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Preferential prescribing and utilization trends of diabetes medications among patients with renal impairment: Emerging role of linagliptin and other dipeptidyl peptidase 4 inhibitors

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Summary

Objectives: Although many newer diabetes medications have become available in the last decade, most have not been widely studied in populations with chronic kidney disease under routine care. Linagliptin, a recently marketed dipeptidyl peptidase 4 (DPP-4) inhibitor, is the only agent in the U.S. that does not require dose adjustment in patients with diabetes mellitus type 2 (T2DM) and renal impairment. We sought to describe baseline kidney function and other key characteristics among patients with diabetes mellitus type 2 (T2DM) initiating linagliptin and other diabetes medications, and to explore prescribing patterns among T2DM patients with moderate to severe renal impairment before and after the launch of linagliptin.

Design: Using a population-based cohort study design nested in a large U.S. commercial healthcare dataset linked to laboratory values, we described characteristics of T2DM patients initiating linagliptin and other diabetes medications between May 2011 (launch of linagliptin) and September 2015. We also explored prescribing trends among T2DM patients with moderate to severe renal impairment (ICD-9 diagnosis code 585.3x-6x) who initiated linagliptin and other diabetes medications between January 2006 to September 2015 (before and after the launch of linagliptin).

Patients: We identified 1,174,476 T2DM patients initiating a diabetes medication (28,900 linagliptin initiators) between 05/2011-09/2015. We also identified 100,847 T2DM patients with moderate to severe renal impairment initiating a diabetes agent between 01/2006-09/2015.

Results and Conclusion: Among patients initiating newer diabetes medications between 05/2011-09/2015, those initiating linagliptin had the highest prevalence of moderate to severe renal impairment, suggesting preferential prescribing in routine care. DPP-4 inhibitors overall were among the most frequently chosen agents among T2DM patients with moderate to severe renal impairment between 01/2006-09/2015. Further investigation of the safety and effectiveness of DPP-4 inhibitors in

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routine care of T2DM patients with renal impairment is needed to either corroborate or discourage current prescribing patterns.

KEYWORDS

channelling, linagliptin, other antidiabetic medications, renal impairment, type 2 diabetes

1 | INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a leading cause of chronic kidney disease (CKD) in the United States, with approximately 40% of diabetes patients having CKD.¹ Reduced renal function can complicate diabetes management resulting in an increased risk of adverse events, for example severe hypoglycaemia, or decreased efficacy. Although many newer diabetes medications have become available in the last decade, most have not been widely studied in CKD populations under routine care, leaving clinicians caring for these patients with little evidence regarding best practices, particularly in patients with more severe renal impairment. Among the recently marketed medications, linagliptin, a dipeptidyl peptidase 4 (DPP-4) inhibitor, is the only agent in the United States that does not require dose adjustment in T2DM patients with renal impairment, suggesting it may be preferentially prescribed among these patients.

We sought to describe baseline kidney function and other key characteristics among T2DM patients initiating linagliptin and other diabetes medications and to explore prescribing patterns among T2DM patients with moderate to severe renal impairment before and after the launch of linagliptin.

2 | METHODS

Within a large U.S. commercial insurance data set (Clinformatics[™] DataMart; OptumInsight, Eden, Prairie, MN, USA), we identified T2DM patients (ICD-9 diagnosis250.x0 or250.x2) initiating linagliptin or other diabetes agents between 05/2011 (linagliptin launch) and 09/2015 (Table 1), with no use of that agent in the previous 6 months. Patient characteristics were measured during the 6 months prior to treatment initiation, and for approximately 30% of the population, included baseline estimated glomerular filtration rate (eGFR)² and haemoglobin A1c (HbA1c). In a separate cohort of T2DM patients with moderate to severe renal impairment (ICD-9 diagnosis code of CKD stage 3 or higher [585.3x-6x]), patterns of diabetes therapy initiation before and after the launch of linagliptin (01/2006-09/2015) were plotted by year for DPP-4 inhibitors (by class and individual agents), metformin, 2nd generation sulphonylureas, GLP-1 receptor agonists, glitazones, SGLT-2 inhibitors, meglitinides and insulin.

3 | RESULTS

Of 1 174 476 T2DM patients initiating a diabetes medication between 05/2011 and 09/2015, 28 900 (2.5%) were linagliptin initiators. The proportion of baseline kidney disease (overall kidney dysfunction, any stage of CKD,³ respectively) was higher among patients initiating linagliptin (22.4%, 12.9%), meglitinides (28.7%, 16.7%) or insulin (27.0%, 13.5%), resulting in a higher burden of comorbidities⁴ compared to patients initiating other diabetes medications. In particular, patients initiating linagliptin, meglitinides or insulin had higher proportions of baseline CKD stage 3 or higher or eGFR <60 mL/min per 1.73 m² (Table 1).

When assessing the prescribing patterns among T2DM patients with moderate to severe renal impairment between 01/2006 and 09/2015 (N = 100 847), initiation of DPP-4 inhibitors, metformin and SGLT-2 inhibitors increased over time, whereas initiation of sulphonylureas, glitazones, meglitinides and insulin decreased (Figure 1). After its launch, linagliptin use among T2DM patients with moderate to severe renal impairment increased over time, whereas the use of other DPP-4 inhibitors either decreased (sitagliptin and saxagliptin) or remained stable (alogliptin) (Figure 1). Secondary analyses restricted to patients with baseline eGFR <60 mL/min per 1.73 m² confirmed observed utilization trends.

4 | DISCUSSION

Among patients initiating newer diabetes medications, those initiating linagliptin had the highest prevalence of moderate to severe renal impairment, suggesting preferential prescribing in routine care. These patterns should be accounted for in the design of noninterventional studies related to linagliptin. Despite the increase in linagliptin use, insulin, sulphonylureas, metformin and other DPP-4 inhibitors, that is sitagliptin, remain the most frequently chosen agents among T2DM patients with moderate to severe renal impairment. While the choice of traditional antidiabetic agents that is insulin, short-acting sulphonylureas and meglitinides is acknowledged,⁵ and the increasing role of metformin has been previously observed,^{6,7} the prominent role of DPP-4 inhibitors among T2DM patients with kidney disease in recent years has been largely undocumented. Such extensive use in clinical practice is unforeseen, as the data on the effects of DPP-4 inhibitors in patients with diabetes

Linagliptin	Other DPP4i	Metformin	2nd gen SU	GLP-1 RA	Glitazones	SGLT2i	Glinides	Insulin
28 900	153 596	465 695	227 036	55 083	46 335	39 048	8695	150 088
60.2 (12.4)	61.8 (12.7)	59.8 (13.2)	62.2 (13.1)	56.2 (11.3)	62.6 (12.7)	56.4 (10.7)	66.9 (12.6)	62.5 (13.5)
12 562 (43.5)	69 861 (45.5)	220 873 (47.4)	100 900 (44.4)	29 099 (52.8)	19 487 (42.1)	16 722 (42.8)	4346 (50.0)	70 516 (47.0)
2.0 (1.6)	1.9 (1.5)	1.6 (1.3)	1.9 (1.6)	1.7 (1.2)	1.8 (1.5)	1.6 (1.1)	2.4 (1.9)	2.5 (2.1)
6478 (22.4)	25 626 (16.7)	43 873 (9.4)	38 369 (16.9)	7376 (13.4)	8604 (18.6)	4010 (10.3)	2497(28.7)	40 582 (27.0)
3734 (12.9)	13 234 (8.6)	18 292 (3.93)	19 344 (8.5)	3384 (6.1)	4685 (10.1)	1584 (4.06)	1454 (16.7)	20 260 (13.5)
174 (0.6)	817 (0.5)	1735 (0.4)	1115 (0.5)	284 (0.5)	295 (0.6)	226 (0.6)	42 (0.5)	830 (0.6)
395 (1.4)	2124 (1.4)	4658 (1.0)	2880 (1.3)	592 (1.1)	798 (1.7)	430 (1.1)	146 (1.7)	2325 (1.6)
2351 (8.1)	8391 (5.5)	10 935 (2.4)	12 092 (5.3)	2094 (3.8)	2998 (6.5)	872 (2.2)	866 (10.0)	11 420 (7.6)
584 (2.0)	1372 (0.9)	619 (0.1)	2159 (1.0)	324 (0.6)	456 (1.0)	43 (0.1)	270 (3.1)	3096 (2.1)
57 (0.2)	140 (0.1)	64 (0.0)	199 (0.1)	25 (0.1)	26 (0.1)	2 (0.0)	20 (0.2)	357 (0.2)
173 (0.6)	390 (0.3)	281 (0.1)	899 (0.4)	65 (0.1)	112 (0.2)	11 (0.0)	110(1.3)	2232 (1.5)
8.3 (4.2)	8.4 (3.3)	7.9 (3.8)	8.6 (4.3)	8.6 (4.3)	8.5 (2.4)	8.8 (3.3)	8.3 (5.1)	9.4 (4.5)
9644 (33.4)	46 324 (30.2)	123 539 (26.5)	59 299 (26.1)	16 530 (30.0)	14 188 (30.6)	14 768 (37.8)	2697 (31.0)	35 339 (23.6)
88.8 (27.4)	92.7 (23.5)	97.0 (19.0)	91.43 (24.4)	96.87 (21.5)	90.6 (24.4)	100.7 (18.3)	82.1 (26.7)	86.70 (27.8)
10 647 (36.8)	49 984 (32.5)	136 719 (29.4)	65 087 (28.7)	18 170 (33.0)	15 051 (32.5)	15 919 (40.8)	3028 (34.8)	41 146 (27.4)
6242 (58.6)	30 396 (60.8)	91 471 (66.9)	38 078 (58.5)	13 008 (71.6)	8441 (56.1)	12 220 (76.8)	1289 (42.6)	21 823 (53.0)
2535 (23.8)	14 450 (28.9)	40 017 (29.3)	19 370 (29.8)	3865 (21.3)	4737 (31.5)	3238 (20.3)	1086 (35.9)	11 952 (29.1)
1870 (17.6)	5138 (10.3)	5231 (3.8)	7639 (11.7)	1297 (7.1)	1873 (12.4)	461 (2.9)	653 (21.6)	7371 (17.9)
883 (8.3)	2806 (5.6)	3755 (2.8)	3940 (6.1)	731 (4.0)	1003 (6.7)	332 (2.1)	310(10.2)	3135 (7.6)
644 (6.1)	1637 (3.3)	1161 (0.9)	2464 (3.8)	411 (2.3)	617 (4.1)	101 (0.6)	204 (6.7)	2381 (5.8)
288 (2.7)	573 (1.2)	245 (0.2)	1020 (1.6)	135 (0.7)	223 (1.5)	24 (0.2)	107 (3.5)	1389 (3.4)
55 (0.5)	122 (0.2)	70 (0.1)	215 (0.3)	20 (0.1)	30 (0.2)	4 (0.0)	32 (1.1)	466 (1.1)
ogliptin, saxagliptir es, thiazolidinedior hronic kidney disee of the Charlson co	n and sitagliptin); 2r nes (i.e rosiglitazone ase, assessed throu, morbidity score. ⁴	ıd gen SU, 2nd gen e, pioglitazone); glir gh ICD-9 diagnosis	eration sulphonylu nides, meglitinides codes; HbA1c, ha	eas (i.e glipizide, { (i.e nateglinide, re emoglobin A1c; e(glimepiride, glybur paglinide); SGLT2 GFR, estimated gl	ide); GLP-1 RA, G ii, SGLT-2 inhibito omerular filtration	LP-1 receptor ago rs (i.e canagliflozii rate.	nists (i.e albiglutide. 1, dapagliflozin, em-
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FIGURE 1 Utilization trends before and after the launch of linagliptin among patients with moderate to severe renal impairment (CKD Stage 3 or higher) initiating a glucose-lowering drug. Other DPP-4i, other DPP-4 inhibitors (ie, alogliptin, saxagliptin and sitagliptin); 2nd gen SU, 2nd generation sulphonylureas (ie, glipizide, glimepiride, glyburide); GLP-1 RA, GLP-1 receptor agonists (ie, albiglutide, dulaglutide, exenatide, liraglutide); glitazones, thiazolidinediones (ie, rosiglitazone, pioglitazone); glinides, meglitinides (ie, nateglinide, repaglinide); SGLT2i, SGLT2 inhibitors (ie, canagliflozin, dapagliflozin, empagliflozin); SD, standard deviation; CKD, chronic kidney disease, assessed through ICD-9 diagnosis codes; HbA1c, haemoglobin A1c; eGFR, estimated glomerular filtration rate. ¹As measured by the Romano modification of the Charlson comorbidity score⁴

Calendar time in years

and kidney dysfunction in routine care are limited, and current guidelines do not specifically recommend the preferential use of these agents over alternative treatments in this population.^{5,8} In the light of this, further investigation of the safety and effectiveness of DPP-4 inhibitors in the routine care of T2DM patients with renal impairment is sorely needed to either corroborate or discourage current prescribing patterns.

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CONFLICTS OF INTEREST

EP, CG, JL and SS report receiving a research grant from Boehringer Ingelheim to support this work. DB and KB are employees of Boehringer Ingelheim.

AUTHOR CONTRIBUTIONS

EP, SS, CG were involved in the concept and design of the study; all authors were involved in acquisition, analysis or interpretation of data;

EP, SS, CG drafted the manuscript; all authors critically revised the manuscript for important intellectual content; JL, EP, CG were involved in statistical analysis; EP, SS supervised the study.

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