

Prescribing Patterns of SGLT2 Inhibitors and GLP-1 RAs in Patients with Type 2 Diabetes and Comorbid Conditions of Cardiovascular Disease, Chronic Kidney Disease, and Obesity

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Abstract

Background: Type 2 diabetes (T2D) is a metabolic condition which increases the risk of cardiovascular disease (CVD) and chronic kidney disease (CKD). Despite these risks, many people with diabetes do not meet treatment goals and thus remain at increased risk of mortality and morbidity associated with diabetes. Two classes of drugs known as sodium-glucose-cotransporter-2-inhibitors (SGLT2 inhibitor) and glucagon-like peptide-1 receptor agonists (GLP-1 RA) have transformed the way obesity, CVD, and CKD is managed in patients with diabetes. Despite their benefits, many people with diabetes are not prescribed these medications as part of an antihyperglycemic regimen.

Methods: This study examined the prescribing patterns for patients with T2D and target comorbidities, including established or high-risk CVD, CKD, obesity, and high hypoglycemia risk in an ambulatory care clinic. Adults were included if they had uncontrolled T2D. The primary objective of this study was to describe the prescribing prevalence of SGLT2 inhibitors and GLP-1 RAs for patients with uncontrolled T2D and target comorbidities. We also compared the demographic characteristics of patients by prescribing patterns.

Results: A total of 16 individuals were included in the study. Overall, 62.5% of all patients were not on an SGLT2 inhibitor or GLP-1 RA despite demonstrated potential benefit(s). Approximately 33% of obese patients, 50% of individuals with CKD or at high risk for CVD, and 40% of individuals having high hypoglycemia risk were on an SGLT2 inhibitor or a GLP-1 RA.

Conclusion: Prescribing of SGLT2 inhibitors and GLP-1 RAs was low in patients with high ASCVD risk, high hypoglycemia risk, obesity, and CKD.

Keywords

Prescribing Patterns, Diabetes, GLP-1 RA, SGLT2 inhibitor, Obesity, Chronic kidney disease, Cardiovascular disease

Abbreviations

CVD: Cardiovascular disease; **T2D:** Type 2 diabetes; **CKD:** Chronic Kidney Disease; **SGLT2 inhibitor:** Sodium-glucose-cotransporter-2-inhibitors; **GLP-1 RA:** Glucagon-like peptide-1 receptor agonists; **CVOTs:** Cardiovascular outcome trials; **EMR:** Electronic Medical Record

Introduction

Background: Diabetes is a metabolic disorder in which the body has abnormally high glucose levels. Type 2 diabetes (T2D) is the most common type of diabetes and occurs as a result of improper insulin use by the body, defective insulin action, or insulin resistance. Approximately 37.3 million Americans have diabetes (11.3% of the US population) and 23% of US adults are undiagnosed (CDC, 2022) [1].

People living with T2D have an increased risk of disease-associated macrovascular complications, including cardiovascular diseases such as myocardial infarction, heart failure, and stroke. Additionally, T2D increases the risk of microvascular complications, including nephropathy, retinopathy, and neuropathy. Among United States (US) adults aged 18 years or older with diagnosed diabetes, 89.8% were overweight or had obesity, defined as a body mass index (BMI) of 25 kg/m² or higher (CDC, 2022) [1]. In 2022, the crude prevalence of end-stage kidney disease (ESRD) with diabetes listed as the primary cause was 38.8% (305,013 out of 785,883 people), and diabetes was the leading cause of ESRD, followed by high blood pressure (26.1%), and glomerulonephritis (14.9%) [1].

Cardiovascular disease is the number one cause of death in patients with T2D, accounting for about two-thirds of all deaths in US patients with T2D [2]. In the state of Louisiana alone, an estimated 32,139 people are diagnosed with diabetes annually and approximately 14.2% of the adult population in Louisiana already has diagnosed diabetes [2]. In 2021, Louisiana had a 12.6% obesity rate among adults with diabetes, placing Louisiana ninth out of 51 states for obesity rates in adults with diabetes nationwide [3].

These complications warrant the management of T2D in a comprehensive, patient-centered approach. Both the ADA and American Association of Clinical Endocrinologists and American College of Endocrinology (AAACE/ACE) provide recommendations aimed at comprehensive treatment and prevention of T2D. AAACE and ADA guidelines both recommend weight loss as an adjunctive treatment for T2D due to beneficial effects on glycemic control with less need for medications. Weight loss also aids some patients to achieve diabetes remission, control blood pressure, and promotes healthy kidney function. ADA and AAACE also recommend minimizing medications associated with weight gain in patients with obesity whenever possible.

In addition, the 2022 ADA Standards of Medical Care in Diabetes recommends first-line therapy for type 2 diabetes based on comorbidities.

Two classes of drugs known as sodium-glucose-cotransporter-2-inhibitors (SGLT2 inhibitors) and glucagon-like peptide-1 receptor agonists (GLP-1 RA) are recommended in patients with diabetes and cardiovascular disease, obesity, or chronic kidney disease. They have been proven to aid in body weight reduction, prevent the progression of CKD, and have cardiovascular protective benefits. Several landmark trials have concluded that SGLT2 inhibitors and GLP-1 RAs are not only safe and effective diabetes therapies, but they are also associated with a host of additional benefits.

The LEADER trial demonstrated that liraglutide reduced CV mortality, nonfatal MI, or nonfatal strokes when compared to placebo [4]. The patients in the liraglutide group achieved a mean change in glycated hemoglobin level (HbA1c) of -0.4% and a body weight that is lower by about 3 kg compared to the placebo group. Additionally, patients in the liraglutide group experienced less new onset of persistent macroalbuminuria, suggesting lower rates of the development and progression of diabetic kidney disease than placebo.

The SUSTAIN-6 trial demonstrated that semaglutide reduced CV mortality, nonfatal MI, or nonfatal strokes, and had renal protective effects when compared to placebo [5]. The patients in the semaglutide 0.5 mg group and semaglutide 1 mg group achieved a mean change in HbA1c of -0.7% and -1.0%, respectively and a body weight that is lower by 2.9 kilograms and 4.3 kilograms, respectively as compared to placebo.

Other landmark trials demonstrated the safety and efficacy of SGLT2 inhibitors, such as empagliflozin. The EMPA-REG OUTCOME trial demonstrated empagliflozin significant reduction in CV mortality with a 38% relative risk reduction in death from cardiovascular causes, a 35% relative risk reduction in hospitalization for heart failure, and a 32% relative risk reduction of all-cause mortality [6]. Impressively, patients in the empagliflozin group lost approximately 3% body weight and experienced a reduction in systolic blood pressure of about 4 mmHg compared to placebo. In addition, a mean decrease in HbA1c at 12 weeks for the 10 mg and 25 mg empagliflozin vs. placebo was 0.54% and 0.6%, respectively.

The EMPA-REG OUTCOME trial also studied renal effects of empagliflozin as a secondary microvascular outcome of the trial and found that patients on empagliflozin experienced slower progression of kidney disease and lower rates of clinically relevant renal events than placebo [7]. Patients in the empagliflozin group experienced significantly less incident or worsening nephropathy, had a significant relative risk reduction of 44% in doubling of serum creatinine, and a significant relative risk reduction of 55% in renal-replacement therapy initiation.

Overall, GLP-1 RAs and SGLT2 inhibitors have transformed the way some diabetes complications can be mitigated. A meta-analysis of eight cardiovascular outcome trials (CVOTs) showed that GLP-1 RAs reduce all-cause mortality by 12% [8]. Similarly, a meta-analysis of eleven CVOTs showed that SGLT2 inhibitors reduced mortality or hospitalization for heart failure (HF) by 23% [9].

Despite the efficacy, safety, and the added benefits associated with their use, SGLT2 inhibitors and GLP-1 RAs may be underutilized as part of antihyperglycemic regimens.

This study aims to report on the prescribing patterns of these two agents in patients with T2D and target comorbid conditions of obesity, CKD, CVD, and high hypoglycemia risk. This study examines participants that are established patients at a Federally Qualified Health Center (FQHC), a type of health center that serves predominantly uninsured or medically underserved patients or populations. Nearly 40% of this FQHC's patients are uninsured [10]. We hypothesize that

diabetic patients are not prescribed GLP-1 RA or SGLT2 inhibitor therapy despite unmet glycemic goals and a compelling need to mitigate comorbidities of obesity, CVD, and CKD. The cost of medications can be a major barrier in this setting, widening the gaps in access and affordability of medical care overall.

Materials and Methods

Trial design and patient selection

In this retrospective chart review analysis, we evaluated prescribing patterns of SGLT2 inhibitors and GLP-1 RAs among 16 patients who were participating in a PharmD/PCP chronic care management program at a federally qualified health center between 1/2021 and 3/2022. Post IRB approval, adults were identified through the electronic medical record (EMR) and included if they had a diagnosis of Type 2 Diabetes, uncontrolled diabetes defined as HbA1c of greater than 7%, were 18 years of age or older, and enrolled in the PharmD/PCP chronic care management program and by default are established patients at the Clinic. Individuals were excluded from the study if they had no previous diagnosis of type 2 diabetes, had a glycated hemoglobin A1c (HbA1c) <7%, were less than 18 years of age, were not enrolled in the PharmD/PCP chronic care management at the clinic, or were not established patients at the clinic. Although a total of 18 individuals were identified as meeting eligibility criteria for the study, two were excluded at the point of data collection. One patient was excluded from the study due to lack of pertinent information present in the EMR and another patient was deceased at the time of data collection.

Data collection

Data collected via retrospective chart review included demographics (age, gender, race, insurance status) and target comorbidities (established clinical atherosclerotic cardiovascular disease, chronic kidney disease, obesity, high hypoglycemic risk, and high risk for cardiovascular disease per 2017 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines). Other information that was collected included provision of whether a patient is prescribed an SGLT2 inhibitor and/or a GLP-1 RA, documented reasons against initiation of a SGLT2 inhibitor or GLP-1 RA, and whether the patient can receive any benefits from starting an SGLT2 inhibitor and/or GLP-1 RA based on target comorbidities. High hypoglycemic risk was defined as having an active prescription for insulin and/or a medication classified as being sulfonylurea. The 10-year ASCVD risk was categorized as low, moderate, or high using the ASCVD Risk Estimator Tool by The American College of Cardiology. The score for each patient was generated by inputting various information, such as demographics, blood pressure, cholesterol, and diabetes and smoking history into the ASCVD Risk Estimator Tool. A 10-year ASCVD risk score below 7.5% is considered low. Any score between 7.5% and 20% is considered intermediate risk, and a score of 20% or higher suggests a high 10-year ASCVD risk. Insurance status was defined as uninsured if there was no documented medical insurance in the EMR. Established chronic kidney disease was defined as having an eGFR

of less than <60 mL/min/1.73 m² and/or having albuminuria. Albuminuria was further divided into microalbuminuria and macroalbuminuria. Microalbuminuria was defined as having a urinary albumin of >30 to <300 mg/g and macroalbuminuria was defined as having a urinary albumin of >300 mg/g. Obesity was defined as having a BMI of ≥30 kg/m².

Statistical analysis

Descriptive statistics (frequencies, percentages, and means) were used to analyze all the collected data. Further descriptive analyses were conducted according to prescription status based on whether patients were prescribed an SGLT2 inhibitor and/or GLP-1 RA or not prescribed an SGLT2 inhibitor and/or GLP-1 RA. Results were stratified according to five characteristics (age, gender, race, insurance type, and obesity).

Results

Baseline characteristics are presented in [table 1](#). At baseline, the average HbA1c was 10.6% among all 16 study patients. HbA1c was similar among patients prescribed SGLT2 inhibitors and/or GLP-1 RAs (10.3%) and patients not prescribed SGLT2 inhibitors and/or GLP-1 RAs (10.9%) and there was no statistical significance in HbA1c between the two groups.

For the primary outcome, an SGLT2 inhibitor or GLP-1 RA prescription, 37.5% of patients were prescribed an SGLT2 inhibitor and/or a GLP-1 RA ([Figure 1](#)). 62.5% of all patients were not on an SGLT2 inhibitor or GLP-1 RA despite demonstrated potential benefit in one or more target comorbidities or conditions, such as CVD, CKD, obesity, and high hypoglycemic risk. Prescribing patterns are displayed in [figure 2](#). Approximately 33% of obese patients on either agent. Half (50%) of individuals with CKD or at high risk for CVD were on either agent, and 40% of individuals having high hypoglycemia risk were on either agent.

[Table 2](#) presents characteristics by prescription status. In the group of patients who were prescribed an SGLT2 inhibitor and/or GLP-1 RA prescription, there was more males (66.7%) than females (33.3%), more African Americans than white or Arabic patients (66.7% vs 33.3% vs 0%), the same

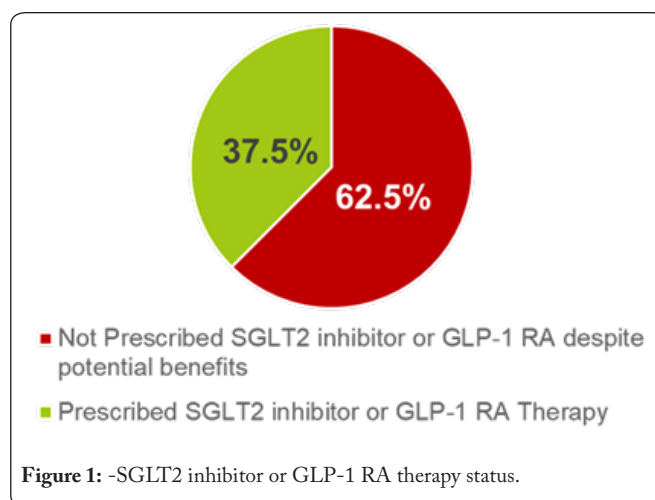
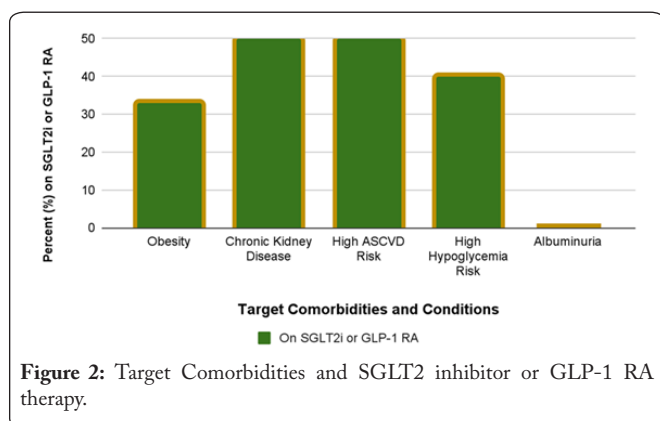


Figure 1: -SGLT2 inhibitor or GLP-1 RA therapy status.

Table 1: Baseline characteristics (N = 16).s

Characteristic	No. (%)	Characteristic	No. (%)
Age, mean (SD), years	52.94 (12.3)	Hemoglobin A1c, mean (SD)	10.64 (1.9)
Gender		Albuminuria	
Male	8 (50)	Microalbuminuria	1 (6.25)
Female	8 (50)	Macroalbuminuria	0 (0)
Race		ASCVD Risk Score (ACC/AHA)	
African American	10 (62.5)	Low	3 (18.75)
White	5 (31.25)	Intermediate	5 (31.25)
Arabic	1 (6.25)	High	4 (25)
		Unknown	4 (25)
Insurance		Therapy	
Medicaid	9 (56.25)	SGLT2i	6 (37.5)
Medicare	1 (6.25)	GLP-1 RA	0 (0)
Uninsured	6 (37.5)	Both	0 (0)
Obesity	9 (56.25)	Established ASCVD or HF	0 (0)
Established CKD	2 (12.5%)	Unmet SGLT2i or GLP-1 Benefits	
		Yes	10 (62.5)
		N/A	6 (37.5)
High Hypoglycemia Risk	15 (93.75)	Established CKD	2 (12.5)



amount of Medicaid patients and uninsured patients (50% vs 50%) and 50% of all who were prescribed an SGLT2 inhibitor or GLP-1 RA were obese.

In the group of patients who were not prescribed an SGLT2 inhibitor or GLP-1 RA, there was more females than males (60% vs 40%), more African Americans than white or Arabic patients (60% vs 30% vs 10%), more Medicaid patients than Medicare or uninsured patients (60% vs 10% vs 30%), and 60% of all those not prescribed were obese an SGLT2 inhibitor and/or GLP-1 RA.

Discussion

In this retrospective analysis, we observed that patients with diabetes are not prescribed GLP-1 RA or SGLT2 inhibitor therapy despite unmet glycemic goals or potential added benefits that may mitigate multiple comorbid conditions observed in these patients.

Table 2: Patient characteristics by prescription status.

	Prescribed SGLT2i or GLP-1 (n = 6)	Not Prescribed SGLT2i or GLP-1 despite potential benefits (n = 10)
Characteristic	No. (%)	No. (%)
Age, mean (SD), years	53.8 (8.11)	52.4 (15.21)
Gender		
Male	4 (66.7)	4 (40)
Female	2 (33.3)	6 (60)
Race		
African American	4 (66.7)	6 (60)
White	2 (33.3)	3 (30)
Arabic	0 (0)	1 (10)
Insurance		
Medicaid	3 (50)	6 (60)
Medicare	0 (0)	1 (10)
Uninsured	3 (50)	3 (30)
Obesity	3 (50)	6 (60)

Similar studies analyzing prescribing patterns of these two agents have been conducted previously. One study analyzed patients with HF and T2D admitted to the cardiology ward of the Medical University of Vienna between 01/2014 and 04/2020 and found that SGLT2 inhibitors remain underutilized in clinical practice in patients with T2DM and HF despite SGLT2 inhibitors demonstrating survival benefits in patients with HF, with only 17.3% of patients with T2DM and HF prescribed an SGLT2 inhibitor [11].

Another study retrospectively examined SGLT2 inhibitors and GLP-1 RA prescribing habits in the University of Mississippi Medical Center from January 2013 to June 2019 and found that prescribing of these two agents occurred most frequently by family/internal medicine followed by endocrinology and lastly, cardiology (6% SGLT2 inhibitor and 1.4% GLP-1 RA) [12-14].

To our knowledge, there have been no studies, to date, that have examined the prescribing patterns in patients with diabetes co-managed in a PharmD/PCP chronic care management program at a FQHC. The uniqueness of our study may help answer more questions and identify unique areas unrepresented in previous studies.

Overall, our analysis found that 37.5% of patients were prescribed either agent (an SGLT2 inhibitor or GLP-1 RA), while 62.5% of all patients were not on either agent despite demonstrating unmet potential benefits of these target therapies, such as cardiovascular, renal, and body weight reduction benefits. This finding is different than the finding by a study by Hamid et al which showed that in patients with T2D and CVD, only 1.4% received an SGLT2 inhibitor and 1.6% received a GLP-1 RA. Our study found that only 33% of obese patients were prescribed either agent, which was very low when considering the AACE/ACE and ADA recommendations and emphasis on the management of obesity in patients with diabetes as part of a comprehensive, patient-centered approach. Heart failure was not present in any of our study participants, possibly due to a smaller sample size; therefore, we could not compare this area to results from previous studies with larger sample size. However, our study found that only half of all participants with CKD or at high risk for CVD were prescribed an SGLT2 inhibitor or GLP-1 RA. This was also surprisingly low given the results of the CVOTs showing that GLP-1 RAs reduce all-cause mortality by 12% [8] and SGLT2 inhibitors reduce mortality or hospitalization for HF by 23% [9].

Hypoglycemia has always been a limiting factor and important complication of glycemic management in patients with diabetes. The EMPA-REG OUTCOME trial safety outcomes demonstrated that a similar percentage of hypoglycemic episodes occurred in empagliflozin group and placebo, confirming that empagliflozin is not associated with a high hypoglycemic risk [7].

The Sustain-6 trial demonstrated that similar rates and occurrences of hypoglycemia were seen with semaglutide compared to placebo [15, 16].

Despite this data, our study revealed that a low percentage (40%) of individuals having high hypoglycemia risk were prescribed either agent analyzed. An evidence level B recommendation from the 2022 ADA Standards of Medical Care in Diabetes encourages the use of antihyperglycemic agents that have a low hypoglycemia risk in patients with high hypoglycemic risk.

A 2019 study found that African Americans with CKD progress five times more quickly to end-stage renal disease, or kidney failure, than Caucasians and that African Americans

were significantly less likely to have their blood pressure controlled compared to other people in early stages of CKD who also had high blood pressure [18].

African Americans are well represented in our study, comprising 62.5% of total participants, yet SGLT2 inhibitor or GLP-1 RA prescribing in this group remained low. In an already high-risk population that is prone to worse outcomes, particularly renal outcomes, the under prescribing of these indicated agents may contribute to even poorer outcomes. One practical implication of this finding is that when considering ADA and other guideline recommendations for individualized patient care, race should also be considered when evaluating patient care and outcomes. Our findings also warrant further studies aimed at identifying areas of improvement, adjustment, or modification in the special management of T2D and CKD in African American patients, a health disparity population.

In this study, we found that there were more males (66.7%) than females (33.3%) in the group of patients who were prescribed an SGLT2 inhibitor or GLP-1 RA. Although the prescribing of these agents in females is nearly half that of males, it may be due to more increased risk of urinary tract infection (UTI) occurrence in females than in males. A recent retrospective cohort study found that females on SGLT2 inhibitors had higher risks for genital infections and urinary tract infections compared with males. UTIs included pyelonephritis, cystitis, urethritis, urethral syndrome in women, and inflammatory prostate diseases in men [19].

While this adverse effect may be a barrier to the prescribing of this otherwise safe, effective, and beneficial antihyperglycemic agent, GLP-1 RAs do not have these adverse effects and were still underutilized in our female participants and overall study participants as well. This finding brings to light both the implication of increased patient education and counseling and the importance of prescriber education. Further work is necessary to identify additional groups at high risk for UTIs and compare alternative therapy regimens with SGLT2 inhibitors.

We observed a higher underutilization of SGLT2 inhibitors and GLP-1 RAs in Medicaid patients than Medicare or uninsured patients (60% vs 10% vs 30%) despite the patients' demonstration of unmet potential benefits. This finding sheds light on the importance of antihyperglycemic medication coverage by insurance, accessibility, and affordability to all. Future studies should examine the gap between treatment guideline recommendations and patient access to these recommended treatments.

The limitations of our study include a small sample size, and lack of documented reasons for not being on SGLT2 inhibitors or GLP-1 RA therapy despite demonstrating unmet potential benefits. However, the sample size is expected as only patients who were established at our clinic and enrolled in the PharmD/PCP chronic care management were included in this study. Although adherence is unknown, prescribing patterns were still low despite unequivocally proven benefits and guideline recommendations to target patient specific comorbidities

when choosing antihyperglycemic agents. More studies may be necessary to investigate the reasons for the underutilization of these two agents in particular patient populations, such as African American patients at increased risk of CKD, obese patients with diabetes, and patients with high risk of hypoglycemia.

Conclusion

Prescribing of SGLT2 inhibitors and GLP-1 RAs was low in patients with high ASCVD risk, high hypoglycemia risk, obesity, and CKD.

Our study highlights the importance of identifying patients with potential unmet benefit(s) from SGLT2 inhibitors and GLP-1 RA therapy for T2D. The under prescribing of these agents should be an area of focus for reducing the gap between ADA and AACE guideline recommendations and practice.

Conflict of Interest

This research was conducted in the absence of any financial, commercial, or any other interests.

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