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Observational Study to Assess Safety of SGLT2 Inhibitors in Type 2 Diabetes Mellitus Patients in Clinical Settings

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KEYWORDS

SGLT 2 inhibitors; Type 2 diabetes mellitus; adverse events; post-marketing surveillance; observational study

ABSTRACT:

Introduction: Type 2 diabetes mellitus (T2DM) poses a significant global burden. Sodium-glucose co-transporter 2 (SGLT2) inhibitors have emerged as promising agents for glycemic control with additional cardiovascular and renal benefits. However, real-world safety data remain limited.

Objectives: To assess the safety profile of SGLT2 inhibitors in Indian clinical settings through active monitoring of adverse events in patients with T2DM.

Methods: A multicentric, prospective observational study was conducted at four hospitals in Pune, Maharashtra and one hospital at Trichy, Tamilandu in India. A total of 500 patients with T2DM receiving SGLT2 inhibitors alone or in combination with other antidiabetic drugs were enrolled and followed for 26 weeks. Adverse events were actively monitored and evaluated. The baseline and week 26 weeks HbA1c were monitored to check the effectiveness of treatment.

Results: The most frequently reported adverse event was genital mycotic infection (9.4%), followed by urinary tract infection (5.2%). Other AEs included ketoacidosis (2.0%), hypotension (1.8%), hypovolemia (1.4%), dehydration (1.2%), and hypoglycemia (1.0%). There was a significant mean reduction in HbA1c from 8.93% to 7.36% over 26 weeks (Δ = 1.57%).

Conclusions: This real-world study confirms that SGLT2 inhibitors are effective in lowering HbA1c in Indian T2DM patients, with an overall acceptable safety profile. While genital and urinary infections were the most common adverse events, serious events like ketoacidosis and hypotension were rare. These findings support the continued use of SGLT2 inhibitors with appropriate monitoring in routine clinical practice.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by persistent hyperglycemia due to insulin resistance and/or impaired insulin secretion. The global prevalence of T2DM continues to rise, with India bearing a significant portion of this burden. The condition is strongly associated with cardiovascular and renal complications, contributing to substantial morbidity and healthcare costs worldwide[1].

Traditional antidiabetic therapies such as metformin, sulfonylureas, thiazolidinediones, and insulin have been the mainstay of treatment for decades. While these agents help lower blood glucose levels, they are often associated with limitations, including weight gain, hypoglycemia, and limited impact on cardiovascular outcomes[2,3]. In

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contrast, sodium-glucose co-transporter 2 (SGLT2) inhibitors represent a novel class of oral antidiabetic drugs that lower blood glucose by promoting urinary glucose excretion through inhibition of glucose reabsorption in the renal proximal tubules[4,5].

SGLT2 inhibitors offer several benefits beyond glycemic control. Clinical trials have demonstrated improvements in body weight, blood pressure, arterial stiffness, and lipid profiles[6,7]. More importantly, landmark trials such as EMPA-REG OUTCOME, CANVAS, and DECLARE-TIMI 58 have shown that these agents significantly reduce the risk of cardiovascular events and slow the progression of diabetic kidney disease[8–10]. Based on these findings, international guidelines recommend SGLT2 inhibitors as preferred second-line agents for patients with cardiovascular or renal comorbidities[11].

Despite these benefits, the safety profile of SGLT2 inhibitors warrants careful consideration. The induction of glycosuria increases the risk of genital mycotic infections and urinary tract infections, particularly in females and those with a history of such infections[12,13]. Additionally, post-marketing surveillance has identified serious adverse events, including euglycemic diabetic ketoacidosis (DKA), hypotension, volume depletion, and rare cases of Fournier's gangrene[14–16]. The U.S. FDA and other regulatory authorities have issued safety communications highlighting these risks[9].

Most safety and efficacy data for SGLT2 inhibitors have been derived from controlled clinical trials. However, there remains a paucity of real-world evidence, especially in Indian clinical settings, where factors such as polypharmacy, patient comorbidities, and treatment adherence may differ significantly from trial populations[17]. Therefore, this study was undertaken to assess the real-world safety profile of SGLT2 inhibitors in Indian patients with T2DM, with a focus on adverse events, treatment efficacy, and prevailing prescription trends.

2. Objectives

Primary Objective:

1) To record and analyze safety incidences (adverse events) reported by patients during routine clinical treatment with SGLT2 inhibitors.

Secondary Objectives:

2) To evaluate efficacy of SGLT2 inhibitors over a 26-week treatment period.

3) To identify treatment preferences among different SGLT2 inhibitors.

3. Methods

3.1 Study Design and Setting

This was a prospective, multicentre, observational cohort study planned at MAEER's Vishwaraj Hospital, Pune (Maharashtra (MH), India), Indo-German Diabetes Clinic, Hadapsar, Pune (MH, India); Cardio-Diabetes Clinic, Undri-Pisoli, Pune (MH, India); Prabhu Diabetes Specialty Centre, a unit of Prabhu Nursing Home, Trichy Tamilnadu (TN, India), and Shaurya Clinic Pisoli, Pune, (MH, India). All sites were high-volume diabetes centers with electronic medical-record (EMR) systems, facilitating standardized data capture. The full study protocol, informed-consent form and supporting documents received approval from the MAEER's Vishwaraj Hospital, Pune Institutional Ethics Committee (IEC) before initiation, and the study was conducted in accordance with the ICH-GCP E6(R2) guidelines.

3.2 Study Population

Adults (≥18 years) with uncontrolled type 2 diabetes mellitus (T2DM), or T2DM with established cardiovascular disease (CVD), who had received at least one dose of a sodium–glucose cotransporter-2 (SGLT2; empagliflozin, dapagliflozin, canagliflozin, remogliflozin, etc.) inhibitor (monotherapy or in combination;) and attended the outpatient department were screened.

A target sample size of ≥500 patients was set to provide stable descriptive estimates of adverse-event (AE) frequencies; no formal power calculation was required because hypothesis testing was limited to exploratory comparisons.

3.3 Enrolment and Follow-up Procedures

Eligible patients were approached consecutively during routine visits. After written informed consent, baseline demographic, clinical and laboratory data were extracted from the EMR and obtained from the patient. Each participant was followed for 26 weeks (±7 days) or until 7 days after permanent discontinuation of the SGLT2 inhibitor, whichever occurred first. Follow-up

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assessments coincided with routine clinic visits at approximately 3 and 6 months; interim telephone contacts were allowed for AE reporting.

3.4 Data Collection

A standardized paper case-report form captured:

- **Demographics:** age, sex, ethnicity, height, weight, body-mass index (BMI).
- **Clinical parameters:** diabetes duration, diabetic complications (retinopathy, neuropathy, foot ulcer), comorbidities, blood-pressure, heart rate.
- **Laboratory measures:** fasting plasma glucose and HbA1c
- **Medication history:** current and prior antidiabetic agents (class, dose, schedule), cardiovascular or nephroprotective drugs, and all concomitant therapies.
- **Adverse events:** description, onset/stop dates, seriousness, outcome, relationship to SGLT2 inhibitor, management and causality assessment (per WHO-UMC criteria).

3.5 Outcome Measures

The outcome measures included proportion of patients experiencing any AE within 26 weeks, with active surveillance for predefined safety signals (lower-limb amputation, ketoacidosis, acute kidney injury, Fournier's gangrene, etc.) plus any newly emerging AE not listed in current product labelling.

3.6 Statistical Analysis

Data cleaning and statistical analyses were performed. Continuous variables are expressed as mean ± standard deviation (SD) or median (inter-quartile range) as appropriate, categorical variables as counts and percentages.

- Categorical outcomes (AE incidence) were compared with χ^2 or Fisher's exact test.
- Between-group comparisons of continuous outcomes (e.g., change in HbA1c from baseline to 26 weeks) employed two-tailed paired or unpaired Student's t-tests ($\alpha = 0.05$).

3.7 Quality Assurance and Data Security

Source documents were periodically monitored against the electronic database for accuracy and completeness. All data were anonymized and stored in password-protected study personnel folders.

3.8 Ethical Considerations

The study adhered to national ethical requirements (Indian Council of Medical Research [ICMR] 2017 guidelines). Participants could withdraw at any time without effect on standard care.

4. Results

The study enrolled a total of 500 patients with type 2 diabetes mellitus. The mean age of the participants was 54.2 years (standard deviation ±12), with an age range of 27 to 92 years, reflecting a middle-aged to elderly population typically affected by T2DM. In terms of sex distribution, 275 participants (55.0%) were male and 225 (45.0%) were female, indicating a slightly higher male predominance in the cohort.

Table 1: Demographic Summary (N = 500)

Variable	Mean	SD	Min	Median	Max
Age (yrs)	54.2	12.0	27	54.0	92
Height (cm)	162.0	9.7	104	163.0	190
Weight (kg)	70.9	14.2	39.4	68.0	138.0
BMI	27.0	4.9	16.7	26.1	50.9

The mean duration of diabetes in the cohort was 7.13 years (SD ±3.55), with a median of 6.6 years. The interquartile range (IQR) was 4.9 years, indicating moderate variability in the duration of illness. At baseline, all 500 study participants had a diagnosis of type 2 diabetes mellitus, as per the inclusion criteria. (Table 2) Hypertension was the most prevalent comorbidity, observed in 52.8% of the cohort, followed by a history of cerebrovascular events (22.8%) and neuropathic pain (17.8%). Peripheral neuropathy and multivitamin deficiencies were each present in 7.2% of subjects. Other notable conditions included hypothyroidism (5.8%), anxiety disorders (5.4%), and dyslipidaemia (5.4%). Micronutrient-related disorders, including various vitamin deficiencies, were common, affecting over 12% of patients in total. Less frequent conditions such as coronary artery disease, depression, and asthma were also reported.

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Table 2 : Baseline Medical-History Profile of the Study Cohort (N = 500)

Rank	Medical-history condition†	Prevalence, %
1	Diabetes mellitus (index disease)	100
2	Hypertension	52.8
3	Stroke / Cerebro-vascular accident	22.8
4	Neuropathic pain	17.8
5	Peripheral neuropathy	7.2
6	Multivitamin deficiency	7.2
7	Hypothyroidism	5.8
8	Anxiety disorders	5.4
9	Dyslipidaemia	5.4
10	Gastro-oesophageal reflux disease (GERD)	5
11	Vitamin deficiency (unspecified)	3.6
12	Fungal infection	3.6
13	Diabetic neuropathy (clinically diagnosed)	2
14	Coronary artery disease (CAD)	1.8
15	Nutritional deficiency (unspecified)	1.6
16	High cholesterol (hypercholesterolaemia)	1.2
17	Depression	1
18	Lower-cholesterol therapy history	1
19	Vitamin D ± calcium deficiency	0.8
20	Asthma / chronic lung disease	0.4
21–41	Other single-subject conditions§	1.8

Note: § The 21 additional conditions each occurred in one subject (0.2 %) and are combined for concise presentation. Less common baseline illnesses (≤ 1 % each) included COPD, coronary-plaque, heart-failure, angina and haemorrhoids; these are grouped as "other" in the summary table for brevity

A total of 500 patients were prescribed SGLT2 inhibitors, either as monotherapy or in combination with other anti-diabetic agents. Of these, 130 patients received SGLT2 inhibitors alone, with Dapagliflozin 10 mg being the most commonly used (105 patients), followed by Remogliflozin Etabonate 100 mg (13 patients). Combination therapy with Biguanides was prescribed to 27 patients, predominantly involving Remogliflozin Etabonate and Metformin. A larger group of 128 patients received SGLT2 inhibitors in combination with DPP-4 inhibitors, with the combination of Dapagliflozin 10 mg and Vildagliptin 100 mg being the most frequent (46 patients). The highest number of patients (215) were prescribed a triple combination of SGLT2 inhibitor, DPP-4 inhibitor, and Biguanide, with Remogliflozin Etabonate 100 mg + Vildagliptin 50 mg + Metformin 500 mg used in 208 patients.

Narrative Summary of Adverse Events (AEs)

Adverse events (AEs) were systematically captured for all 500 study participants. Among them, 95 patients (19%) reported at least one AE of interest during the treatment period. The most frequently reported event was genital mycotic infections, occurring in 47 patients (9.4%), which aligns with known effects of SGLT2 inhibitors due to glycosuria and altered local immunity.

Other notable AEs included urinary tract infections (UTIs) in 24 patients (4.8%), and diabetic ketoacidosis (DKA) in 9 patients (1.8%), a serious but rare class-related adverse outcome. Additional events included hypotension (8 patients, 1.6%) and hypovolemia (7 patients, 1.4%), likely related to the osmotic diuretic effect of the drug class.

To evaluate the statistical significance of adverse event (AE) incidence, both the Chi-squared (χ^2) test and Fisher's exact test were applied. Out of 500 study participants, 109 patients (21.8%) reported at least one AE, while 391 patients (78.2%) did not report any AE of interest during the treatment period.

The Chi-squared test yielded a χ^2 statistic of 407.404 ($p < 0.0001$), and Fisher's exact test confirmed a statistically significant association (*odds ratio* = 0.088, $p < 0.0001$). These findings indicate that the observed frequency of AEs was highly unlikely to have occurred by chance.

The statistical outcome reinforces the importance of close monitoring for known class-related adverse effects associated with SGLT2 inhibitors, especially in real-world clinical settings. The low odds ratio suggests that while AEs were not widespread, when they did occur, they were significantly associated with the pharmacological effects of the drug class.

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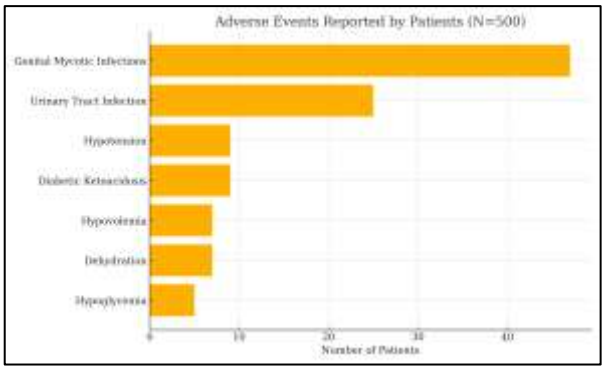
Figure 1: Reported Adverse Events Among Study Participants (N=500)



The change in glycosylated hemoglobin (HbA1c) levels from baseline (enrollment visit) to Visit 3 was analyzed in a paired manner among all 500 study participants who had complete data. The mean HbA1c at enrollment was notably elevated, reflecting the uncontrolled diabetic status of the cohort. Following treatment with SGLT2 inhibitors, either alone or in combination with other antidiabetic agents, a statistically significant reduction in HbA1c was observed.

The mean change in HbA1c was –1.51% (SD ±3.95). A paired Student's *t*-test demonstrated that this reduction was highly significant ($t = -8.542$, $p < 0.0001$), indicating a consistent improvement in glycemic control over the follow-up period.

5. Discussion

This multicenter observational study investigated the safety and tolerability of sodium-glucose co-transporter 2 (SGLT2) inhibitors in a real-world cohort of 500 Indian patients with type 2 diabetes mellitus (T2DM). The primary aim was to assess the incidence and pattern of adverse events (AEs) associated with SGLT2 inhibitor therapy, while secondary objectives included evaluating glycemic outcomes and prescription preferences.

The most commonly reported adverse events were genital mycotic infections (9.4%) and urinary tract infections (UTIs) (4.8%). These findings are consistent with known effects of SGLT2 inhibitors, as glycosuria creates a favorable environment for fungal and bacterial growth[12–13]. Clinical trials and meta-analyses have similarly reported higher incidence rates of genital infections among SGLT2 inhibitor users, particularly in females and those with prior history of infections[4–5].

Notably, cases of mild diabetic ketoacidosis (DKA) (1.8%), hypotension (1.6%), and hypovolemia (1.4%) were also observed. These events reflect the osmotic diuretic and caloric loss effects of SGLT2 inhibitors, which may lead to intravascular volume depletion, especially in patients with renal impairment or those receiving diuretics[6–8]. The U.S. FDA has issued warnings regarding SGLT2 inhibitor-associated DKA and advises careful monitoring, particularly during acute illness or surgery[9].

The incidence of hypoglycemia remained low (1.0%), consistent with prior evidence indicating that SGLT2 inhibitors, when not combined with insulin or sulfonylureas, pose a minimal risk of hypoglycemia due to their insulin-independent mechanism of action[10–12]. This safety advantage has been validated in multiple clinical trials and meta-analyses.

In terms of efficacy, a significant mean HbA1c reduction of 1.57% over 26 weeks ($p < 0.0001$) was observed, supporting real-world effectiveness of SGLT2 inhibitors. This magnitude aligns well with previously published trials, which report average HbA1c reductions of 0.5% to 1.0% depending on baseline glycemia and treatment combinations[13–15].

Among the prescribed regimens, the triple-drug combination of Remogliflozin Etabonate + Vildagliptin + Metformin was most common, suggesting a trend towards multidrug strategies in Indian clinical practice. This may reflect the need to target multiple metabolic pathways to achieve glycemic goals in complex T2DM cases[16].

While the majority of patients experienced a decline in HbA1c, the wide range suggests heterogeneity in treatment response, including a few cases with marked increases likely due to poor adherence, disease progression, or other clinical factors. These results support the effectiveness of SGLT2 inhibitors in improving glycemic outcomes in a real-world cohort of patients with uncontrolled type 2 diabetes mellitus.

Importantly, our findings mirror safety signals identified in global clinical trials (e.g., EMPA-REG OUTCOME, CANVAS, DECLARE-TIMI 58), but with valuable real-world context from Indian patients[8–10]. This emphasizes the need for context-specific post-marketing surveillance and supports the continued use of SGLT2 inhibitors with appropriate patient education and monitoring.

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6. Conclusion:

This prospective observational study confirms that SGLT2 inhibitors are generally well-tolerated and effective in improving glycemic control among Indian patients with type 2 diabetes mellitus in real-world clinical settings. Genital and urinary tract infections were the most frequently observed adverse events, but their incidence was manageable with appropriate patient education and prompt treatment. The low occurrence of serious AEs such as ketoacidosis and hypotension underscores the importance of individualized risk assessment, particularly in elderly patients or those with predisposing conditions. The observed reduction in HbA1c further supports the clinical benefit of SGLT2 inhibitors, whether used alone or in combination with DPP-4 inhibitors and biguanides. Given the increasing adoption of SGLT2 inhibitors in diabetes management, this study provides important real-world evidence to guide clinicians on safe prescribing practices and AE surveillance in diverse patient populations. Continued post-marketing monitoring and larger population-based studies are recommended to further refine the safety profile of this therapeutic class in the Indian context.

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