TEMPORAL CHANGES IN CHARACTERISTICS OF MEDICATION-INITIATOR COHORTS OF PATIENTS WITH CKD AND TYPE 2 DIABETES IN JAPAN

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Background and aim

- The clinical landscape for the treatment of people with CKD and type 2 diabetes (T2D) is rapidly evolving with the introduction of new treatments, e.g., sodium-glucose cotransporter-2 inhibitors (SGLT-2i), glucagon-like peptide-1 receptor agonists (GLP-1RA), and finerenone.
- Currently, limited evidence is available that shows the temporal changes in the profiles of medication-initiator cohorts in people with CKD and T2D.
- The FINEGUST study (EUPAS48148; NCT05526157) is a multinational observational cohort study and part of the FOUNTAIN multi-database research platform.[1]
- The aim of this study was to describe temporal changes in the baseline characteristics of medication-specific cohorts of SGLT-2i and GLP-1RA in Japan.

Methods

- Country-specific analysis in Japan
- Data source: the Japan Chronic Kidney Disease Database Extension (J-CKD-DB-Ex).
- Medication-specific cohorts of adults (aged ≥18 years) with CKD and T2D, including new users of sodium-glucose cotransporter-2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1RA) were identified.
- Patients with type 1 diabetes, kidney cancer, or kidney failure were excluded.
- The medication-initiator cohorts were identified in two separate time periods (Period I: January 1st, 2014 – June 30th, 2021; Period II: July 1st, 2021–December 31st, 2022), to assess temporal changes in the characteristics of the medication-initiator cohorts before and after July 2021.
- For each cohort and study period, baseline characteristics of new users were described and the standard mean differences (SMD) between periods I and II were calculated.
- Based on the previous literature,[2] SMDs of 0.2, 0.5, and 0.8 were defined as small, medium, and large differences in the level of covariates between the two time periods.

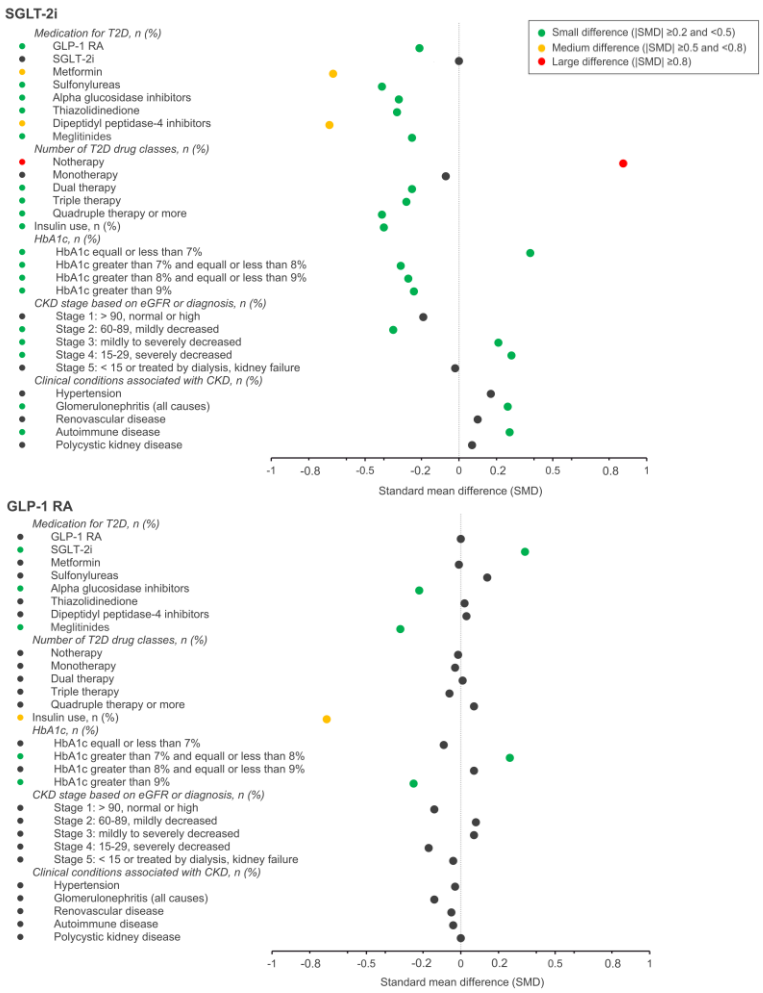
Results

- During the study periods I and II, 1,157 and 1,122 SGLT-2i, and 329 and 369 GLP-1RA new users were identified, respectively (Table).
- For SGLT-2i new users, moderate decreases in the number of persons with prior metformin and dipeptidyl peptidase-4 inhibitor use, and a large increase in the number of persons with no T2D medications other than insulin between periods I and II were observed (Fig.).
- In the GLP-1RA cohorts, there was a moderate decrease in persons with insulin use (Fig).

Table 1. Key baseline characteristics of persons included in the study.

	SGLT2i		GLP-1RA	
	Period I N = 1157	Period II N = 1122	Period I N = 329	Period II N = 369
Age years, mean (SD)	67.1 (11.7)	69.5 (12.9)	66.1 (13.6)	68.2 (11.9)
Male, n (%)	726 (62.7)	812 (72.4)	196 (59.6)	240 (65.0)
Comorbidities, n (%)				
Hypertension	957 (82.7)	993 (88.5)	293 (89.1)	325 (88.1)
Congestive heart failure	717 (62.0)	781 (69.6)	194 (59.0)	212 (57.5)
Coronary heart disease	677 (58.5)	679 (60.5)	197 (59.9)	216 (58.5)
Cerebrovascular disease	484 (41.8)	444 (39.6)	171 (52.0)	131 (37.1)

Fig. SMD of variables related to the treatment of CKD and T2D.



Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, hemoglobin A1C; SGLT-2i, sodium-glucose cotransporter-2 inhibitor; SMD, standard mean difference; T2D, type 2 diabetes. The gray circle indicates no differences between the study period I and the study period II.

Conclusion

With the introduction of new treatments and emerging evidence supporting cardiorenal protective effect in people with CKD and T2D, several changes in the characteristics of the user of these medications were observed.

The results suggest that these medications were prescribed earlier in the course of T2D treatment.

Reference

1. Oberprieler NG, Pladevall-Vila M, Johannes C, Layton JB, Golozar A, Lavalee M, et al. FOUNTAIN: a modular research platform for integrated real-world evidence generation. *BMC Med Res Methodol*. 2024; **24**: 224.
2. Austin PC. Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. *Stat Med*. 2009; **28**(25): 3083-3107.

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