Patient characteristics and time to discontinuation of anti-hyperglycemics in routine clinical care from UK and US: a multi-database descriptive study

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Introduction

- Glycemic control is important for patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) to delay progression to kidney failure.
- With an array of anti-hyperglycemic medications available, there is limited contemporary understanding of treatment heterogeneity in real-world routine care.
- This study aims to describe real-world patient characteristics and patterns of treatment with anti-hyperglycemics in routine clinical care from the US and UK.

Methods

Study population

Adults with CKD and T2D, who initiate any of the anti-hyperglycemic drugs of interest. CKD was defined according to KDIGO as having a record of either: 1) diagnostic codes for CKD, 2) two measures of eGFR below 60 mL/min/1.73 m2 separated 90 to 548 days, or 3) two measures of UACR above 30 mg/g separated 90 to 548 days. T2D was defined based on diagnostic codes. Code lists and medical definitions are harmonized according to the FOUNTAIN research platform criteria.

Study design

Retrospective multidatabase, multicountry observational study. We generated six non-mutually exclusive cohorts of patients who initiated either:

- Dipeptydil peptidase 4 inhibitor (DPP4i),
- Glucagon-like peptide 1 receptor agonist (GLP1-RA),
- Insulin,
- Metformin,
- Sodium-glucose co-transporter-2 inhibitor (SGLT2i), or
- Sulfonylurea.

The index date was set at the time of initiation of one of these treatments.

Study period

The study period ran from January 1st, 2012, to December 31st, 2020.

Data sources

Claims and electronic medical records databases converted to the Observational Medical Outcomes PArtnerships (OMOP) Common data model (CDM). All databases were transformed to OMOP CDM following ETL specifactions protocol and standardized vocabulary mappings. Databases included are described in table 1.

Table 1. Data sources used in the study

Name	Type and country	Description
Optum Clinformatics Data Mart (OPTUM)	Claims // USA	Administrative health claims for members of a large care US company. Includes medical and pharmacy claims, lab results, and member eligibility data.
Truven MarketScan (MSCAN)	Claims // USA	Data from commercial claims and encounters (CCAE) and Medicare supplemental beneficiaries (MDCR). CCAE is a claims database for active employees, early retirees, and their dependents. MDCR is a claims database for Medicare active and retired employees and their dependents.
Optum de-identified Electronic Health Record (OPTUM EHR)	EHR // USA	Longitudinal patient-level data from more than 50 healthcare provider organizations. It captures clinical, operational, and financial information recorded by physicians at the time of care.
CPRD GOLD (GOLD)	EHR // UK	Data from UK general practitioners, providing a generalizable dataset.
CPRD Aurum (AURUM)	EHR // England	Primary care records capturing information on demographics, diagnoses and symptoms, drug use, laboratory tests, etc.

Statistical analysis

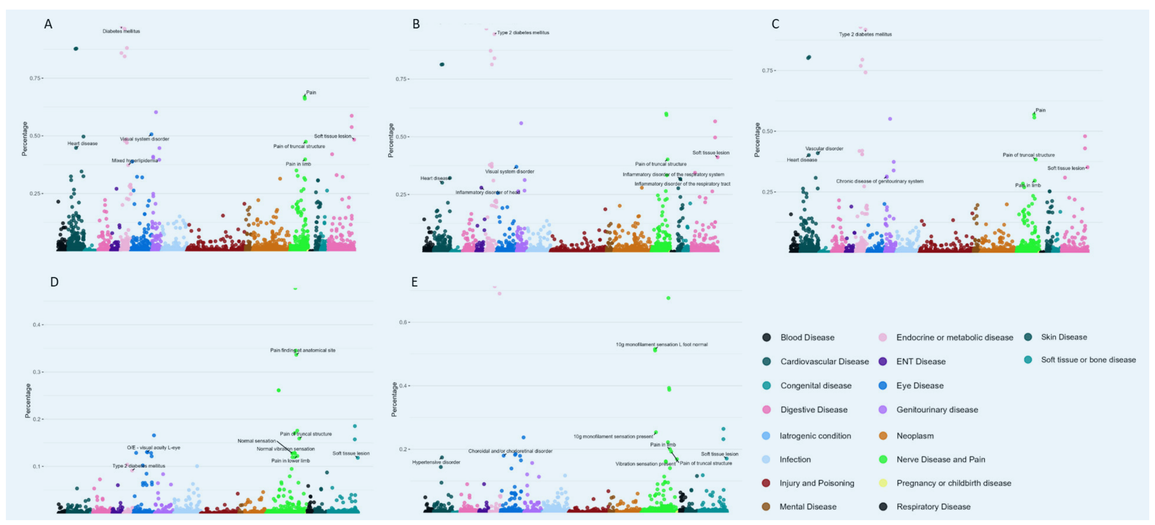
Patients were characterized at baseline (defined as the period 1-year prior to index) using descriptive analyses. Kaplan Meier curves were used to describe treatment discontinuation which was defined as a ≥90-day gap following an index prescription.

Results

Characteristics

A total of 167.8 million patients across all databases were assessed. Our cohorts' size ranged between 242,015 for SGLT2i and 650,447 for insulin across all databases. We observed little variability in baseline characteristics across the six cohorts except that SGLT2i and GLP-RA initiators were more likely to be male and younger. We observe similar distribution of baseline comorbidities across cohorts with some variation between databases. Figure 1 shows Manhattan plots with frequency of cocurence of multiple conditions in SGLT2i initiators. Prevalence of hypertension is higher in the US databases compared to the UK databases. For example, the prevalence of hypertension is higher in the US databases compared to the UK databases. We also observe a low prevalence of T2D in GOLD, this is likely due to a variation of coding since our cohort definitions required a T2D occurrence. In GOLD many patients with T2D had an observation of a screening for T2D rather than an explicit diagnosis code, which would impact our Manhattan plots and baseline tables.

Figure 1. Manhattan plot of frequency of occurence of multiple health conditions at baseline in SGLT2i initiators in five databases. A) OPTUM; B) MSCAN; C) OPTUM EHR; D) GOLD; E) AURUM



Abbreviations: CKD: Chronic kidney disease; DPP-4i: dipeptidyl peptidase-4 inhibitor; GLP-1 RA: glucagon-like peptide 1 receptor agonist; RAAS: renin-angiotensin-aldosterone system; SGLT2i: sodium-glucose cotransporter-2 inhibitor; T2D: Type 2 diabetes

Treatment patterns

Anti-glycemic drugs were taken in tandem with the index drug. Most commonly, metformin was co-prescribed within the first 90 days of initiating any of the other anti-hyperglycemics, and metformin initiators tend to be receiving only metformin (Fig. 2). Figure 3 shows the time to treatment discontinuation for each monotherapy across the different databases. SGLT2 has the highest median time to discontinuation in both UK databases. In the US databases, metformin showed the highest time to discontinuation. In the UK, we observed less discontinuation of SGLT2i and GLP1-RA as monotherapy compared to other drugs based on the median time to discontinuation, however this pattern is less apparent in US databases. Regarding the use of treatments not aiming to control glucose levels, patterns were similar across cohorts with a higher use of RAASi and lipid modifying agents, but we observed differences between UK and US (Fig. 4).

Figure 2. Frequency of anti-hyperglycemic drugs use post-index 90, 180, 365, 730 days

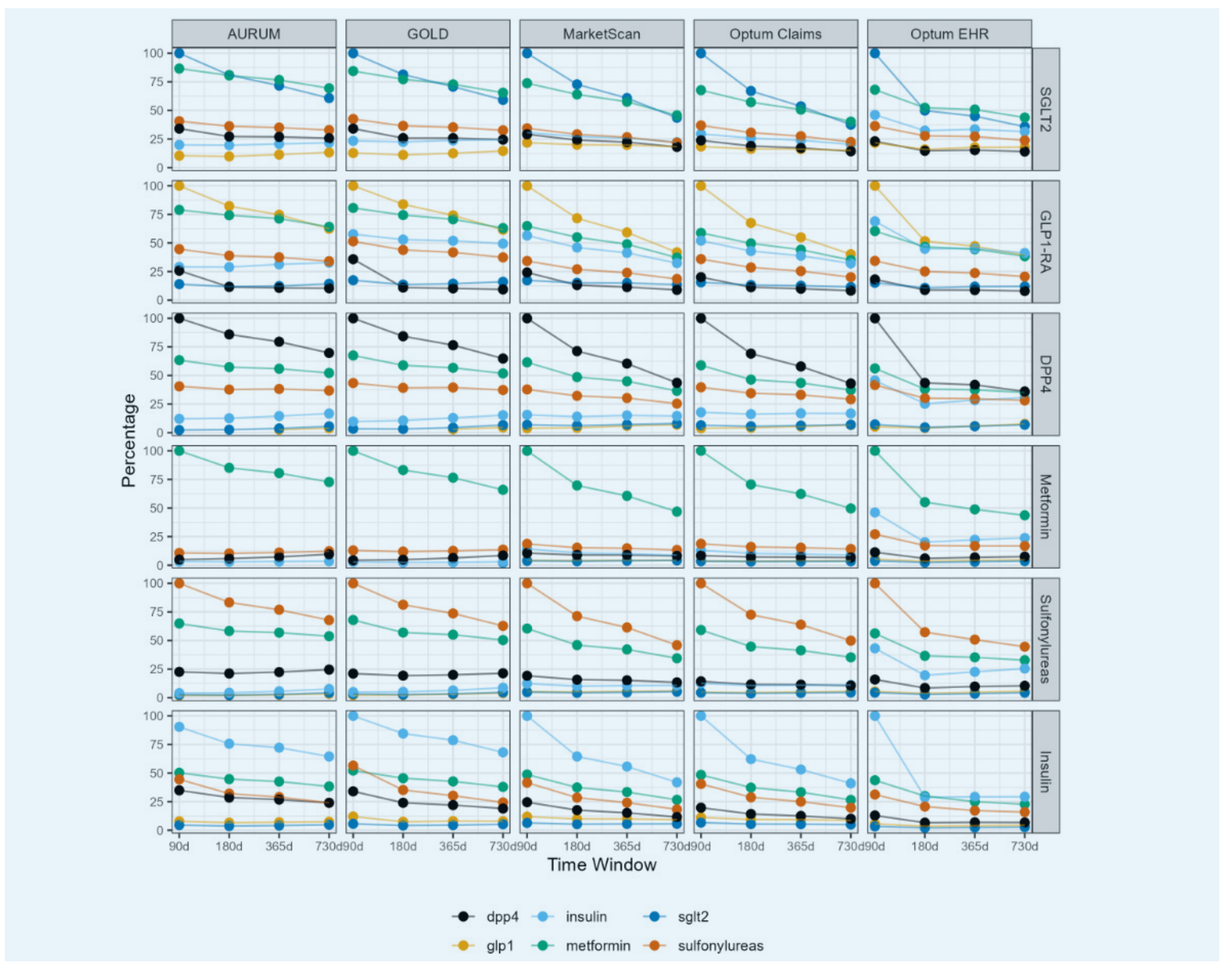


Figure 3. Kaplan meier plots for discontinuation of index drugs in monotherapy (90, 180, 365, 730 days)

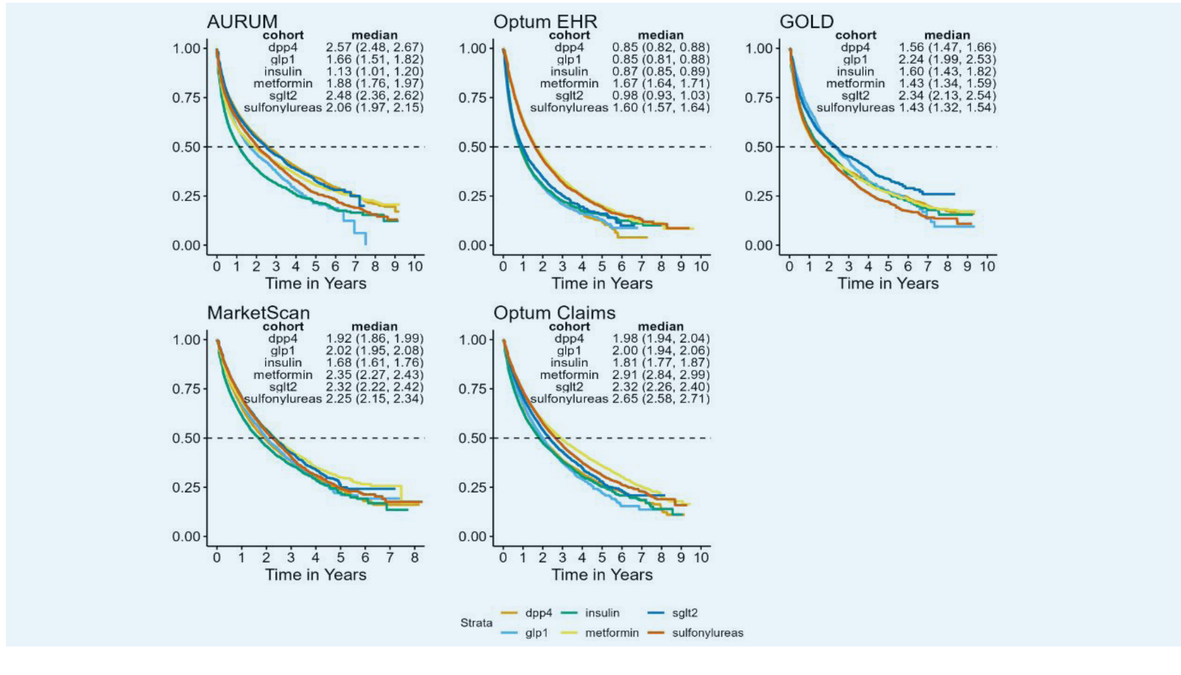
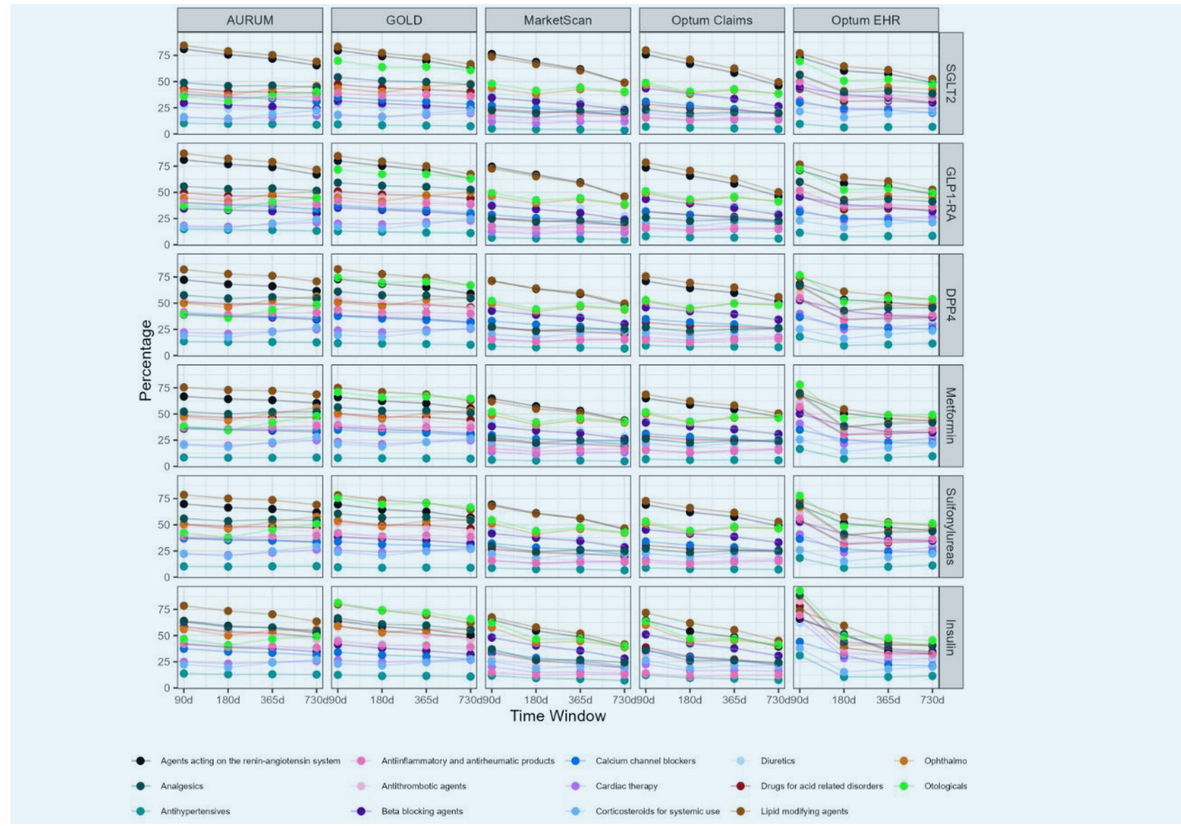


Figure 4. Frequency of post index use of drugs classes use at 90, 180, 365, 730 days



Conclusions

- Our contemporary study shows similar CKD-T2D patient profiles at initiation of anti-hyperglycemic medications within routine care with the exception of metformin,
- We observed between country variation in treatment patterns which may reflect differences in the care setting from which each data derive.
- Changes along treatment journey with anti-hyperglycemics is common in patients with CKD and T2D
- Persistence is highest for metformin and SGLT2i in the UK and US, respectively.

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