



Research Article

Real-World Drug Utilization of Fixed-Dose Combination Sitagliptin, Dapagliflozin, and Metformin in Type 2 Diabetes Mellitus Across Clinics in India: A Multicentric Observational Study

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Abstract

Objective: To evaluate the real-world clinical use of FDC of Sitagliptin + Dapagliflozin + Metformin in patients with T2DM across India.

Methods: This multicenter, cross-sectional, observational study was conducted across 157 clinics in India from Oct 2023 to Apr 2024. Medical records of 774 patients with T2DM who were prescribed FDC of sitagliptin + dapagliflozin + metformin were analyzed. Data included demographic data, comorbidities, medical history, and laboratory values. Descriptive statistical analysis was performed. Approval was obtained from the Independent Ethics Committee prior to study initiation.

Results: Among 774 patients (mean age: 54.3±10.2 years; 64.7% male), 35.9% were treatment-naïve, while 59.6% had been switched from other antidiabetic therapies. The most common comorbidities were obesity (45.1%), cardiovascular disease (44.2%), and dyslipidemia (32.3%). The mean HbA1c was 8.47±1.28%, suggesting suboptimal glycemic control prior to FDC initiation. Nearly half (48.2%) of the participants reported a family history of diabetes. Concomitant prescriptions included antihypertensive agents (43.9%) and statins (21.1%). The incidence of hypoglycemia was low (0.09%) in this study.

Conclusion: Sitagliptin + Dapagliflozin + Metformin FDC is being adopted in India for both treatment-naïve and previously treated patients, particularly those with multiple comorbidities. Its clinical use reflects a shift towards combination therapies that provide broader metabolic and cardiovascular benefits in real-world practice.

Keywords: Type 2 Diabetes Mellitus; Sitagliptin; Dapagliflozin; Metformin; Fixed-Dose Combination; Real-World Study; India

Introduction

Type 2 diabetes mellitus (T2DM) is a major public health challenge in India, with over 100 million adults affected. Its progressive pathophysiology, characterized by insulin resistance, declining β -cell function, increased hepatic glucose output, and enhanced renal glucose reabsorption, necessitates early and sustained intervention with combination therapy [1].

Metformin remains the cornerstone of T2DM management due to its ability to reduce hepatic gluconeogenesis, enhance peripheral insulin sensitivity, and provide long-term cardiovascular safety. However, monotherapy with metformin often fails to provide durable glycemic control, highlighting the need for additional agents targeting complementary pathways [2].

Sitagliptin, a selective dipeptidyl peptidase-4 (DPP-4) inhibitor, enhances incretin activity, thereby stimulating insulin secretion and suppressing glucagon in a glucose-dependent manner [3,4]. Dapagliflozin, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, reduces renal glucose reabsorption and promotes glycosuria, with additional benefits such as modest weight loss, blood pressure reduction, and cardio-renal protection [5,6], in combination with metformin this triple combination—metformin, sitagliptin, and dapagliflozin—offers a complementary and synergistic approach to glycemic control by targeting different pathophysiological mechanisms in type 2 diabetes: hepatic glucose overproduction, impaired incretin response, and renal glucose reabsorption. This multi-targeted strategy provides more comprehensive and durable glycemic control compared with monotherapy, while also delivering metabolic and cardiorenal advantages [7-10].

This fixed-dose combination (FDC) not only provides pathophysiological complementarity but also reduces pill burden, thereby potentially improving adherence in patients who would otherwise require multiple medications [10]. Clinical trials—including CompoSIT-R [11] (sitagliptin + metformin), DECLARE-TIMI 58 [12] (dapagliflozin), and an Indian phase 3 trial of dapagliflozin + sitagliptin + metformin XR [10] have demonstrated significant benefits in glycemic control and cardio-renal outcomes. These findings underscore the value of early and comprehensive combination therapy in Indian patients, many of whom present late with poorly controlled diabetes and a high cardiometabolic risk.

Despite these encouraging data, there is a paucity of large-scale, real-world evidence on how this triple FDC is being prescribed in India, particularly across diverse outpatient practices, in both treatment-naïve and pretreated patients, and in those with multiple

comorbidities. This study addresses this gap by systematically analyzing the clinical profiles, comorbidities, and prescribing patterns of patients initiated on sitagliptin + dapagliflozin + metformin FDC across India. This study aimed to assess the real-world clinical application, prescribing practices, and patient characteristics associated with the FDC of sitagliptin, dapagliflozin, and metformin in patients with T2DM.

Methodology

This was a multicentric, cross-sectional, observational study conducted across 157 outpatient clinics in India between October 2023 and April 2024. The study was designed to evaluate the real-world utilization patterns of the FDC of Sitagliptin + Dapagliflozin + Metformin for the treatment of T2DM.

The study was conducted in accordance with the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, ethical principles originating from the Declaration of Helsinki, International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines, and all applicable local regulatory requirements. Ethics Committee approval was obtained from the Good Society for Ethical Research (EC Registration: ECR/69/Indt/DL/2013/RR-19).

Medical records of patients with a confirmed diagnosis of T2DM who had been prescribed the FDC of Sitagliptin + Dapagliflozin + Metformin by their treating physician were included for analysis. Both treatment-naïve patients and those switched from other antidiabetic therapies were included to reflect real-world practices. Medical records with incomplete or missing data were excluded.

Patient data were extracted from medical records and entered into a structured electronic Case Report Form (eCRF) for analysis. The data captured included demographic characteristics (age, sex, body weight, height, and vital signs), medical and family history, comorbidities, duration of diabetes, lifestyle factors (e.g., smoking and alcohol use), and concomitant drug use. Laboratory parameters, including Fasting Blood Glucose (FBG), Postprandial Glucose (PPG), Glycated Hemoglobin (HbA1c) levels, renal function, and lipid profiles, were also collected.

To ensure data reliability, site investigators received training in eCRF entry, and the data were reviewed for completeness and accuracy by study monitors. Any discrepancies were resolved with the site investigators prior to the database lock, in line with Good Clinical Practice (GCP) standards.

The primary endpoint was to evaluate the real-world use of FDC of sitagliptin + dapagliflozin + metformin FDC in outpatient practice across India. The secondary endpoints included patient demographics, medical history, comorbidities, concomitant medications, and laboratory parameters.

All analyses were descriptive in nature. Continuous variables were summarized using the mean ± Standard Deviation (SD) or median with interquartile range, depending on the distribution. Categorical variables are presented as frequencies and percentages. No inferential statistics or hypothesis testing were performed because of the observational and exploratory nature of the study.

Results

A total of 774 patients were included in this analysis. The average age was 54.3 ± 10.2 years, with the majority of patients falling within the middle-aged group (40–60 years old). Men represented nearly two-thirds of the population (64.7%), reflecting the Gender imbalance often seen in clinic-based Indian cohorts. The mean body weight of 75.6 ± 11.5 kg indicated that many patients were overweight or obese, consistent with the rising prevalence of obesity-driven diabetes in India. The mean pulse rate was 84.7 ± 10.1 bpm. The sociodemographic profile of the study population is presented in (Table 1).

Parameter	Mean ± SD / %	Range
Age (years)	54.3 ± 10.2	26–80
Male sex (%)	64.7	–
Female sex (%)	32.3	–
Weight (kg)	75.6 ± 12.2	41–109
Height (cm)	162.3 ± 11.8	123–191
Systolic BP (mmHg)	134.0 ± 20.7	70–199
Diastolic BP (mmHg)	91.5 ± 18.6	65–160
Pulse rate (bpm)	84.7 ± 10.1	56–115
Duration of diabetes (years)	6.3 ± 5.1	–

Table 1: Baseline Demographic and Clinical Characteristics (N = 774).

Prescription Patterns

Notably, 278 patients (35.9%) were prescribed sitagliptin + dapagliflozin + metformin as their first-line therapy (drug-naïve patients), underscoring the growing conviction of Indian physicians in initiating patients directly on a triple FDC. Most patients (461, 59.6%) were switched from various other regimens, including DPP4i, SGLT2i, Sulphonylurea and TZDs. This switch frequently occurred because patients had suboptimal control or tolerability concerns. The data highlight a real-world shift away from sulphonylurea-based combinations toward safer, more effective, and cardio metabolically protective options. The prescription patterns are shown in (Figure 1).

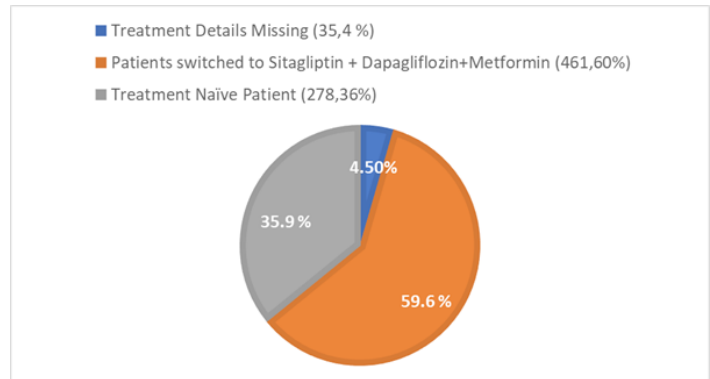


Figure 1: Prescription pattern of sitagliptin + dapagliflozin + metformin.

Glycemic Status

The average baseline HbA1c of 8.47 ± 1.3% confirmed inadequate control at the time of FDC initiation. Both fasting (185.7 ± 59.2 mg/dL) and postprandial (281.3 ± 73.4 mg/dL) glucose levels were elevated, indicating the need for more intensive therapy. The use of triple FDC in such patients illustrates its perceived role in delivering rapid and sustained glycemic benefits. (Table 2) shows the glycemic status.

Parameter	Mean ± SD	Range
Fasting blood glucose (mg/dL)	185.7 ± 59.2	82–474
Postprandial glucose (mg/dL)	281.3 ± 73.4	76–552
HbA1c (%)	8.5 ± 1.3	5.4–13

Table 2: Glycemic Status.

Comorbidities and Risk Profile

The most frequent comorbidities were obesity (45.1%), cardiovascular disease (44.2%), and dyslipidemia (32.3%). Other conditions included chronic kidney disease (10.1%), anxiety/depression (11.9%), obstructive sleep apnea (5.0%), and osteoporosis (6.3%). Additional medical history findings included recurrent urinary tract infections (7.6%), shortness of breath (6.8%), chest pain (10.3%), and physical activity limitations (24.9%). Hospitalization for any cause in the previous year was reported in 4.7% of patients. A family history of diabetes was present in 48.2% of the patients, and 27.9% reported smoking or tobacco use. (Figure 2) illustrates the distribution of comorbidities in the study population.

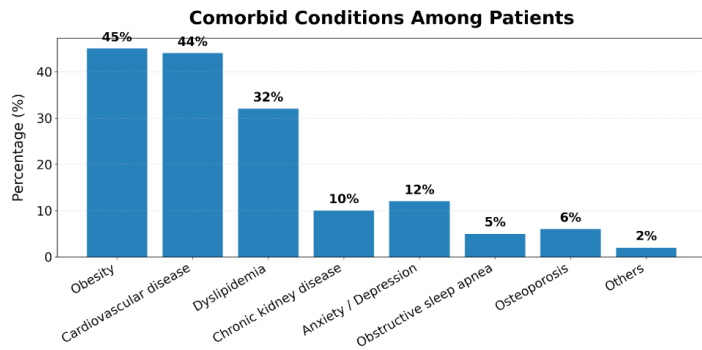


Figure 2: Distribution of comorbidities in study population.

Lipid abnormalities were widespread: Mean total cholesterol, LDL cholesterol, and triglyceride levels were 202 mg/dL, 122 mg/dL, and 207 mg/dL, respectively, with only the HDL cholesterol remaining in an acceptable range (mean 66 mg/dL). Renal function tests showed a mean serum creatinine level of 1.9 mg/dL. (Table 3) shows the laboratory parameters of the study population.

Parameter	Mean ± SD	Range
Serum creatinine (mg/dL)	1.9 ± 3.0	0.02–18.2
Serum albumin (g/dL)	3.9 ± 1.3	1–6.8
BUN (mg/dL)	19.6 ± 6.7	10–34
Total cholesterol (mg/dL)	202.0 ± 60.4	52–409
LDL-C (mg/dL)	122.5 ± 58.3	27–321
HDL-C (mg/dL)	65.6 ± 43.4	22–260
Triglycerides (mg/dL)	207.4 ± 85.0	66–504

Table 3: Laboratory Parameters of the Study Population.

Concomitant Medications

Management strategies extend beyond glucose control. Many patients received additional therapies: 43.9% took antihypertensives, predominantly telmisartan, and 21.1% were prescribed statins. (Figure 3) illustrates the use of concomitant medications in the study population.

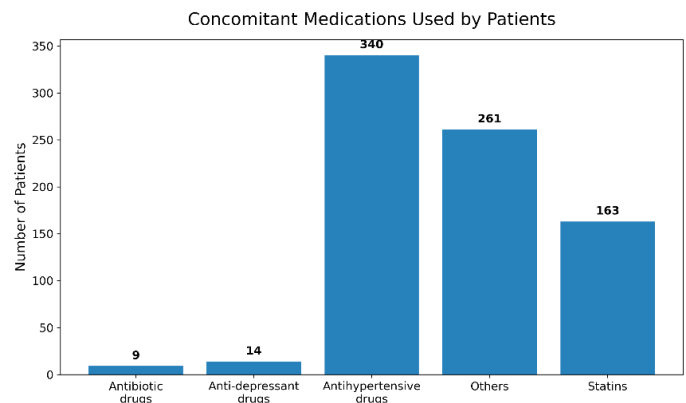


Figure 3: Concomitant medication uses in the study population.

Safety Outcomes

The number of hypoglycemic episodes reported in the past year was 76 in total, corresponding to an overall incidence of 0.09%. The episodes ranged from 1 to 7 per patient, with a mean of 2.38 ± 1.50 and a median of 2 episodes. All events were mild, self-limiting, and did not require hospitalization. This low rate is consistent with the glucose-dependent mechanisms of sitagliptin and dapagliflozin, supporting the favorable safety profile of the triple FDC in real-world practice. (Table 4) shows the hypoglycemia episodes reported in the past year.

Parameter	Value
Mean episodes	2.38
Median episodes	2
Range (episodes)	1–7

Table 4: Hypoglycemia Episodes Reported in the Past Year.

In summary, sitagliptin, dapagliflozin, and metformin were used in a broad spectrum of patients, including newly diagnosed individuals, those with failure to respond to prior therapy, and those with multiple cardiometabolic comorbidities. The elevated baseline HbA1c, high prevalence of obesity and cardiovascular disease, and minimal hypoglycemia illustrate both the clinical need and appropriateness of this FDC in the real-world Indian setting.

Discussion

This multicenter study provides compelling real-world evidence for the clinical adoption of the Sitagliptin + Dapagliflozin + Metformin FDC in India. Our results demonstrate the extensive use and clinical reasons for its prescription.

In clinical practice, many patients progress beyond metformin monotherapy within a few years of diagnosis. Traditional dual regimens, such as metformin + sulfonylurea or metformin + DPP-4 inhibitor, may initially improve glycemia but are often associated with weight gain, hypoglycemia, or limited durability [13,14]. Several triple therapy options exist for T2DM, the sitagliptin + dapagliflozin + metformin FDC offers a more balanced efficacy–safety profile compared with traditional regimens [12,15]. Combinations such as metformin plus sulfonylurea plus DPP-4 inhibitor may improve glycemic control but are frequently associated with weight gain and an increased risk of hypoglycemia, limiting their long-term acceptability. Similarly, metformin + sulfonylurea + SGLT2 inhibitor regimens improve glycemia and weight but still carry a risk of hypoglycemia due to the sulfonylurea component. GLP-1RA–based triple regimens (e.g., metformin + GLP-1RA + SGLT2 inhibitor) are highly effective for weight loss and cardio-renal benefits, but their high cost and injectable mode of administration often restrict widespread adoption in India [16–18]. In this context, the all-oral, once-daily sitagliptin + dapagliflozin + metformin FDC represents a practical and safe alternative.

The rationale behind this combination is its complementary mechanisms of action: metformin reduces hepatic glucose output, sitagliptin augments incretin-driven insulin secretion, and dapagliflozin promotes urinary glucose excretion while providing benefits for the cardiovascular and renal systems. This multifaceted approach makes it superior to dual therapy, particularly for patients with long-standing or uncontrolled diabetes [15,19].

Our findings are consistent with prior evidence. The CompoSIT-R trial [20] confirmed the effectiveness of adding sitagliptin to metformin, whereas the DECLARE–TIMI 58 [12] trial established the cardiovascular and renal protective effects of dapagliflozin. In addition, the study by Jabbour et al. [21] further demonstrated that dapagliflozin added to sitagliptin (with or without metformin) significantly improved glycemic control and reduced body weight without increasing hypoglycemia risk. In India, phase 3 studies including the dapagliflozin–sitagliptin–metformin XR trial, the MESIDA [15] trial, and the randomized study by Sahay et al. [22] all confirmed the superiority of triple therapy over dual therapy. Most recently, a large multicenter trial published in *Advances in Therapy* (2025) [10] demonstrated that dapagliflozin + sitagliptin + metformin was significantly more effective than sitagliptin + metformin in lowering HbA1c, fasting plasma glucose, and body

weight in Indian patients uncontrolled on metformin monotherapy, further validating our real-world findings.

From the patient’s perspective, the triple FDC offers distinct advantages. Many Indian patients face challenges of polypharmacy, particularly in the presence of hypertension and dyslipidemia [23]. A once-daily FDC reduces pill burden, simplifies therapy, and may enhance adherence [24]. Another important observation is the very low rate of hypoglycemia, which is reassuring in populations with high cardiometabolic risk [25].

The implications for clinical practice are significant. In India, where many patients present late with poor glycemic control and multiple comorbidities, there is a growing shift toward earlier use of triple FDCs. This approach aligns with contemporary guidelines emphasizing comprehensive management that integrates glycemic control with cardiovascular and renal protection [26,27].

This study has certain limitations. First, its retrospective and observational design limits the ability to establish causal inferences or assess treatment efficacy over time. Second, the lack of a comparator group prevents direct evaluation of whether the triple FDC offers superior outcomes compared with other therapeutic regimens in similar patient populations. Third, the relatively short observation window does not allow conclusions on long-term glycemic durability, cardiovascular outcomes, or renal protection. Finally, as the study was conducted in urban and semi-urban outpatient clinics, the findings may not fully represent rural or resource-limited settings across India. Despite these limitations, the study provides valuable real-world insights into prescribing practices and patient profiles associated with the use of sitagliptin + dapagliflozin + metformin FDC in India.

Conclusion

The study demonstrates that sitagliptin + dapagliflozin + metformin FDC is not only effective and safe in diverse Indian patient populations but also has the potential to transform diabetes management by simplifying therapy and addressing the multiple cardiometabolic needs of patients. Prospective studies are needed to assess the long-term cardiovascular and renal outcomes in these populations.

Ethics Approval Statement

The work presented in this study was in accordance with the study protocol, the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, the ethical principles that have their origin in the Declaration of Helsinki, International Council for Harmonisation (ICH) Good Clinical Practice (GCP), and all applicable local regulatory requirements. Independent Ethics Committee approval was obtained prior to study initiation and data collection

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Conflict of Interest Statement

Sumit Bhushan, Rahee Borulkar, Amey Kamble and Saiprasad Patil are employees of Glenmark. All other investigators/authors have no conflicts of interest that are directly relevant to the content of this article.

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