitor use after transplant ($N = 18\,988$).

Baseline characteristics	Received SGLT2 inhibitors ($n = 2224$) (%)	Received non–SGLT2 inhibitor agents ($n = 16\,764$) (%)
SGLT2 inhibitor pre-KTx		**
Yes	1.3	.4
No	98.7	99.6
Year of treatment		**
2015 to 2018	18.4	53.2
2019 to 2021	81.6	46.8
Age, y		**
18 to 30	2.9	4.0
31 to 44	18.6	16.6
45 to 59	47.1	41.7
60 to 74	30.6	35.9
≥75	.7	1.8
Sex		**
Female	34.4	38.5
Male	65.7	61.6
Race and ethnicity		*
White	43.6	44.1
Black	25.1	27.5
Hispanic	20.2	19.0
Asian	9.3	7.4
Other	1.8	2.1
Highest level of education		*
College or higher	47.9	45.1
Grade/high school	45.2	48.5
Not reported	6.8	6.4
Body mass index, kg/m^2		**
<18.5	.4	1.1
18.5 to <25	16.4	19.0
25 to <30	33.7	35.8
30 to<35	30.3	29.3
>35	19.3	14.8
Functional status		*
Activities with no assistance	81.4	82.3
Activities with some assistance	12.1	12.6
Activities with total assistance	2.0	1.8
Not reported	4.5	3.2
Cause of ESKD		**
Hypertension	17.5	21.4
Diabetes mellitus type I	2.2	1.4
Diabetes mellitus type II	47.0	37.9
Glomerulonephritis	14.9	16.2
Polycystic kidney disease	9.0	10.1
Other	9.3	13.0
Primary payer		**
Private	35.0	31.0
Public	64.8	68.9
Self/Other	.2	.2
Comorbid conditions at listing		
Hypertension	61.3	59.8
Diabetes mellitus	58.8	48.5**
Coronary artery disease	4.8	3.9*
Cerebral vascular disease	1.8	1.7
Peripheral vascular disease	10.3	10.9
COPD	.5	.8
Previous transplant		*
Yes	1.7	2.5
No	98.3	97.5
Donor types		**
Living donor	36.0	31.8
Deceased, KPDI < 20%	16.7	15.9
Deceased, KDPI 20%–85%	44.3	48.1
Deceased, KDPI > 85%	3.0	4.2

Note: Percentages are column percentages.
Abbreviations: COPD, chronic obstructive pulmonary disease; ESKD, end-stage kidney disease; KDPI, kidney donor profile index; KTx, kidney transplant; SGLT2, sodium-glucose cotransporter-2.
*$p < .05$–$.002$.
**$p < .002$.

barriers to the use of these agents.[23] Despite Medicare generally covering the SGLT2 inhibitor class in 2019, out-of-pocket costs remained high, being at least $1000 annually. High out-of-pocket expenditures have been extensively reported to be linked to treatment nonadherence, leading in turn to greater income-based discrepancies in health outcomes. This implies that the treatment and outcome inequalities present in patients with T2DM likely exist among KTx recipients.

Given the association of race and ethnicity with income, insurance status, and out-of-pocket spending, individuals from historically disadvantaged groups disproportionately face barriers to accessing effective medications and experience inferior health outcomes. Prior studies have found that even after adjustment for household income, insurance coverage, and educational attainment, racial disparities in the use of the newest generation of glucose-lowering drugs persist.[22] The remaining variation may be explained by differences in the quality of health care facilities at which patients receive care and implicit biases of prescribing physicians.

In addition to race- and income-based disparities, sex-based differences exist in the prescription of medications for diabetes and the

management of cardiovascular diseases.[24] Although large trials show no difference in the efficacy or safety of SGLT2 inhibitors by sex, female sex is consistently associated with significantly lower use of this drug class.[22,25] Our results resonate with these patterns and show an emerging trend toward racial, sex-based, and socioeconomic inequities in the use of SGLT2 inhibitors after KTx within our short study period. We found less frequent use of SGLT2 inhibitors in female KTx recipients than male KTx recipients. Other published studies of patients with nontransplant T2DM have also reported that SGLT2 inhibitors were less often prescribed for women than men, while women were more likely to start glucagon-like peptide 1 receptor agonists than men.[26,27] It has been suggested that this may be related to physicians' fear of the urinary tract infection complications with SGLT2 inhibitors, or female patients' interest in weight loss with glucagon-like peptide 1 receptor agonists.[27] More detailed studies are needed to investigate the reasons for sex differences in SGLT2 inhibitor prescription.

Our study has limitations. First, because our analyses were limited to claims data, we could not assess other medical information such as glycemic control, history of urinary tract infection, and functional status, which might affect the decision-making and treatment goals. Pharmacy fill data inherently lack information on medication indication, but have been extensively used for pharmacoepidemiology studies in the KTx and living donor populations.[28–32] Patterns were robust in sensitivity analysis of patients with pretransplant diabetes. Insurance plan coverage may evolve and medication utilization patterns might be different in more recent data. These data may not reflect actual medication use, because not all filled prescriptions are used. Pharmacy fill records are an indirect but validated measure of medication exposure.[33–35] Despite these limitations, these data add important information on SGLT2 inhibitor use among KTx recipients in real-world practice.

In conclusion, while large-scale clinical trials are needed to evaluate the efficacy and safety of SGLT2 inhibitor therapy in the transplant setting, attention should also focus on reducing treatment disparities related to social determinants of health. It is important for healthcare professionals and policy makers to be aware of disparities in medication use among KTx patients, monitor disparities as evidence accumulates on best practices, and take actions to ensure that appropriate medications are accessible to all patients who may benefit.

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CONFLICT OF INTEREST STATEMENT

Krista L. Lentine, David A. Axelrod, and Mark A. Schnitzler receive consulting fees from CareDx. Krista L. Lentine receives speaker honoraria from Sanofi. The other authors have no relevant interests to disclose.

DATA AVAILABILITY STATEMENT

Scientific Registry of Transplant Recipients (SRTR) data reported were supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for SRTR.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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