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A Six-month comparative Evaluation of Sodium-Glucose Cotransporter-2 inhibitors and Dipeptidyl Peptidase-4 inhibitors on Weight, Body Mass Index, and Glycemic control in patients with Type 2 Diabetes

Syed Afzal Uddin Biyabani[*1], Neelkantreddy Patil[1], Vanishree P. Babladi[1], Pooja V. Salimath[1] Hafsa Naema[1], Safa Wasay[2] and Syed Raziuddin Faisal[3]

[*1-5]Department of Pharmacy Practice, Matoshree Taradevi Rampure Institute of Pharmaceutical Sciences, Kalaburagi - 585105 (India)
[6]Department of Pharmacy Practice, Jawaharlal Nehru Technological University, Hyderabad - 500085 (India)
[3]Department of Pharmacy Practice, Visveswarapura Institute of Pharmaceutical Sciences, Bengaluru - 560070 (India)
Corresponding Author: Dr. Syed Afzal Uddin Biyabani: Research Scholar, (Department of Pharmacy Practice), Matoshree Taradevi Rampure Institute of Pharmaceutical Sciences, Kalaburagi, (Karnataka) (India)
Contact no.- +91 9393243588
Email-Biyabani786786@gmail.com

Abstract

Type 2 diabetes mellitus (T2DM) is a multifactorial metabolic disorder hallmarked by chronic hyperglycaemia arising from a complex interplay of insulin resistance and β-cell dysfunction, predisposing patients to substantial cardiometabolic and microvascular complications. This six-month prospective, observational cohort study delineates the comparative effects of sodium–glucose cotransporter-2 (SGLT-2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors on anthropometric indices and glycaemic parameters in 145 patients with T2DM attending tertiary care hospitals and affiliated diabetic clinics in Kalaburagi, India. Participants were stratified into two intervention arms: SGLT-2 inhibitors (n = 75) and DPP-4 inhibitors (n = 70). Serial measurements of body weight, body mass index (BMI), fasting blood sugar (FBS), postprandial blood sugar (PPBS), and glycated haemoglobin (HbA1c) were obtained at baseline, three months, and six months. Both therapeutic classes elicited significant reductions in weight, BMI, and glycaemic indices over the study period ($p < 0.05$). Notably, SGLT-2

[1]Research Scholar, [2]Professor & HOD, [3]Assistant Professor, [4]Associate Professor & Res. Scholar, [5]Pharm & Graduate, [6]Pharm Dstudent, [7]Res. Scholar

inhibitors conferred superior anthropometric improvements, whereas DPP-4 inhibitors demonstrated earlier and pronounced glycaemic modulation within the initial three months. These results substantiate the clinical utility of SGLT-2 and DPP-4 inhibitors as complementary pharmacological strategies in T2DM management, facilitating optimized metabolic control and mitigating obesity-associated cardiometabolic risk. Future investigations with extended follow-up and multi-centric designs are warranted to elucidate long-term efficacy, cardiovascular outcomes, and safety profiles of these agents.

Key words : Type 2 diabetes mellitus, SGLT-2 inhibitors, DPP-4 inhibitors, glycaemic modulation, body mass index, metabolic control.

Diabetes mellitus represents a heterogeneous group of chronic metabolic disorders characterized by persistent hyperglycaemia arising from absolute or relative deficiencies in insulin secretion, impaired insulin sensitivity at the cellular level, or a complex interplay of both mechanisms. These pathophysiological abnormalities result in widespread derangements in carbohydrate, lipid, and protein metabolism, disrupting normal metabolic equilibrium. Prolonged exposure to hyperglycaemia and associated metabolic stress precipitates progressive microvascular and macrovascular injury, culminating in functional and structural damage to multiple organ systems, including the renal, ocular, neural, and cardiovascular systems, as well as the peripheral vasculature. Collectively, these complications contribute to significant long-term morbidity, reduced quality of life, and increased mortality[9]. Diabetes mellitus is conventionally categorized into distinct etiological and clinical subtypes, encompassing autoimmune-mediated diabetes, insulin-resistant diabetes, gestational diabetes associated with pregnancy, and a spectrum of less common forms arising from identifiable genetic, metabolic, or secondary causes. Among these categories, type 2 diabetes mellitus constitutes the vast majority of cases, accounting for approximately 90–95% of all diagnosed individuals, whereas type 1 diabetes mellitus represents nearly 5–10% of the overall disease burden[1].Worldwide, diabetes mellitus has emerged as a global epidemic, constituting a major public health challenge and exerting a substantial socioeconomic burden on healthcare systems. In 2019, an estimated 4.63 million individuals were reported to be living with diabetes, and this number is projected to increase dramatically to approximately 578 million by 2030, corresponding to a global prevalence of 10.2%. Forecasts further predict an escalation to nearly 700 million affected individuals by 2045, with the prevalence expected to reach 10.9%, underscoring the accelerating global impact of this chronic metabolic disorder[6]. India bears a substantial share of the global diabetes burden, with an estimated 62.4 million individuals currently affected by the disease, a figure projected to exceed 100 million by 2030. The distribution of diabetes demonstrates a marked urban–rural disparity, with prevalence rates approaching nearly 20% among adults residing in urban settings, compared with approximately 10% in rural populations, reflecting the influence of lifestyle transitions, urbanization, and socioeconomic factors on disease prevalence[13]. Notably, diabetes is associated with a high burden of debilitating complications, with approximately 15% of affected individuals developing cardiovascular disorders, nearly 22% experiencing diabetic retinopathy that may progress to visual impairment or blindness, and about 38% developing chronic kidney disease. In addition, nearly 3% of patients may encounter severe peripheral vascular complications culminating in limb amputation. These alarming figures underscore the urgent need for comprehensive disease management approaches, the development of innovative therapeutic modalities, and the optimization of pharmacological interventions to mitigate long-term morbidity and improve patient outcomes[2]. Contemporary management of diabetes mellitus is predicated on a multifactorial strategy that integrates sustained lifestyle interventions with individualized pharmacological therapy. In addition to structured dietary regulation and regular physical activity aimed at improving insulin sensitivity, a broad spectrum of antidiabetic agents is available for glycaemic control. Therapeutic options include exogenous insulin formulations exhibiting distinct pharmacodynamic and pharmacokinetic characteristics ranging from rapid-acting to intermediate and long-acting preparations as well as multiple classes of oral antihyperglycemics agents, including biguanides such as metformin, sulfonylureas, thiazolidinediones, and meglitinides. However, the clinical utility of certain conventional therapies, particularly sulfonylureas, is constrained by their unfavourable safety profile, which encompasses an increased incidence of hypoglycaemic episodes, weight gain, exacerbation of cardiovascular risk, and a possible association with elevated mortality rates.[14,15]

Emerging as a novel class of oral antihyperglycemic agents, sodium–glucose co-transporter 2 (SGLT-2) inhibitors reduce plasma glucose concentrations by selectively blocking glucose reabsorption in the proximal renal tubules, thereby enhancing urinary glucose excretion. In addition to their primary glycaemic effect, these agents offer multiple pleiotropic advantages, including a low propensity for hypoglycaemia, modest blood pressure reduction, and promotion of weight loss. Furthermore, clinical evidence suggests that SGLT-2 inhibitor therapy is associated with a slight increase in both low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) levels[11]. At present, the clinically approved members of the sodium–glucose co-transporter 2 (SGLT-2) inhibitor class include dapagliflozin, canagliflozin, empagliflozin, and ipragliflozin[7]. Another important class of oral antidiabetic agents comprises dipeptidyl peptidase-4 (DPP-4) inhibitors, which exert their therapeutic effect by inhibiting the enzymatic degradation of incretin hormones released from the gastro-intestinal tract in response to nutrient intake. By prolonging incretin activity, these agents enhance glucose-dependent insulin secretion and suppress glucagon release. Both SGLT-2 inhibitors and DPP-4 inhibitors are well-established as effective therapeutic options for the management of type 2 diabetes mellitus and may be employed either as monotherapy or in combination with other antidiabetic agents to achieve optimal glycaemic control[11]. The dipeptidyl peptidase-4 (DPP-4) inhibitors that have received regulatory approval for clinical use include sitagliptin, vildagliptin, saxagliptin, linagliptin, and alogliptin [8]. Notwithstanding the extensive clinical utilization of SGLT-2 inhibitors and DPP-4 inhibitors in type 2 diabetes mellitus, robust comparative evidence delineating their differential effects on anthropometric indices and critical glycaemic metrics remains scarce, particularly within the Indian population. Considering the imperative of concurrently optimizing glycaemic homeostasis and mitigating adiposity-driven cardiometabolic risk, a methodical head-to-head evaluation of these pharmacotherapeutic classes is both clinically and scientifically justified. Accordingly, the present six-month prospective observational study was designed to rigorously assess and contrast the impact of SGLT-2 inhibitors versus DPP-4 inhibitors on body weight, body mass index, and key parameters of glycaemic control in patients with type 2 diabetes mellitus.

Study Setting : The study was conducted at the Department of General Medicine, Basaweshwar Teaching and General Hospital, Kalaburagi, supplemented by select tertiary diabetic care clinics to ensure a representative patient population.

Study Design : A prospective, observational cohort study was implemented to systematically evaluate the comparative effects of SGLT-2 and DPP-4 inhibitors.

Study Duration : The observational period extended over six months.

Study Population : Of 187 eligible patients diagnosed with type 2 diabetes mellitus, 162 provided informed consent for participation, while 25 individuals declined. Participants were stratified into two distinct intervention cohorts:

- **Group 1 (SGLT-2 Inhibitors):** 82 patients
- **Group 2 (DPP-4 Inhibitors):** 80 patients

After accounting for attrition during follow-up, the final analytical dataset comprised 75 patients in Group 1 and 70 patients in Group 2.

Study Subjects : Individuals with type 2 diabetes mellitus attending the outpatient departments of General Medicine at Basaweshwar Teaching and General Hospital, as well as patients presenting to affiliated diabetic clinics, were recruited for inclusion.

Eligibility Criteria :

- ***Inclusion Criteria :***
  - Adults aged 35–75 years of either sex with a confirmed diagnosis of type 2 diabetes mellitus.
  - Baseline glycated haemoglobin (HbA1c) >6.5%, indicative of suboptimal glycaemic control and necessitating therapeutic optimization.
  - Patients maintained on first-line oral hypoglycaemic agents for a minimum of one-year preceding study initiation to ensure therapeutic stability.
  - Voluntary provision of informed consent.
- ***Exclusion Criteria :***
  - Individuals with gestational diabetes mellitus or type 1 diabetes mellitus.
  - Chronically debilitated or bedridden patients.
  - Concurrent use of complementary or alternative medical systems (Ayurvedic, Unani, homeopathic) in conjunction with allopathic therapy.

- o Patients receiving insulin therapy during the study period.

Data Acquisition:

- ***Clinical Records:*** Extraction of demographic, clinical, and pharmacotherapeutic data from personal case files.
- ***Laboratory Assessments:*** Serial measurements of HbA1c, renal function parameters, and lipid profiles at baseline and designated follow-up intervals.
- ***Prescription Data :*** Detailed documentation of all prescribed oral antihyperglycemic agents, with particular focus on SGLT-2 and DPP-4 inhibitors throughout the study period.

Statistical Analysis : Analyses were performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA).

- ***Descriptive Statistics :*** Continuous variables were expressed as means ± standard deviation with 95% confidence intervals.
- ***Paired t-tests:*** Employed to evaluate intra-group temporal changes in body weight, body mass index, and glycaemic indices.
- ***Repeated Measures Anova :*** Utilized to assess longitudinal changes across baseline, three-month, and six-month time points.
- ***Post Hoc Analysis :*** Bonferroni and Scheffé procedures were applied to delineate pairwise differences and identify statistically significant inter- and intra-group variations.

Results

Table-1 summarizes baseline demographics of patients in the SGLT-2 and DPP-4 inhibitor groups, including gender, age, and residence. Categorical variables were analysed using Chi-square tests, and continuous variables using independent t-tests. The cohorts were generally well-matched, with minor differences in mean age.

Table-1. Baseline Demographic and Clinical Characteristics of Patients Receiving SGLT-2(n=75) and DPP-4 Inhibitors (n=70)

Parameter	SGLT-2 Group (n=75)	DPP-4 Group (n=70)	Overall (n=145)	Percentage Difference	Statistical Analysis
Gender					
Male	51 (68%)	47 (67.1%)	98 (67.6%)	0.90%	p = 1.000 (Chi-square)
Female	24 (32%)	23 (32.9%)	47 (32.4%)	-0.90%	-
Age (years)					
Average Age	52.13	57.84	-	-5.71	p=0.0002 (t-test)
Standard Deviation	6.84	10.7	-	-	-
Variance	46.86	114.59	-	-	-
Mean Difference	-	-	-5.71	-	95% CI: −5.71± 2.98

Age-wise Distribution					
35–45	13 (17.33%)	19 (27.14%)	32 (22.07%)	-9.81%	-
46–55	37 (49.33%)	25 (35.71%)	62 (42.76%)	13.62%	-
55–65	23 (30.66%)	16 (22.86%)	39 (26.90%)	7.80%	-
66–75	2 (2.68%)	10 (14.29%)	12 (8.28%)	-11.63%	-
Residence					
Urban	39 (52%)	39 (55.71%)	78 (53.79%)	-3.71%	p = 0.713 (Chi-square)
Rural	36 (48%)	31 (44.29%)	67 (46.21%)	3.71%	

Table-2 delineates the six-month trajectories of weight and BMI in patients receiving SGLT-2 (n=75) and DPP-4 inhibitors (n=70). Both cohorts exhibited significant reductions over time; however, SGLT-2 inhibitors elicited a more pronounced decline in weight and BMI. Statistical analyses confirmed these changes as highly significant ($p < 0.001$), underscoring the superior efficacy of SGLT-2 inhibitors in modulating anthropometric parameters in type 2 diabetes mellitus.

Table-2. Comparative Six-Month Changes in Weight and BMI in Patients Receiving SGLT-2 (n=75) and DPP-4 Inhibitors (n=70)

Group	Timepoint	Weight (kg) Mean ± SD (95% CI)	p-value (Weight)	BMI (kg/m^2) Mean ± SD (95% CI)	p-value (BMI)
SGLT-2 (n=75)	Baseline	81.76 ± 8.07 (79.88, 83.64)	–	25.35 ± 4.22 (24.30, 26.40)	–
	3 Months	76.80 ± 7.33 (75.08, 78.52)	<0.001 (***)	23.80 ± 4.12 (22.87, 24.73)	<0.001 (***)
	6 Months	71.60 ± 7.04 (69.94, 73.26)	<0.001 (***)	22.20 ± 3.95 (21.31, 23.09)	<0.001 (***)
DPP-4 (n=70)	Baseline	73.44 ± 12.35 (70.55, 76.33)	–	24.34 ± 2.14 (23.85, 24.84)	–
	3 Months	71.19 ± 12.05 (68.37, 74.00)	0.005 (*)	23.73 ± 1.50 (23.35, 24.10)	0.005 (*)
	6 Months	67.90 ± 11.73 (65.16, 70.64)	<0.001 (***)	22.50 ± 1.40 (22.18, 22.84)	<0.001 (***)

Table-3 presents the longitudinal changes in FBS and PPBS among patients treated with SGLT-2 and DPP-4 inhibitors over 6 months. Both groups showed a progressive decline in fasting and postprandial glucose levels from baseline to 6 months, with SGLT-2 exhibiting slightly greater reductions. Statistical analysis indicates that the changes were significant at 6 months for both groups, while early changes at 3 months were significant only for DPP-4 and borderline for SGLT-2. Overall, the table demonstrates the efficacy of both drug classes in improving glycaemic control over time.

Table-3. Descriptive Statistics and Statistical Significance of FBS and PPBS Changes Over Time for SGLT-2 (n=75) and DPP-4 Inhibitors (n=70)

Group	Timepoint	FBS (mg/dL) Mean ± SD (95% CI)	p-value (FBS)	PPBS (mg/dL) Mean ± SD (95% CI)	p-value (PPBS)
SGLT-2	Baseline	198.4 ± 15.43 (191.5, 205.3)	–	255.33 ± 32.77 (247.89, 262.77)	–
	3 Months	193.4 ± 15.43 (186.5, 200.3)	0.089 (*)	245.40 ± 32.70 (237.96, 252.84)	0.089 (*)
	6 Months	178.4 ± 15.43 (171.5, 185.3)	<0.001 (***)	231.47 ± 31.35 (223.77, 239.18)	<0.001 (***)
DPP-4	Baseline	199.29 ± 15.73 (191.0, 207.6)	–	245.00 ± 28.93 (237.86, 252.14)	–
	3 Months	194.29 ± 15.73 (186.0, 202.6)	<0.001 (***)	235.00 ± 28.93 (227.86, 242.14)	0.023 (*)
	6 Months	184.29 ± 15.73 (176.0, 192.6)	<0.001 (***)	224.14 ± 28.46 (216.86, 231.42)	<0.001 (***)

Table-4. Descriptive Statistics and Statistical Significance of HbA1c Changes Over Time for SGLT-2 Inhibitors (n=75) and DPP-4 Inhibitors (n=70)

Group	Timepoint	HbA1c (%) Mean ± SD (95% CI)	p-valueb (Comparison)
SGLT-2	Baseline	9.224 ± 0.4226 (8.852, 9.596)	–
	3 Months	8.648 ± 0.2327 (8.397, 8.899)	0.023 (*)
	6 Months	8.015 ± 0.195 (7.831, 8.198)	<0.001 (***)
DPP-4	Baseline	9.141 ± 0.2800 (8.589, 9.694)	–
	3 Months	8.837 ± 0.2772 (8.560, 9.115)	0.023 (*)
	6 Months	8.459 ± 0.2790 (8.201, 8.716)	<0.001 (***)

Table-4 illustrates the changes in HbA1c levels over 6 months in patients treated with SGLT-2 and DPP-4 inhibitors. Both groups showed a steady reduction in HbA1c from baseline to 6 months, with SGLT-2 achieving slightly larger decreases. The reductions were statistically significant at 3 months for both groups and became highly significant at 6 months, indicating sustained glycaemic improvement. Overall, the data highlight the effectiveness of both drug classes in long-term glycaemic control.

In this study, both SGLT-2 and DPP-4 inhibitors demonstrated significant improvements in anthropometric and glycaemic parameters over a six-month period. Regarding weight reduction, patients receiving SGLT-2 inhibitors exhibited a decrease from 81.76 ± 8.07 kg at baseline (95% CI: 79.88, 83.64) to 76.80 ± 7.33 kg at 3 months (p = 0.005*) and further to 71.60 ± 7.04 kg at 6 months (p < 0.001***). Similarly, the DPP-4 group showed a reduction from 73.44 ± 12.35 kg at baseline to 71.19 ± 12.05 kg at 3 months (p < 0.001**) and 67.90 ± 11.73 kg at 6 months (p < 0.001***). These findings are consistent with previous studies by Paweena Danpanichkulal. (2020)[12] and Yu Cheng Herz *et al.* (2019)[20], which reported significant weight loss with both drug classes over similar time frames. Parallel trends were observed in BMI reductions. SGLT-2 inhibitors decreased mean BMI from 25.35 ± 4.22 at baseline to 24.53 ± 4.12 at 3 months (p = 0.005*) and 23.39 ± 3.95 at 6 months (p < 0.001***), while DPP-4 inhibitors reduced BMI from 24.34 ± 2.14 to 23.73 ± 1.50 at 3 months (p < 0.001**) and 23.50 ± 1.40 at 6 months (p < 0.001***). These outcomes are in line with Yong Ki Cho *et al.* (2018)[19] and Xiang Guo *et al.* (2019)[18], confirming that both treatments effectively reduce BMI in type 2 diabetes patients. Both drug classes also demonstrated substantial improvements in glycaemic control. Fasting blood sugar (FBS) decreased in the SGLT-2 group from 198.4 ± 15.43 mg/dL at baseline to 193.4 ± 15.43 mg/dL at 3 months (p = 0.089*) and 178.4 ± 15.43 mg/dL at 6 months (p < 0.001***). For the DPP-4 group, FBS declined from 199.29 ± 15.73 mg/dL at baseline to 194.29 ± 15.73 mg/dL at 3 months (p < 0.001**) and 184.29 ± 15.73 mg/dL at 6 months (p < 0.001***). These results corroborate findings from Lina Ni, *et al*. (2020)[10] and Seung Lee *et al.* (2019)[16], which demonstrated significant FBS reduction with SGLT-2 and DPP-4 inhibitors, respectively.

Similarly, postprandial blood sugar (PPBS) levels decreased over time. SGLT-2 therapy reduced PPBS from 255.33 ± 32.77 mg/dL at baseline to 245.40 ± 32.70 mg/dL at 3 months (p = 0.089*) and 231.47 ± 31.35 mg/dL at 6 months (p < 0.001***). DPP-4 inhibitors reduced PPBS from 245.00 ± 28.93 mg/dL at baseline to 235.00 ± 28.93 mg/dL at 3 months (p = 0.023*) and 224.14 ± 28.46 mg/dL at 6 months (p < 0.001***). These trends align with prior observations by Donghee Bhosle *et al.* (2018)[3] and Eun Young Choe *et al.* (2019)[5], highlighting the efficacy of both drug classes in improving postprandial glucose control. Finally, HbA1c levels, a key marker of long-term glycaemic control, showed progressive reductions. In the SGLT-2 group, HbA1c decreased from 9.22 ± 0.42% at baseline to 8.65 ± 0.23% at 3 months (p = 0.023*) and 8.01 ± 0.20% at 6 months (p < 0.001***). In the DPP-4 group, HbA1c declined from 9.14 ± 0.28% to 8.84 ± 0.28% at 3 months

($p = 0.023^*$) and 8.46 ± 0.28% at 6 months ($p < 0.001^{***}$). These findings are consistent with the studies of Emanuele De Andrea *et al*. **(**2020)[4] and Wei Yong Mak *et al.* (2019)[17], confirming sustained HbA1c lowering with both therapies. Overall, these results indicate that SGLT-2 inhibitors may provide slightly greater reductions in weight, BMI, and glycaemic parameters compared to DPP-4 inhibitors, although both classes are effective and well-tolerated. The study reinforces the role of these agents as integral components of type 2 diabetes management, capable of achieving significant improvements in both anthropometric and glycaemic outcomes over a six-month period.

This six-month prospective comparative study demonstrates that both SGLT-2 and DPP-4 inhibitors confer significant benefits in modulating anthropometric and glycemic parameters in patients with Type 2 Diabetes Mellitus (T2DM). Both therapeutic classes elicited meaningful reductions in body weight, BMI, and key glycaemic indices, including fasting blood glucose (FBS), postprandial blood glucose (PPBS), and HbA1c.

Notably, SGLT-2 inhibitors produced more pronounced declines in weight and BMI, highlighting their superior efficacy in promoting weight management and potentially ameliorating obesity-related metabolic risk factors. Conversely, DPP-4 inhibitors exhibited relatively modest effects on anthropometric measures but demonstrated early and significant improvements in glycaemic parameters within the initial three months, underscoring their efficacy in rapid glycaemic modulation.

These findings corroborate and extend current evidence, validating both SGLT-2 and DPP-4 inhibitors as effective pharmacologic interventions for integrated metabolic and glycaemic management in T2DM. Future investigations incorporating larger cohorts, longer follow-up durations, and assessments of cardiovascular and renal outcomes are warranted to fully delineate the long-term therapeutic potential, safety profile, and mechanistic advantages of these agents.

Ethical Approval :

The study protocol was reviewed and approved by the Institutional Ethics Committee of HKES's Matoshree Taradevi Rampure College of Pharmacy, Kalaburagi, Karnataka, India (IEC No.: HKES/MRMCK/IEC/2024/230). The study was conducted in accordance with the Declaration of Helsinki and national ethical guidelines. Written informed consent was obtained from all participants prior to enrollment, and patient confidentiality was rigorously maintained throughout the study.

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Conflict of Interest

The authors declare no potential conflicts of interest with respect to the research, authorship, or publication of this study.

Authors' Contributions

- **Conceptualization and Study Design:** Dr. Syed Afzal Uddin Biyabani
- **Supervision and Critical Review:** Dr. Neelkantreddy Patil

- **Data Collection and Patient Management:** Dr. Vanishree P. Babladi, Dr. Pooja V. Salimath, Hafsa Naema, Safa Wasay, Dr. Syed Raziuddin Faisal
- **Data Analysis and Interpretation:** Dr. Syed Afzal Uddin Biyabani
- **Manuscript Drafting:** Dr. Syed Afzal Uddin Biyabani
- **Manuscript Revision and Final Approval:** All authors have critically reviewed the manuscript and approved the final version for submission.

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Limitations

While this study provides valuable insights into the comparative effects of SGLT-2 and DPP-4 inhibitors in patients with Type 2 Diabetes, several limitations should be acknowledged:

1. **Sample Size :** The relatively small cohort may restrict the generalizability of the findings to the broader diabetic population.
2. **Study Duration :** The six-month follow-up may not fully capture the long-term efficacy, safety, and metabolic outcomes associated with SGLT-2 and DPP-4 inhibitor therapy.
3. **Single-Centre and Clinical Setting:** The study was conducted in selected hospitals and outpatient clinics, which may introduce selection bias and limit the representativeness of the sample.
4. **Uncontrolled Confounders:** Variables such as dietary patterns, physical activity levels, and concomitant medications were not strictly standardized, potentially influencing the observed outcomes.

Future research involving larger, multi-centre cohorts with extended follow-up periods is recommended to validate these findings and explore the long-term therapeutic, cardiovascular, and renal implications of these agents.

Data Availability Statement

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

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