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Original Article

A Real-world Comparative Analysis of DPP-4 Inhibitors Versus SGLT2 Inhibitors in Type 2 Diabetes Mellitus

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ABSTRACT

Background: Diabetes has steadily increased in India over the last three decades, with 77 million people having diabetes as of 2019, which is expected to rise to 134 million by 2045. Over 90 % of these cases are of type 2 diabetes. The newer antidiabetics like dipeptidyl peptidase IV (DPP-IV) inhibitors and sodium-glucose transporter-2 (SGLT-2) inhibitors are prescribed nowadays in type 2 diabetic patients. However, the relative efficacy and safety of these two new drug groups are unknown.

Objectives: We conducted this study to evaluate the efficacy and safety of DPP-IV inhibitors and SGLT-2 inhibitors as add-on therapies in type 2 diabetic patients attending a tertiary care teaching hospital.

Methods: This was a prospective, observational, comparative study conducted at GCS hospital, Ahmedabad, India, from November 2020 to October 2022.

Results: In this study, 125 patients of either gender were enrolled and analysed. Of the 125 patients, 82 have been prescribed DPP-IV inhibitors (65.6%), and 43 were prescribed SGLT-2 inhibitors (34.4 %). SGLT-2 inhibitors had a more substantial decrease in HbA1c than DPP-IV inhibitors at weeks 12 (-1.13±1.33 vs -0.39±1.40, $P<0.05$) and 24 (-1.87±1.74 vs -1.07±1.58, $P<0.05$). The total number of adverse events was lower in the DPP-IV inhibitor group than in the SGLT 2 inhibitor group (18.3% vs 46.5%). Urinary tract infection was the most common adverse event in the SGLT-2 inhibitor group. While in the DPP-IV inhibitor group, gastrointestinal adverse events were common.

Conclusion: Though SGLT-2 inhibitors have shown better efficacy outcomes, their possible adverse drug reactions should be kept in mind by physicians.

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Introduction

Diabetes mellitus (DM) is a chronic disease that significantly burdens the healthcare system. Its prevalence is increasing worldwide, especially in developing countries like India. Globally, 537 million people are living with diabetes as of 2021, as per the International Federation of Diabetes, and its number is expected to rise to 784 million by 2045 [1]. In India, there are 77 million people with diabetes as of 2019, and this is expected to rise to 134 million by 2045. Over 90 % of these cases are of type 2 diabetes [2].

DM is a chronic metabolic disorder characterized by a high blood glucose concentration, hyperglycaemia, caused by insulin deficiency, often combined with insulin resistance. Impaired insulin secretion, insulin resistance, excessive hepatic glucose production, and abnormal fat metabolism are the solid pathophysiological bases for developing type 2 DM [3].

Oral antidiabetic drugs are preferred to maintain blood glucose levels within the normal range in patients with type 2 DM. Most international guidelines recommend the use of metformin together with lifestyle changes as the first line of management in newly diagnosed type 2 diabetes patients. If the HbA1c target is not achieved after giving monotherapy, then sequential add-on treatment should be started. Discrepancies between the guidelines mainly relate to the recommendations for second-line agents. Among second-line agents, sulfonylureas (SUs) are the oldest non-insulin glucose-lowering drugs [4]. Over the last decade, several new antidiabetic drugs have been introduced, enabling physicians to tailor therapy for each patient [5].

The newer antidiabetic drugs like dipeptidyl peptidase-IV (DPP-IV) inhibitors and sodium-glucose transporter-2 (SGLT-2) inhibitors are prescribed nowadays as add-on therapy in type-2 diabetic patients. Oral glucose releases incretins like GLP-1 (glucagon-like peptide-1), which amplify glucose-induced insulin release. DPP-IV is an endogenous enzyme that cleaves and inactivates GLP-1. The DPP-IV inhibitors thus prolong the half-life of endogenous GLP-1 by inhibiting DPP-IV. These drugs increase circulating GLP-1 and insulin concentrations and decrease glucagon concentration. DPP-IV inhibitors monotherapy has been demonstrated to improve glycaemic control and β-cell function with a low risk of hypoglycaemia or gastrointestinal side effects and no weight gain [6]. SGLT-2 inhibitors block SGLT-2 transporters in the kidney and inhibit glucose reabsorption from the renal tubules. Current studies have shown significant improvement in glycemic control, cardiovascular outcomes, and metabolic parameters in patients with type 2 diabetes [7].

DPP-IV inhibitors and SGLT-2 inhibitors, which have novel mechanisms of action, are less likely to cause weight gain and hypoglycaemia; therefore, the use of these drugs is increasing [8]. It is essential to confirm which drug is more appropriate as an add-on therapy to metformin in diabetic patients. So, this study was carried out with a primary objective to compare the effect of DPP-IV inhibitors and SGLT-2 inhibitors on HbA1c levels in type 2 diabetic patients in the western part of India.

Materials and Methods

A prospective, observational, comparative study was conducted to evaluate the efficacy and safety of DPP-IV inhibitors and SGLT-2 inhibitors as an add-on therapy to metformin in patients with type 2 DM at GCS Hospital, Ahmedabad, India, from November 2020 to October 2022. Patients of type-2 DM≥18 years of age and of either gender attending the department of General Medicine, whose glycemic control is not achieved satisfactorily by metformin and who require DPP-IV inhibitors / SGLT-2 inhibitors as an add-on therapy, willing to participate and giving written informed consent were consecutively enrolled. Patients taking insulin therapy or being prescribed both DPP-IV inhibitors as well as SGLT-2 inhibitors simultaneously as an add-on therapy were excluded. As, it was a prospective observational study, all patients who fulfilled the study criteria and came to the department of General Medicine between November 2020 to October 2022 were consecutively enrolled without a predefined sample size. Patients were prescribed either DPP-IV inhibitor or SGLT-2 inhibitor based on physician's decision. After recruitment, each patient was followed up at 4-week intervals up to 24 weeks. Details of the prescribed treatment and investigations were recorded at each visit. Before starting the study, ethical approval was obtained from the institutional ethics committee. A descriptive statistical analysis was carried out using Microsoft Excel 2021. The primary endpoint was to determine the changes in HbA1c levels at 12 and 24 weeks. HbA1c changes were analyzed using a paired t test at 12 and 24 weeks in both study groups. An unpaired t test was applied to check the difference in changes of HbA1c from baseline to weeks 12 and 24 between the two study groups.

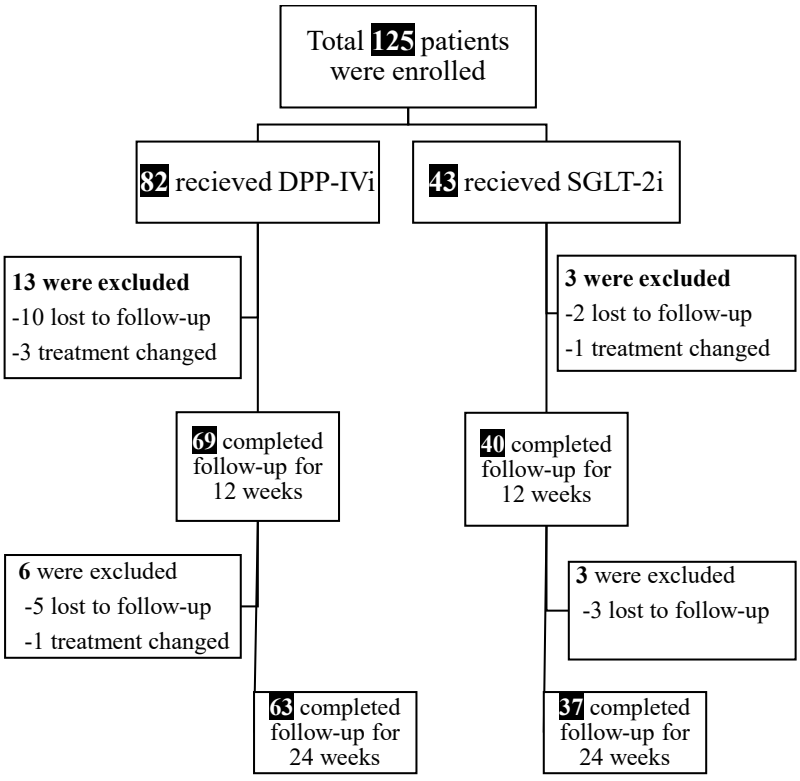

Figure 1. Flowchart of participants' enrolment and follow-up

Note: DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

Results and Discussion

In this study, 125 patients of either gender were enrolled and analyzed according to their age, gender, disease diagnosis, and the treatment prescribed. As shown in Figure 1, a total of 109 patients completed the follow-up for 12 weeks, and 100 completed the follow-up for 24 weeks. Of 125 patients, 82 have been prescribed DPP-IV inhibitors (65.6%), and 43 were prescribed SGLT-2 inhibitors (34.4%). There was no any statistically significant difference in baseline characteristics between both groups (P<0.05). In the DPP-IVi group, 49 patients were treated with vildagliptin, and 33 were treated with teneligliptin. On the other hand, in the SGLT-2i group, 24 patients were prescribed dapagliflozin, and 19 were prescribed remogliflozin. In the SGLT-2i group, mostly a single drug formulation was prescribed (88.4%). While in the DPP-4i group, fixed-dose combinations (FDCs) were prescribed more than a single formulation (74.4%). In FDCs, both groups of drugs were combined with metformin (Figure 2). Metformin 500 mg twice a day was given to both groups.

Baseline characteristics like mean age, gender, weight, blood pressure, HbA1c, fasting blood sugar (FBS), postprandial blood sugar (PPBS) and concomitant diseases are documented for both the DPP-IV inhibitor (DPP-IVi) group and the SGLT-2 inhibitor (SGLT-2i) group. The mean age of the patients in our study was 58.59±10.21 years. This number is similar to other studies where a figure of around 60 years of age has been the most common for patients with type 2 DM [9–11]. Hypertension was seen as the most common comorbidity in 70% of patients. This number is also reported by a study where most patients had hypertension [12]. In contrast, Ling et al. have reported dyslipidemia as the most common comorbidity in 72% of patients [13]. Hypertension is twice as frequent in patients with diabetes compared with those who do not have diabetes. Diabetes and hypertension are closely interlinked because of similar risk factors, such as endothelial dysfunction, vascular inflammation, arterial remodelling, atherosclerosis, dyslipidemia, and obesity [14] (Table 1).

In our study, at 12 weeks, only SGLT-2i showed a statistically significant decrease in HbA1c level compared to the baseline value (mean difference [MD]=-1.13±1.33%, P=0.019). While at 24 weeks, both DPP-IVi and SGLT-2i showed a statistically significant decrease in HbA1c level compared to the baseline value (MD=-1.07±1.58, P<0.0001; -1.87±1.74, P<0.0001, respectively). As per the results, SGLT-2i had a more sub-

Table 1. Patients' demographics and baseline characteristics

Parameter		Mean±SD/No. (%)			P (Unpaired t-test)
		Study Population (n=125)	DPP-IVi Group (n=82)	SGLT-2i Group (n=43)	
Age (y)		58.59±10.21	58.48±10.19	58.52±10.28	0.221
Gender	Male	48(38)	32(39.02)	16(37.21)	0.084#
	Female	77(62)	50(60.98)	27(62.79)	
Weight (kg)		65.92±11.03	64.59±10.63	68.47±11.45	0.069
Blood pressure (mm Hg)	SBP	133.47±16.02	132.37±14.5	135.58±18.58	0.327
	DBP	81.54±8.48	80.72±7.87	83.12±9.45	0.159
Duration of DM (y)		4±1.33	4.01±1.34	4±1.32	0.990
HbA1c (%)		9.47±2.13	9.23±1.94	9.95±2.42	0.095
Blood sugar (mg/dL)	FBS	181±59.81	173.31±58.08	206.46±75.7	0.061
	PPBS	261±84.89	254.25±90.01	293.5±106.54	0.072
Concomitant disease (n)	Hypertension	88	56	32	0.671#
	Cardiovascular disease	42	26	16	
	Hypothyroidism	15	08	07	
	Dyslipidemia	15	07	08	
	Others	10	5	5	

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Abbreviations: SBP: Systolic blood pressure; DBP: Diastolic blood pressure; DM: Diabetes mellitus; FBS: Fasting blood sugar; PPBS: Postprandial blood sugar.

#Chi-square test.

stantial decrease in HbA1c than DPP-IVi at weeks 12 and 24 (Table 2, Figure 3). In a similar type of study, there was a statistically significant reduction in HbA1c at ≥52 weeks, favouring SGLT-2i compared to DPP-IVi (MD [95% CI]=-0.11% [-0.2%, -0.03%]) but no significant difference at ≤26 weeks (MD [95% CI]= -0.05% [-0.16%, 0.05%]) [15]. In another similar type of study done by Scheen AJ et al., the HbA1c difference was slightly greater with SGLT-2i (−0.8±0.2% from 8.03±0.35%) than with DPP-IVi (−0.71±0.23% from 8.05±0.43%; P=0.0354) [16]. In contrast, a study conducted by Cha et al. shows no significant difference in the mean HbA1c between DPP-IVi and SGLT-2i at 24 weeks (8.3±1.1 vs 8±0.9%, P=0.110) [17]. However, recent head-to-head studies have suggested that SGLT2 inhibitors may result in a greater glucose-lowering effect than DPP-IV inhibitors in people having an HbA1c of around 9%. In contrast, for people with type 2 diabetes who have an HbA1c of around 7%, a DPP-IV inhibitor may achieve a greater glucose-lowering effect [18, 19]. Most of the studies have shown a greater reduction in HbA1c levels in SGLT-2 inhibitor-treated patients. So, we can say that SGLT-2 inhibitors have a better effect on HbA1c reduction compared to DPP-IV inhibitors.

Table 2. Comparing HbA1c changes from baseline (Mean±SD difference) to weeks 12 and 24 between the two groups

Changes in HbA1c%	DPP-IV Inhibitors	SGLT-2 Inhibitors	Unpaired t-test Statistic (P)
Between baseline and 12 weeks	-0.39±1.4	-1.13±1.33	2.70 (0.008)
Between baseline and 24 weeks	-1.07±1.58	-1.87±1.74	2.34 (0.021)

DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

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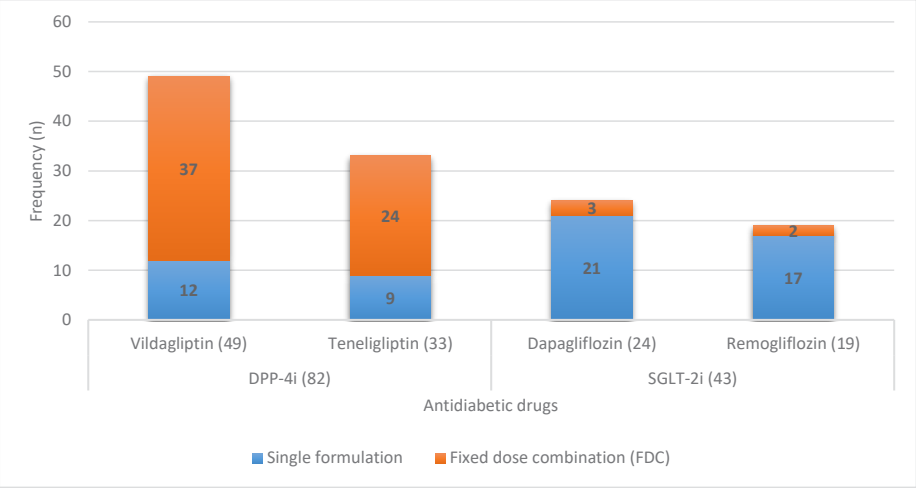

Figure 2. Prescribed DPP-IV inhibitors and SGLT-2 inhibitors (n=125)
DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

In our study, both DPP-IVi and SGLT-2i groups showed a significant decrease in FBS levels at 24 weeks (MD=-22.73±40.97, P=0.002; -46.67±57.16, P=0.003, respectively) (Figure 4). As mentioned in Table 3, SGLT-2i had a more substantial decrease in FBS than DPP-IVi at 24 weeks (P=0.017). Similar results were found in a study conducted by Wang et al. where SGLT-2 inhibitors achieved greater reductions in fasting plasma glucose compared with DPP-IV inhibitors (Standardised MD -0.48; 95% CI, -0.56%, -0.41%; P<0.0001) [20]. In another similar study by Inoue et al. median reductions in FPG were -10.9% to -14.4% for SGLT2i and -9.6$ to -12.6% for DPP-IVi [8]. So, it can be concluded that SGLT-2i has a better reduction in FBS compared to DPP-IVi.

In our study, the mean change in PPBS from baseline to 24 weeks was statistically significant in both groups (Figure 5). As mentioned in Table 4, SGLT-2i had a better effect on PPBS compared to DPP-IVi. In a similar type of study done by Strojek et al. 2 h post-prandial glucose in response to an oral glucose tolerance test was reduced by 32 and 35 mg/dL with dapagliflozin 5 and 10 mg, respectively, whereas FPG was reduced by 21 and 28 mg/dL, respectively [21]. In a study by Choe et al. on the effect of DPP-IV inhibitors on metabolic parameters in patients with type 2 diabetes, there were changes in the PPG levels between baseline and 24 weeks in the sitagliptin group (MD= -45.3±72.4) [22].

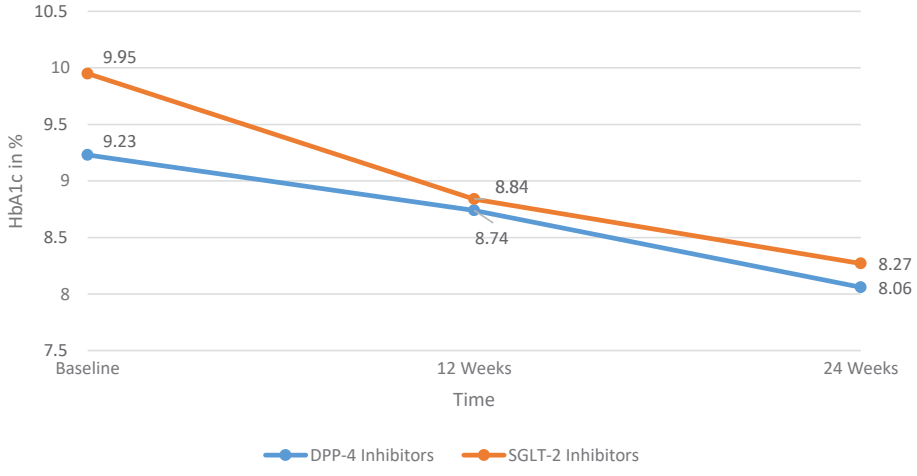

Figure 3. Mean HbA1c level during follow-up
DPP-4: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

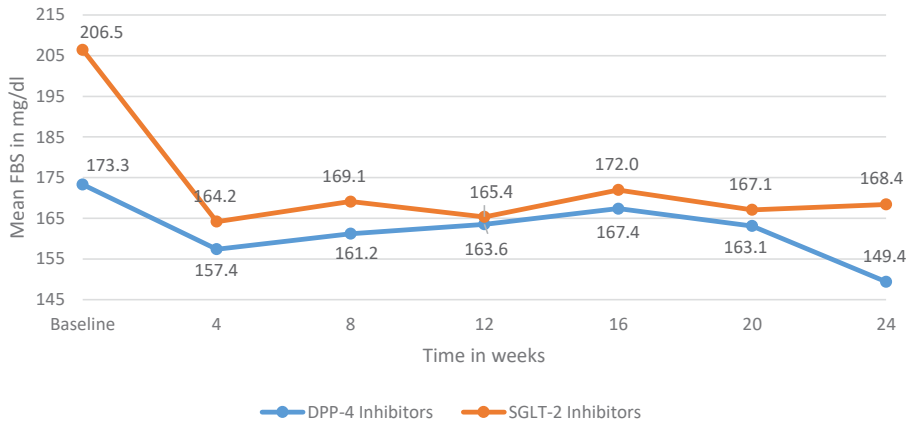

Figure 4. Mean FBS during follow-up
DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

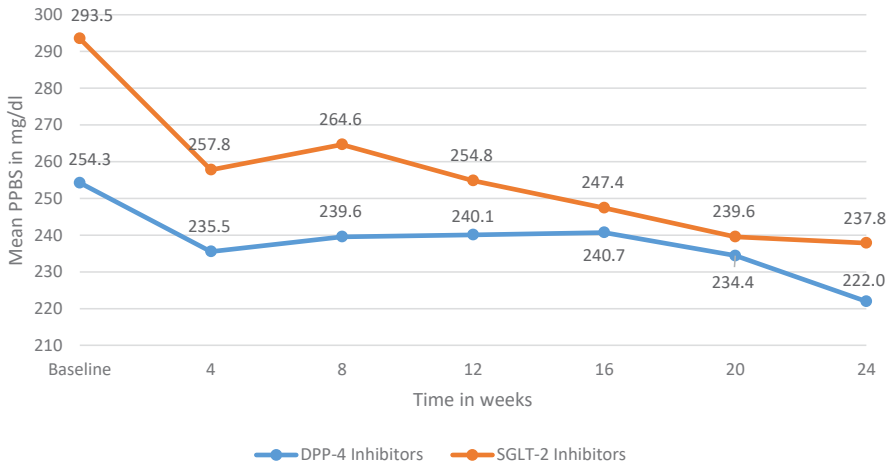

Figure 5. Mean PPBS during follow-up
DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2; postprandial blood sugar.

In this study, we have found that drug-related adverse events were more common in the SGLT-2i group compared to the DPP-IVi group (46.5% vs 18.3%). Urinary tract infection (UTI) was the most common adverse event in the SGLT-2i group. While in the DPP-IVi group, gastrointestinal adverse events were common. Other adverse events, like dizziness and polyuria, were similar in both groups. There were no events of hypoglycaemia in either group, which is common with other antidiabetic drugs (Table 5). Similar studies noted that SGLT-2i-treated patients had significantly more urinary tract infections compared to DPP-IVi group [15, 23, 24]. The side effects of SGLT2 inhibitors are predictable from their mechanism of action. SGLT-2i exerts its glucose-lowering effect by down-regulating the glucose excretion threshold in the kidneys, thereby increasing glucose excretion through the urine. Patients with type 2 diabetes are already at an increased risk of urinary tract infections and genital infections due to an increased amount

Table 3. Comparing FBS changes from baseline to week 24 between the two groups

Group	Changes In Fbs From Baseline To Week 24 In Mg/Dl (Mean±SD Difference)	Unpaired t-test Statistic (P)
DPP-IVi	-22.73±40.97	2.432 (0.017)
SGLT-2i	-46.67±57.16	

Abbreviations: DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2; FBS: Fasting blood sugar.

Table 4. Comparing of PPBS changes from baseline to week 24 between the two groups

Group	Changes of PPBS From Baseline to Week 24 in mg/dL (Mean±SD Difference)	Unpaired t-test Statistic (P)
DPP-IVi	-31.58±40.97	2.203 (0.030)
SGLT-2i	-67.48±85.53	

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Abbreviations: DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2; PPBS: Postprandial blood sugar.

Table 5. Summary of adverse events in both groups

Adverse Events	No. (%)	
	DPP-IVi (n=82)	SGLT-2i (n=43)
Total No. of events	15 (18.3)	20(46.5)
Urinary tract infection	1(1.2)	9(20.9)
Abdominal pain	5(6.1)	3(6.9)
Diarrhea	5(6.1)	2(4.6)
Nausea	3(3.6)	3(6.9)
Dizziness	1(1.2)	2(4.6)
Polyuria	0	1(2.3)

DPP-IV: Dipeptidyl peptidase IV; SGLT-2: Sodium-glucose transporter-2.

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of glucose in the urine. That is why urinary tract and genital infections are common with SGLT-2i [25]. The most common adverse effects in patients receiving vildagliptin included headache, nasopharyngitis, cough, constipation, dizziness, and increased sweating [26]. Gastrointestinal events and dizziness were the most common ADRs following teneligliptin [27]. Reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing variants, have correlations with the use of sitagliptin, vildagliptin, and saxagliptin in postmarketing data [28]. However in our study, no serious adverse events were reported. 4 patients in the DPP-4i group and 1 patient in the SGLT-2i group discontinued due to adverse events.

Conclusion

SGLT-2 inhibitors provide better glycaemic control compared to DPP-IV inhibitors as an add-on therapy to metformin in type-2 diabetes, which was also evident in previous studies. Both SGLT-2 inhibitors and DPP-IV inhibitors can be used to treat patients with type 2 DM unable to achieve normoglycemia, as they are well tolerated, do not induce weight gain, and have a very low chance of hypoglycaemia. Though SGLT-2 inhibitors have shown better efficacy outcomes, their possible adverse drug reactions should be kept in mind by physicians.

Strengths and limitations

In this study, patients were followed up for a significant period of 6 months. We have also analyzed several investigations to check the efficacy outcomes. It can be useful for some to compare these trends of antidiabetic drug use in type 2 diabetic patients. This study might also be useful to revise hospital pharmacies and help physicians in deciding the proper treatment approach.

As far as the limitations are concerned, it was a single-centre study in a tertiary care teaching hospital, which may not reflect the scenario at other healthcare facilities. Due to physicians' concerns, treatment allocation was not randomized. We have not assessed cardiovascular and renal outcomes in these patients during the study.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Institutional Ethics Committee of GCS Medical College Hospital and Research Centre (DcGI Reg. No.: ECR/339/Inst/GJ/2013/RR-16).

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Authors' contributions

Conceptualization: Sumit Patel; Methodology and funding administration: Parth Patel; Data collection: Parth Patel, Xama Patel, and Zankrut Patel; Data analysis: Parth Patel and Zankrut Patel; Investigation: Xama Patel; Writing the original draft: Parth Patel; Review & editing: Zankrut Patel; Supervision: Akanksha Prajapati.

Conflict of interest

The authors declared no conflict of interest.

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