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A Prospective Observational Study to Evaluate the Efficacy and Safety of Sodium Glucose Cotransporter-2 Inhibitors in Patients of Type II Diabetes Mellitus

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ABSTRACT

Background: Type 2 Diabetes Mellitus is a major metabolic disorder associated with significant morbidity and mortality. Sodium-glucose cotransporter-2 (SGLT2) inhibitors are a newer class of antidiabetic agents that improve glycemic control and provide additional metabolic benefits.
Aim: To evaluate the efficacy and safety of SGLT2 inhibitors in patients with type 2 diabetes mellitus.
Materials and Methods: This prospective observational study was conducted in the Department of General Medicine and the Department of Pharmacology at Dr Ram Manohar Lohia Institute of Medical Sciences. A total of 93 patients with type 2 diabetes mellitus receiving SGLT2 inhibitors as add-on therapy were included. Baseline and 3-month follow-up assessments included HbA1c, lipid profile, fasting blood sugar (FBS), body weight, body mass index (BMI), systolic blood pressure (SBP), and diastolic blood pressure (DBP). Adverse drug reactions were also recorded. Primary outcome assessment included change in HbA1c. Secondary outcomes included changes in lipid profile and safety assessment. Additional exploratory analyses were performed for fasting blood sugar, body weight, body mass index and blood pressure parameters.Statistical analysis was performed using Jamovi version 2.6.44, and $p < 0.05$ was considered statistically significant.
Results: Mean HbA1c significantly decreased from 8.82 ± 0.76% at baseline to 8.26 ± 0.79% after 3 months ($p < 0.001$). Significant reductions were also observed in fasting blood sugar, body weight, BMI, systolic blood pressure, and diastolic blood pressure ($p < 0.001$). HDL-C levels increased significantly, while triglyceride levels decreased significantly after therapy. A mild increase in LDL-C was observed. Most patients (94.6%) did not report any adverse drug reactions. Genital itching (3.2%) and urinary discomfort (2.2%) were the commonly observed adverse effects.
Conclusion: SGLT2 inhibitors were found to be effective and safe as add-on therapy in patients with type 2 diabetes mellitus. They provided significant glycemic and metabolic benefits with minimal adverse drug reactions.

Keywords*: SGLT2 inhibitors, Type 2 diabetes mellitus, HbA1c, Glycemic control, Adverse drug reactions, Lipid profile.*

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterised by insulin resistance, impaired insulin secretion, and persistent hyperglycemia. It is one of the most common non-communicable diseases worldwide and has emerged as a major public health concern because of its rapidly increasing prevalence and associated complications [1]. India has one of the largest diabetic populations globally, and the burden of T2DM continues to increase due to urbanisation, sedentary lifestyle, obesity, unhealthy dietary habits, and genetic predisposition [2].

Persistent hyperglycemia in T2DM is associated with long-term microvascular and macrovascular complications, including diabetic nephropathy, neuropathy, retinopathy, ischemic heart disease, cerebrovascular disease, and peripheral vascular disease [3]. Poor glycemic control significantly increases morbidity and mortality among diabetic patients. Glycated haemoglobin (HbA1c) is considered the standard marker for assessment of long-term glycemic control and is widely used for monitoring therapeutic response [4].

The management of T2DM primarily focuses on achieving optimal glycemic control while minimising adverse effects and preventing complications. Lifestyle modifications along with oral antidiabetic drugs such as metformin, sulfonylureas, thiazolidinediones, and DPP-4 inhibitors are commonly used in routine clinical practice [5]. However, many patients fail to achieve adequate glycemic targets despite combination therapy, necessitating the introduction of newer therapeutic agents with additional metabolic benefits.

Sodium-glucose cotransporter-2 (SGLT2) inhibitors are a relatively newer class of oral antidiabetic agents that lower blood glucose levels by inhibiting glucose reabsorption in the proximal renal tubules, thereby promoting urinary glucose excretion [6]. Unlike several conventional antidiabetic drugs, the mechanism of action of SGLT2 inhibitors is independent of insulin secretion and insulin sensitivity, which reduces the risk of hypoglycemia [7]. Commonly used SGLT2 inhibitors include dapagliflozin, empagliflozin, and canagliflozin.

In addition to glycemic improvement, SGLT2 inhibitors have demonstrated beneficial effects on body weight, blood pressure, and cardiovascular as well as renal outcomes [8]. Major cardiovascular outcome trials such as EMPA-REG OUTCOME and CANVAS have shown significant reductions in cardiovascular mortality, hospitalisation due to heart failure, and progression of renal disease among patients receiving SGLT2 inhibitors [9,10]. These pleiotropic benefits have resulted in increasing use of this drug class in patients with T2DM, especially those with coexisting cardiovascular and renal risk factors.

Despite their proven efficacy, SGLT2 inhibitors are associated with certain adverse effects such as genital mycotic infections, urinary tract infections, polyuria, dehydration, and rarely, diabetic ketoacidosis [11]. Therefore, evaluation of their safety and effectiveness in real-world clinical settings is essential, particularly in the Indian population, where limited observational data are available.

The present prospective observational study was undertaken to evaluate the efficacy and safety of SGLT2 inhibitors in patients with type 2 diabetes mellitus attending the outpatient department of General Medicine at Dr. Ram Manohar Lohia Institute of Medical Sciences. The study aimed to assess the effect of SGLT2 inhibitors on glycemic control as measured by HbA1c, evaluate changes in lipid profile and document adverse drug reactions over a follow-up period of three months.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted jointly by the Department of Pharmacology and the Department of General Medicine at Dr Ram Manohar Lohia Institute of Medical Sciences. The Department of General Medicine was responsible for patient recruitment, clinical evaluation, and prescription of sodium-glucose cotransporter-2 (SGLT2) inhibitors, while the Department of Pharmacology coordinated data collection, monitoring of adverse drug reactions, and statistical analysis. The study was carried out in the Outpatient Department (OPD) of General Medicine.

Study Duration

The total duration of the study was 18 months, which included patient recruitment, baseline assessment, follow-up visits, data entry, and statistical analysis.

Ethical Approval
Prior approval for the study was obtained from the Institutional Ethics Committee of Dr Ram Manohar Lohia Institute of Medical Sciences. Written informed consent was obtained from all participants before enrollment after explaining the objectives and procedures of the study in simple language. Confidentiality of patient information was maintained throughout the study, and participation was entirely voluntary. Participants were free to withdraw from the study at any stage without affecting their treatment.

Sample Size
A total of 93 patients with type 2 diabetes mellitus were enrolled in the study. Sample size estimation was based on a previous study by Dognanay et al., which reported a reduction in HbA1c of 0.7% after 12 weeks of SGLT2 inhibitor therapy in patients with baseline HbA1c of 8.7 ± 1.4%.
The sample size was calculated using the following formula:

$$\square = \frac{(\square_{1-\square/2} + \square_{1-\square})^2 \times (2\square^2)}{\square^2}$$

Where:

$Z_{1-\alpha/2}$ = 1.96 at 95% confidence interval

$Z_{1-\beta}$ = 1.28 at 90% power

S = Standard deviation = 1.4

D = Expected mean difference = 0.7

Adding 10% for non-consent and loss to follow-up, final sample size was estimated as 93.

Inclusion Criteria
Patients were included in the study if they fulfilled the following criteria:

1. Age ≥18 years
2. Diagnosed with type 2 diabetes mellitus as per American Diabetes Association (ADA) criteria
3. Already receiving oral antidiabetic medications such as metformin, sulfonylureas, or DPP-4 inhibitors
4. HbA1c value equal to or greater than 7%
5. Prescribed SGLT2 inhibitors as add-on therapy by the treating physician

Exclusion Criteria
Patients were excluded if they had any of the following conditions:

1. Type 1 diabetes mellitus
2. Pregnancy or lactation
3. Age >75 years
4. History of malignancy, thyroid disorders, severe liver disease, chronic kidney disease, congestive heart failure, or rheumatoid arthritis
5. Active or recurrent urinary tract infection or history of pyelonephritis
6. Estimated glomerular filtration rate below recommended limits for SGLT2 inhibitor use
7. Recent surgery or acute illness
8. Diagnosed osteoporosis with bone mineral density ≤ −2.5

Data Collection Procedure
Patients attending the General Medicine OPD with known or newly diagnosed type 2 diabetes mellitus were screened for eligibility. Those fulfilling the inclusion and exclusion criteria were enrolled after obtaining written informed consent.

Baseline demographic and clinical details, including age, gender, duration of diabetes, comorbidities, medication history, and relevant clinical findings, were recorded in a predesigned Case Record Form (CRF). Baseline laboratory investigations, such as glycated haemoglobin (HbA1c) and lipid profile, were documented before initiation of SGLT2 inhibitor therapy.

The selection and dosage of SGLT2 inhibitors were determined solely by the treating physician as part of routine clinical practice. No intervention or modification in treatment was made by the investigators.

All enrolled patients were advised to continue their routine diabetic management and were followed up after three months of therapy. During follow-up, repeat laboratory investigations, including HbA1c and lipid profile, were performed. Patients were also interviewed regarding any adverse drug reactions or discomfort experienced during treatment, and these events were documented and assessed for their possible association with SGLT2 inhibitor therapy.

Outcome Measures

Primary Outcome

- Change in HbA1c level from baseline to 3-month follow-up after initiation of SGLT2 inhibitor therapy.

Secondary Outcomes

- Changes in lipid profile
- Documentation and assessment of adverse drug reactions associated with SGLT2 inhibitors

Exploratory Analyses

- Fasting blood sugar
- Body weight
- Body mass index
- Systolic blood pressure
- Diastolic blood pressure

Tools for Data Collection and Analysis

1. Case Record Form (CRF) for recording demographic details, clinical history, comorbidities, and adverse drug reactions
2. Microsoft Office Excel 2021 for data entry and preliminary data management
3. Jamovi statistical software version 2.6.44 for statistical analysis

Methodology Flowchart

1. Patients with type 2 diabetes mellitus were screened according to inclusion and exclusion criteria.
2. Eligible patients were enrolled after obtaining written informed consent.
3. Baseline demographic, clinical, HbA1c, and lipid profile data were recorded.
4. SGLT2 inhibitors were initiated as add-on therapy by the treating physician.
5. Patients were followed up after 3 months of treatment.
6. Repeat HbA1c and lipid profile investigations were performed during follow-up.
7. Patients were assessed for adverse drug reactions related to SGLT2 inhibitor therapy.
8. Baseline and follow-up parameters were statistically analyzed using appropriate tests.

Statistical Analysis

Data were entered into Microsoft Office Excel 2021 and analysed using Jamovi statistical software version 2.6.44. Quantitative variables were expressed as mean ± standard deviation, while categorical variables were represented as frequencies and percentages.

Normality of continuous variables was assessed using the Shapiro–Wilk test. Quantitative variables were expressed as mean ± standard deviation and categorical variables as frequency and percentage. Paired t-test was used for normally distributed variables, whereas Wilcoxon signed-rank test was used for non-normally distributed variables. A p-value <0.05 was considered statistically significant.

RESULTS

Table 1: Distribution of Baseline Demographic Characteristics of Study Population (n = 93)

Study Variables	Category	Frequency (n)	Percentage (%)
Sex	**Female**	**32**	**34.4**
	Male	**61**	**65.6**
Smoking Status	**Current Smoker**	**11**	**11.8**
	Former Smoker	**37**	**39.8**

	Never Smoked	**45**	**48.4**
Hypertension Status	**No**	**35**	**37.6**
	Yes	**58**	**62.4**

Table 1 presents the baseline demographic and clinical characteristics of the study population.The cohort showed a male predominance (65.6%). Nearly half of the participants were never smokers (48.4%). Hypertension was present in 62.4% of patients.

Table 2: Assessment of Demographic and Metabolic Parameters of Study Population (n = 93)

Study Variable	Minimum	Maximum	Mean ± Standard Deviation
Age (years)	**40.0**	**73.5**	**54.401 ± 8.6544**
Height (cm)	**155.0**	**162.0**	**159.591 ± 3.3435**
Duration of Diabetes (years)	**0.6**	**24.9**	**5.949 ± 4.0683**
Baseline HbA1c (%)	**7.50**	**11.16**	**8.8245 ± 0.7599**
Baseline LDL (mg/dL)	**40.0**	**201.0**	**111.667 ± 40.7517**
Baseline HDL (mg/dL)	**20.0**	**70.0**	**41.161 ± 11.8728**
Baseline Triglycerides (mg/dL)	**50.0**	**358.0**	**184.237 ± 83.6687**

Table 2 summarizes the continuous baseline characteristics of the participants. The mean age was 54.40 ± 8.65 years. Mean duration of diabetes was 5.95 ± 4.07 years, indicating established disease. Baseline mean HbA1c was 8.82 ± 0.76%, reflecting suboptimal glycemic control at study entry. Baseline lipid parameters were also recorded to allow evaluation of treatment-related changes.

Table 3: Effect of SGLT2 Inhibitors on HbA1c at Baseline and After 3 Months (n = 93)

HbA1c (%)	Minimum	Maximum	Mean ± Standard Deviation	P-value
Baseline	**7.50**	**11.16**	**8.8245 ± 0.75997**	
After 3 Months	**6.70**	**11.08**	**8.2580 ± 0.78911**	**<0.001**

Mean HbA1c decreased from 8.82 ± 0.76% at baseline to 8.26 ± 0.79% after 3 months. Mean reduction was 0.56%. This reduction was statistically significant ($p<0.001$), suggesting improved glycemic control following SGLT2 inhibitor therapy.

Table 4: Effect of SGLT2 Inhibitors on Lipid Profile at Baseline and After 3 Months (n = 93)

Lipid Parameter (mg/dL)	Minimum	Maximum	Mean ± Standard Deviation	P-value
Baseline LDL-C	**40.0**	**201.0**	**111.667 ± 40.7517**	
After 3 Months LDL-C	**40.0**	**205.0**	**114.462 ± 41.4458**	**0.002**
Baseline Total Cholesterol	**120.0**	**314.0**	**196.151 ± 44.6871**	
After 3 Months Total Cholesterol	**120.0**	**333.0**	**198.602 ± 50.2410**	**0.265**
Baseline HDL-C	**20.0**	**70.0**	**41.161 ± 11.8728**	
After 3 Months HDL-C	**20.0**	**70.0**	**42.151 ± 11.8477**	**<0.001**
Baseline Triglycerides	**50.0**	**358.0**	**184.237 ± 83.6687**	
After 3 Months Triglycerides	**50.0**	**356.0**	**161.118 ± 76.3296**	**<0.001**

Table 5: Distribution of Adverse Drug Reactions Among Study Participants (n = 93)

Adverse Drug Reaction (ADR)	Number of Patients	Percentage (%)
Genital itching	**3**	**3.2**
Urinary discomfort	**2**	**2.2**
No ADR Reported	**88**	**94.6**

Table 6: Effect of SGLT2 Inhibitors on Other Metabolic Parameters at Baseline and After 3 Months (n = 93)

Parameter	Baseline (Mean ± SD)	After 3 Months (Mean ± SD)	P-value
Weight (kg)	**79.01 ± 10.38**	**77.67 ± 10.40**	**<0.001**
BMI (kg/m²)	**30.11 ± 3.96**	**29.60 ± 3.96**	**<0.001**
FBS (mg/dL)	**267.15 ± 22.55**	**227.90 ± 29.35**	**<0.001**
SBP (mmHg)	**137.13 ± 15.65**	**134.31 ± 16.22**	**<0.001**
DBP (mmHg)	**83.07 ± 11.30**	**81.47 ± 11.57**	**<0.001**

Table 7: Subgroup Analysis of HbA1c Reduction According to Baseline HbA1c Levels

Baseline HbA1c Group	Mean Baseline HbA1c (%)	Mean HbA1c After 3 Months (%)	Mean ΔHbA1c (%)	P-value
High (>9%)	**9.67**	**9.03**	**0.64**	**0.78**
Moderate (8–9%)	**8.46**	**7.93**	**0.54**	**0.00002**
Lower (<8.0%)	**7.76**	**7.29**	**0.48**	**0.15**

DISCUSSION

The present prospective observational study evaluated the efficacy and safety of SGLT2 inhibitors in patients with type 2 diabetes mellitus over a period of three months. The findings demonstrated significant improvement in glycemic control, body weight, blood pressure, and lipid parameters with minimal adverse drug reactions.

In the present study, male patients constituted 65.6% of the study population, while females accounted for 34.4%. Similar male predominance has been reported in previous studies evaluating SGLT2 inhibitor therapy in patients with T2DM [12]. Hypertension was observed in 62.4% of patients, reflecting the high prevalence of cardiovascular comorbidities among diabetic patients. This observation is in accordance with earlier epidemiological studies demonstrating the close association between diabetes mellitus and hypertension [3].

The primary outcome of the study was the change in HbA1c levels following initiation of SGLT2 inhibitor therapy. Mean HbA1c decreased significantly from 8.82 ± 0.76% at baseline to 8.26 ± 0.79% after three months of treatment ($p < 0.001$). Similar reductions in HbA1c have been reported in previous clinical trials evaluating dapagliflozin, empagliflozin, and canagliflozin [13,14]. The glucose-lowering effect of SGLT2 inhibitors results from increased urinary glucose excretion due to inhibition of renal glucose reabsorption in the proximal convoluted tubule [6].

Subgroup analysis in the present study demonstrated that patients with higher baseline HbA1c levels experienced greater reductions after therapy. Numerically greater reductions were observed among patients with higher baseline HbA1c values; however, subgroup differences did not consistently achieve statistical significance, likely because of smaller subgroup sample sizes. Similar findings have been reported by Wilding et al., suggesting that patients with poor baseline glycemic control derive greater benefit from SGLT2 inhibitor therapy [15].

The present study also demonstrated significant reductions in fasting blood sugar levels. Mean fasting blood sugar decreased from 267.15 ± 22.55 mg/dL to 227.90 ± 29.35 mg/dL after treatment ($p < 0.001$). This finding further confirms the efficacy of SGLT2 inhibitors in improving glycemic parameters in inadequately controlled diabetic patients.

Body weight and BMI also showed statistically significant reductions after treatment. Mean body weight decreased from 79.01 ± 10.38 kg to 77.67 ± 10.40 kg, while BMI decreased from 30.11 ± 3.96 kg/m² to 29.60 ± 3.96 kg/m² ($p < 0.001$). Similar reductions in body weight have been consistently observed in earlier studies [16]. The weight-lowering effect of SGLT2 inhibitors is primarily attributed to caloric loss due to glycosuria and osmotic diuresis. This additional benefit is clinically important because obesity commonly coexists with T2DM and contributes to insulin resistance.

Significant improvement in blood pressure parameters was also observed in the present study. Mean systolic blood pressure decreased from 137.13 ± 15.65 mmHg to 134.31 ± 16.22 mmHg, while diastolic blood pressure decreased from 83.07 ± 11.30 mmHg to 81.47 ± 11.57 mmHg ($p < 0.001$). Similar antihypertensive effects have been reported in large cardiovascular outcome trials such as EMPA-REG OUTCOME and CANVAS [9,10]. These effects are believed to occur secondary to natriuresis, osmotic diuresis, and reduction in intravascular volume.

Regarding lipid profile, HDL-C levels increased significantly while triglyceride levels decreased significantly after treatment. Mean HDL-C increased from 41.16 ± 11.87 mg/dL to 42.15 ± 11.84 mg/dL, and triglycerides decreased from 184.23 ± 83.66 mg/dL to 161.11 ± 76.32 mg/dL ($p < 0.001$). A modest but statistically significant increase in LDL-C was observed. Similar findings have been reported previously, and current evidence suggests that this increase does not offset the overall cardiovascular and renal benefits associated with SGLT2 inhibitor therapy. Similar lipid alterations are thought to result from changes in energy utilization and fatty acid metabolism induced by SGLT2 inhibition. Although the mechanism of LDL-C elevation is not completely understood, the overall cardiovascular benefits of SGLT2 inhibitors outweigh this modest increase.

Assessment of safety outcomes revealed that SGLT2 inhibitors were generally well tolerated. The majority of patients (94.6%) did not report any adverse drug reactions. Genital itching and urinary discomfort were the only reported adverse effects, occurring in 3.2% and 2.2% of patients, respectively. These findings are consistent with earlier studies that

identified genital mycotic infections and urinary symptoms as the most common adverse effects associated with SGLT2 inhibitors [11,18]. Importantly, no severe adverse events such as diabetic ketoacidosis, severe hypoglycemia, or hospitalisation were observed during the study period.

Absence of a control group limited direct comparison of outcomes attributable solely to SGLT2 inhibitor therapy. The study was conducted at a single tertiary care centre with a relatively small sample size and short duration of follow-up. Therefore, long-term cardiovascular and renal outcomes could not be evaluated. In addition, the observational design limits the establishment of direct causality. Despite these limitations, the study provides valuable real-world evidence regarding the efficacy and safety of SGLT2 inhibitors in Indian patients with T2DM.

Overall, the findings of the present study suggest that SGLT2 inhibitors are effective and safe as add-on therapy in patients with inadequately controlled type 2 diabetes mellitus. In addition to improving glycemic control, these agents demonstrated favorable effects on body weight, blood pressure, and lipid profile with minimal adverse drug reactions.

CONCLUSION

SGLT2 inhibitors were found to be effective and safe as add-on therapy in patients with Type 2 Diabetes Mellitus. Significant reductions in HbA1c, fasting blood sugar, body weight, BMI, and blood pressure were observed after three months of treatment. Favorable changes in lipid profile, particularly increased HDL-C and reduced triglycerides, were also noted. Adverse drug reactions were minimal and mild in nature. Overall, SGLT2 inhibitors provided good glycemic and metabolic benefits with an acceptable safety profile.

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