To compare the effect of Sodium-Glucose Cotransporter-2 inhibitors vs Dipeptidyl Peptidase-4 inhibitors on weight loss and glycemic control in patient with type 2 diabetes

Maryum Batool[1], Muhammad Bilawal Abbas Janjua[2], Maria Zafar[3], Ali Sufyan[4], Fiza Shafi[4], Bushra Liaqat[4]

ABSTRACT

Objective: To compare the efficacy of Dapagliflozin (Sodium-Glucose Cotransporter-2 inhibitors) and Sitagliptin (Dipeptidyl Peptidase-4 inhibitors) in terms of lowering body weight and improving glycemic control.
Study Design: Comparative analytical study.
Place and Duration: Department of General Medicine, Pakistan Institute of Medical Sciences, Islamabad over a period of 6 months from 1st October 2021to 1st April 2022.
Methodology: Participants were assigned to receive either Dapagliflozin 10 mg daily (Group A, n=96) or Sitagliptin 100 mg daily (Group B, n=96) alongside ongoing therapy. Baseline data on demographics, diabetes duration, body weight, Glycated Hemoglobin (HbA1c) and Fasting Blood Sugar (FBS) were collected. Patients were followed for six months after which outcome variables were measured.
Results: A total of 192 patients were included, with 68.2% male and 31.8% female. Significant reduction in HbA1c was observed from baseline 8.65 ± 0.39% to 7.49 ± 0.46% (p<0.001) and from 8.83 ± 0.42% to 8.02 ± 0.46% (p<0.001) in both the groups A and B respectively. Both groups also had a significant decline in body weight and fasting glucose (p<0.001). Group A showed a greater reduction in all three parameters i.e. HbA1c, body weight and fasting glucose as compared to Group B (p<0.001).
Conclusion: SGLT-2 inhibitors outperform DPP-4 inhibitors in diabetes mellitus type 2 diabetes patients in terms of glycemic control, weight loss and body weight reduction.
Keywords: SGLT-2 Inhibitors, DPP-4 Inhibitors, Glycemic Control, Type 2 Diabetes Mellitus, Weight reduction, HbA1c.

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INTRODUCTION

Diabetes mellitus is one of the most common non communicable diseases, silently progressive by nature with innumerable complications resulting in mortality and morbidity and a great impact on health expenditure worldwide.[1] According to estimates from 2021, it affects 10.5% (536.6 million) of the population globally and the prevalence is predicted to rise up to 12.2% (783.2 million) in 2045.[2] After China and India, Pakistan has the world's third highest diabetes prevalence rate, having 33 million diabetic patients, as per the International Diabetes Federation projections from 2022.[3]

Diabetes is a multifaceted condition. Several environmental variables, in addition to genetic predisposition, have been linked to the development of diabetes. When compared to the western population, Asian diabetic individuals have various distinguishing characteristics. Genetic susceptibility, metabolic syndrome, beta cell dysfunction, increased visceral fat mass and reduced lean muscle mass are among these characteristics.[4]

Type 2 diabetes is characterized by a steady reduction in pancreatic beta cell activity, which requires a gradual escalation of anti-diabetic drugs, eventually leading to the insulin treatment. Hypoglycemia and weight gain, on the other hand, are among the typical adverse effects which contribute towards the barriers for the physicians in initiating insulin therapy.[5]

Despite an expanding number of pharmacological and non-pharmacological therapies, managing hyperglycemia and its complications in type 2 diabetes is still challenging. The ADA-EASD consensus report recommends metformin as the initial treatment for all type 2 diabetic patients and an add on therapy with other drugs such as SGLT2 inhibitors or GLP-1 receptor

1. Medical Officer, THQ Hospital, Kahuta
2. Post Graduate Resident of Nephrology, Dr. Abdul Qadeer Khan Hospital, Kahuta Research Laboratries, Islamabad
3. Medical Officer, Pakistan Institute of Medical Sciences, Islamabad
4. Post Graduate Resident of General Medicine, Pakistan Institute of Medical Sciences, Islamabad

Correspondence:
Fiza Shafi
Post Graduate Resident of General Medicine,
Pakistan Institute of Medical Sciences, Islamabad
E-mail: fiza.shafi14@gmail.com.

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agonist according to cardiovascular risk stratification.[6] However, along with other guidelines, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) have advised an individualized approach according to available resources, attitudes, hypoglycemia risk, disease duration and comorbidities.[7]

Dipeptidyl peptidase-4 inhibitors (DPP-4is) and sodium-glucose cotransporter type-2 inhibitors (SGLT2is) are two types of oral hypoglycemic used to treat type 2 diabetic mellitus Following the failure of metformin monotherapy in combination with lifestyle, SGLT-2i or a DPP-4i can be added to the treatment depending upon the glycemic control, body weight, tolerability and co morbid conditions.[8]

A meta-analysis of 116 randomized control trials, SGLT-2 inhibitors were observed to contribute to a mean weight loss of 1.79 kg being significantly superior when compared with placebo.[9] Another study compared the effectiveness of dapagliflozin, an SGLT-2 inhibitor with DPP-4 inhibitors, concluding dapagliflozin to be superior in achieving glycemic control and body weight reductions.[10]

There is an unmet need for therapies that avoid hypoglycemia, weight gain, fluid retention, and cardiovascular problems along with lowering blood glucose levels. However, data for Pakistan about the effects of SGLT-2 inhibitors on non-glycemic indicators is insufficient. As a result, this study was conducted to show how SGLT-2 inhibitors and DPP-4 inhibitors affect weight reduction and glycemic management.

METHODOLOGY

This comparative study was conducted at Department of General Medicine, Pakistan Institute of Medical Sciences, Islamabad. The open label study was conducted over a total duration of 6 months. Sample size was calculated by WHO calculator to be 96 in each group, making a total of 192. Patient with T-2DM, on metformin monotherapy with HbA1c greater than 7.5% who need treatment escalation in oral antihyperglycemics were included using non probability consecutive sampling technique. Both genders of age 18-60 years were included after excluding patients with CKD having GFR less than 45 ml/min/1.73m2, a recent history of UTI, a history of genital or fungal infections, pregnancy or lactation and those having acute illness.

Data collection was done after approval from hospital ethical committee on 10th June 2021 with ERB number F.1-1/2015/ERB/SZABMU/784. A total of 210 patients were included and enrolled into each group (105 each) using lottery method, thereby minimizing selection bias. 8 patients were lost to follow up in Group A while 3 patients discontinued therapy due to side effects. 6 patients were lost to follow up in Group B. Leaving with total of 192 patients for analysis. Group A was Dapagliflozin 10 mg once daily while Group B was given Sitagliptin 100 mg once daily in addition to the ongoing therapy. Baselines characteristics of participants like name, age, gender, duration of diabetes, Body weight, HbA1c, FBS was recorded in Proforma. The date of first prescription of SGLT2 inhibitors and DPP4 inhibitors was defined as medication index date. Follow up data was retrieved after six months of medication index date.

Data Analysis: All the data was entered and analyzed by using the SPSS V.25. Mean and standard deviation for numerical variables i.e. weight loss, HbA1c. FBS, was calculated. Frequency and percentage was calculated for categorical variables like gender, treatment assigned and adverse effects reported during follow up visit. 16 patients were loss to follow up and were excluded from analysis. Independent sample t-test was applied to compare mean weight loss, HbA1c and FBS between groups whereas Paired sample t-test was performed to do in group analysis. P value < 0.05 was considered as significant.

RESULTS

A total of 192 patients were included, out of which 68.2% (N=131) were male and 31.8% (N=61) were female. Patient's age ranged from 42 years to 60 years with mean of 52 ± 4.98 years. Baseline mean body weight was 69.94 ± 7.8 Kg and mean HbA1c was 8.74 ± 0.41 %. Paired sample t-test analysis of SGLT-2 inhibitor group comparing baseline and 6 month follow up shows significant reduction in these parameters. Likewise Paired sample t-test analysis of DPP4 inhibitor group comparing baseline and 6 month follow up shows significant fall in these parameters as given in Table-I.

Table I: Comparison of body weight, HbA1c and fasting blood sugars at baseline and at follow up after 6 months among the study population taking SGLT-2 and DPP-4 inhibitor (N=192).

Characteristic		Baseline	Follow up	t test	p-value
		Mean (SD)	Mean (SD)		
SGLT2 inhibitor	Body weight (Kg)	71.6 (8.52)	64.98 (8.47)	45.6	<0.001
	HbA1c (%)	8.65 (0.39)	7.49 (0.46)	44.68	<0.001
	Fasting sugars (mg/dl)	247.15 (28.59)	149.55 (11.84)	32.06	<0.001
DPP4 inhibitor	Body weight (Kg)	68.28 (6.66)	64.95 (6.71)	24.04	<0.001
	HbA1c (%)	8.83 (0.42)	8.02 (0.46)	45.37	<0.001
	Fasting sugars (mg/dl)	251.52 (28.22s)	182.59 (18.85)	20.68	<0.001

Table II: Reduction in body weight, HbA1c and fasting blood sugars from baseline to follow up after 6 months among the study population taking SGLT-2 and DPP-4 inhibitor (N=192).

Characteristic	SGLT2 inhibitor group	DPP4 inhibitor group	t test	p-value
	Mean reduction (SD)			
Body weight reduction (Kg)	6.63 (1.42)	3.33 (1.36)	16.39	<0.001
HbA1c reduction (%)	1.16 (0.25)	0.81 (0.18)	10.82	<0.001
Fasting sugars reduction (mg/dl)	97.59 (29.82)	68.93 (32.66)	6.35	<0.001

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Comparing the outcome parameters between SGLT2 inhibitor and DPP4 inhibitor, the mean reduction in each of HbA1c, Weight and Fasting sugars was more in SGLT2 inhibitor as compared to DPP4 inhibitor. Applying independent sample t-test, this relation was statistically significant as given in Table II. The comparison of mean HbA1c reduction between the two groups has been depicted in Figure 1.

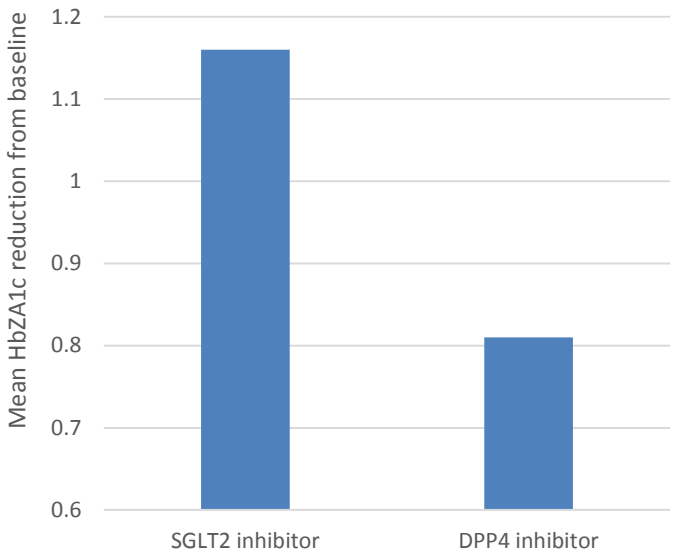

Figure 1: A comparison of mean HbA1c reduction (%) among SGLT2 inhibitor and DPP4 inhibitor (p < 0.001)

DISCUSSION

The present study was conducted at the outpatient department of a public sector tertiary care hospital of Islamabad, Pakistan to compare the efficacy of SGLT-2 and DPP-4 inhibitors in terms of lowering body weight and improving glycemic control. Both SGLT-2 "sodium glucose cotransporter 2" inhibitors and DPP-4 "dipeptidyl peptidase-4" inhibitors can be used to manage type 2 diabetes mellitus in case of poor glycemic control.

Hemoglobin A1c (HbA1c), which represents the average blood glucose levels over the previous three months, is essential to measure in order to evaluate long-term glycemic control. In our study we found out that both SGLT-2 and DPP-4 inhibitors cause decrease in HbA1c with SGLT-2 inhibitors being more effective as compared to DPP-4 inhibitors. HbA1c level in SGLT-2 inhibitors-using patients was 8.65 (0.39) at baseline and was reduced to 7.49 (0.46) at follow-up and our results were consistent with the study by Hopf et al. which showed a significant decrease in HbA1c following the usage of SGLT-2 inhibitors from 8.9 ± 1.8 to 7.9 ± 1.2.[11] In our study, patients using DPP-4 inhibitors also had decreased HbA1c levels from 8.83 (0.42) to 8.02 (0.46). This result was aligned with the study by Subrahmanyan et al. which signifies that average reduction in HbA1c while using DPP-4 inhibitorsrange from-0.5 to -1.0% with monotherapy.[12] Ayako et al. also mentioned a significant reduction in the HbA1c level in patients using SGLT-2 inhibitors (7.7 ±0.92 at baseline to 7.1± 0.74 after 24 weeks) and in patients using DPP4 inhibitors (7.2±0.92 at baseline to 7.2± 0.72 after 24 weeks) which was in line with our study.[13] Similarly a study carried out by Masataka et al. showed a decline in HbA1c levels with the usage of SGLT-2 inhibitors and DPP-4 inhibitors.[14] SGLT-2 inhibitors cause reduction in HbA1c levels by inhibiting glucose reabsorption in the kidneys and thus promoting excess glucose excretion through urine while DPP-4 inhibitors enhance insulin release and reduce glucagon levels in response to meal and improving HbA1c levels. Scheen et al. mentioned that decline in HbA1c was predominantly found more with SGLT-2 inhibitors (Group A) as compared to DPP-4 inhibitors (Group B) i.e. (-0.80±0.20% in group A from baseline 8.03±0.35% versus -0.71±0.23% in group B from baseline 8.05±0.43%) similar to our results. It concluded that SGLT-2 inhibitors reduced HbA1c markedly as compared to DPP-4 inhibitors.[15] This is because SGLT-2 inhibitors directly block SGLT-2 receptors in kidney and directly cause excess glucose excretion through kidney while DPP-4 inhibitors enhance insulin secretion and reduce glucagon levels in response to meals, which primarily helps regulate blood glucose levels after eating. Additionally, SGLT-2 inhibitors have beneficial effects on weight loss and insulin sensitivity causing more reduction in HbA1c15'.[16]

People with type-2 diabetes have been demonstrated to lose weight when using SGLT-2 and DPP-4 inhibitors in our study but weight reduction was more marked with SGLT-2 inhibitors as compared to DPP-4 inhibitors. After using SGLT-2 inhibitors weight loss was observed from 71.6 (8.52) to 64.98 (8.47), similarly Alaeldin et al. also showed reduction in weight of patients using SGLT-2 inhibitors with baseline weight was (85.5 ± 17 kg) compared to that at 6 months it was (84.0 ± 17.2 kg).[17] Another study carried out by Satilmis et al. showed that there was significant reduction in weight (83±13 at baseline to 79±12 after 6 month of treatment using SGLT-2 inhibitors.[18] Horibe et al. also mentioned significant reduction in weight after utilization of SGLT-2 inhibitors.[19] In our study patients using DPP-4 inhibitors also had weight loss i.e. 68.28 (6.66) at baseline to 64.95 (6.71) after follow-up which was in align with a study carried out by Hesham et al. showing patients using DPP-4 inhibitors had a weight loss from 88.8±13.3 kg at baseline to 88.1±13.6 kg after follow up.[20] DPP-4 inhibitors drugs cause weight lose by boosting insulin sensitivity and decreasing hunger, while SGLT-2 inhibitors promote weight loss by increasing glucose excretion.[21] Results depicted by Humayun et al. showed that there was greater reduction in weight in patients using SGLT-2 inhibitors i.e. 61.02±7.43 at baseline to 57.89±7.25 after 12 weeks of follow-up than compared to patients using DPP-4 inhibitors 60.12±7.67 at baseline to 60.35±6.40 after 12 weeks of follow-up which is comparable to our results.[22] A study carried out by John et al. also showed greater weight reduction while using SGLT-2 inhibitors than using DPP-4 inhibitors.[23] Another similar study depicted that patients using SGLT-2 inhibitors had robust effects on reducing Body weight as compared to patients who were using DPP-4 inhibitors22. Hesham et al. also mentioned that body weight of patients in Group A (SGLT-2 inhibitors) and Group B (DPP-4 inhibitors) at baseline was 91.4±13.2 and 88.8±13.3 kg respectively and weight after follow up visit was

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89.4±13.2 and 88.1±13.6 kg in both Group A and Group B respectively which also had similarity to our findings20. SGLT-2 inhibitors create negative energy balance causing increase urinary glucose excretion, leading to a loss of calories in the form of glucose. Further, these cause reduction in visceral fat thus improve insulin sensitivity while DPP-4 inhibitors do not directly affect glucose excretion or energy balance and thus cause modest reduction in weight loss.[24]

Both DPP-4 and SGLT-2 inhibitors lower blood sugar levels but SGLT-2 inhibitors cause more reduction in fasting blood sugars in patients than patients using DPP-4 inhibitors. In our study fasting blood sugars reduced from 247.15 (28.59) to 149.55 (11.84) after follow-up in patients using SGLT-2 inhibitors. These results were comparable to the study carried out by by Irtaza et al. which showed reduction in fasting blood sugar from 101mg/dl at baseline to 94mg/dl.[25] Satilmis et al. also showed reduction in fasting blood sugars (196±73 at baseline to 149±54 after 6 months of treatment) in patient using SGLT-2 inhibitors18. SGLT-2 inhibitors encourage the excretion of glucose and reduce blood sugar by preventing its reabsorption in the kidneys while DPP-4 inhibitors increase the incretin hormones, which lower blood glucose by increasing insulin and decreasing glucagon.[26] Satilmis et al. stated that patients treated with SGLT-2 inhibitors had reduced fasting plasma glucose (196±73 149±54) which is in line with our study findings. This might be connected to a larger HbA1c decrease with the SGLT-2 inhibitors than with the DPP4 inhibitors.[18] SGLT2 inhibitors cause increase excretion of glucose through kidney thus reducing blood glucose, independent of insulin while DPP-4 inhibitors cause insulin excretion and suppress glucagon release, which is dependent on food intake and body's insulin release and thus cause modest lowering in blood sugars as compared to SGLT2 inhibitors.

The study had limitations due to its small sample size which might not be representative of the general population given the variation in age, dietary habits and clinical features. Since the study was conducted at a single tertiary care hospital in Islamabad, the results might not accurately represent the experiences of patients in other regions. The results' applicability is further constrained by the lack of side effect and complication evaluations. Non-probability consecutive sampling further increased the risk of selection bias and the six-month follow-up time might not be enough to record how SGLT-2 and DPP-4 inhibitors affect body weight, glycemic management, cardiovascular risk, and other health outcomes over the long run.

We recommend multi-centered trials with more diverse patient population across different regions accounting for variations in life style factors, age and clinical features. Longer follow-up periods are required to assess the long-term side-effects of SGLT-2 and DPP-4 inhibitors. Randomized controlled trials (RCTs) utilizing probabilistic sampling methods should be offered to reduce selection bias. Additionally, studies should integrate advance technologies like continuous glucose monitoring and tele-medicine to enhance the accuracy of results.

CONCLUSION

SGLT-2 inhibitors are superior to DPP-4 inhibitors in terms of glycemic parameters as HbA1c and fasting blood sugars. SGLT-2 inhibitors also offer superior weight loss than DPP-4 inhibitors in type-2 Diabetes Mellitus. Both drugs provide excellent efficacy as a treatment escalation option in type-2 Diabetes Mellitus.

AUTHOR'S CONTRIBUTION

Batool M: Data collection, Manuscript writing, Proof reading and final approval
Janjua MBA: Data collection, Literature research, Manuscript writing
Zafar M: Conceived data
Sufyan A: Designed research methodology, Data analysis
Shafi F: Designed research methodology, Literature research
Liaqat B: Conceived data, Data analysis

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