



Research Article

# Real-world Drug Utilization of Fixed-Dose Combination of Sitagliptin + Dapagliflozin in Type 2 Diabetes Mellitus Patients Across India: A Cross-sectional Multicenter Study

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## Abstract

**Objective:** To assess real-world prescribing patterns of Sitagliptin + Dapagliflozin FDC in T2DM patients in India. **Methods:** This multicentre, cross-sectional observational study was conducted across 100 clinics in India from January to June 2024. Medical records of 873 patients with T2DM who were prescribed FDC of sitagliptin (100 mg) + dapagliflozin (10 mg) were analysed. **Results:** A total of 873 patients were analysed with mean age was  $55.26 \pm 11.46$  years and 66.3% males. The duration of diabetes was  $7.02 \pm 5.86$  years. About one-third of patients (36.8%) were treatment-naive, while 62.8% were switched from prior oral therapy due to poor glycemic control and comorbidities. The FDC was most often combined with metformin, with limited use in triple therapy or alongside insulin in advanced cases. Obesity (44.9%), cardiovascular disease (44.8%), and dyslipidemia (33.6%) were prevalent comorbidities. Family history of diabetes was reported by 47.9%, and 18.9% had a personal history of smoking. Concomitant drugs were commonly prescribed, among which antihypertensives (47.8%) and lipid-lowering/antiplatelet agents (32.3%) were most prominent. Baseline mean HbA1c was  $8.28 \pm 1.25\%$ , fasting plasma glucose  $171.8 \pm 55$  mg/dL, and postprandial glucose  $262.8 \pm 67.7$  mg/dL. Hypoglycemia in the past year had occurred in 24.8% of patients, averaging 2.88 episodes per patient, mainly due to background treatments rather than the FDC. **Conclusion:** Sitagliptin + Dapagliflozin FDCs are rapidly becoming a mainstay of diabetes care in India. Their widespread adoption reflects strong clinician confidence in effective glycemic and metabolic control across diverse patients.

**Keywords:** Type 2 Diabetes Mellitus; Sitagliptin; Dapagliflozin; Fixed-Dose Combination; Real-World Evidence

## Introduction

Type 2 diabetes mellitus (T2DM) is a prevalent, chronic metabolic condition driven by insulin resistance and  $\beta$ -cell dysfunction with impaired glucose regulation. The burden of T2DM is increasing worldwide, and it has enormous implications on morbidity, mortality, and cost to healthcare [1-3]. Due to its chronic nature, early and effective intervention is essential to ensure long-term glycemic control and to prevent long-term complications [4,5].

The American Diabetes Association (ADA) guidelines recommend individualized treatment strategies based on comorbidities, patient preferences, and access, with metformin typically being the preferred first-line therapy. Owing to the inevitable progressive loss of  $\beta$ -cell function, monotherapy tends to prove inadequate, and early combination therapy is required to attain and maintain glycemic goals. Notably, in those with atherosclerotic cardiovascular disease (ASCVD), increased ASCVD risk, chronic kidney disease (CKD), or heart failure (HF), the guidelines stress the use of medications with established cardio-renal benefit, specifically sodium-glucose cotransporter-2 inhibitors (SGLT2is) and dipeptidyl peptidase-4 inhibitors (DPP-4is) [6-9].

Evidence from randomized clinical trials supports the early use of combination therapy in individuals with newly diagnosed T2DM. In addition to DPP-4is, SGLT2is have become a valuable therapeutic category in the management of T2DM. Through the inhibition of glucose reabsorption by the renal proximal tubule, these drugs enhance urinary glucose excretion, thereby decreasing blood glucose levels, reducing body weight, and lowering blood pressure. Increasing evidence suggests that SGLT2is are effective in cardiovascular and renal protection [10].

Large trials and real-world database analyses have demonstrated that SGLT2is treatment is linked to decreases in heart failure hospitalization, major adverse cardiovascular events, and all-cause mortality, at times even when it is compared with metformin as initial therapy [11]. When used in combination with other antidiabetic medications, such as DPP-4is and SGLT2is, these can provide additive benefits. Recent meta-analysis and systematic review illustrated that body weight reduction, together with the improvement of glycemic control, was achieved by the combination of SGLT2i + DPP4i without raising the risk of hypoglycemia or urinary tract infections [12,13].

In the Asian-Indian population, combination therapy is especially relevant. The population is marked by higher insulin resistance, reduced  $\beta$ -cell function, abdominal obesity, and the concurrence of cardiovascular risk factors. The US FDA has licensed SGLT2i + DPP4i fixed-dose combinations and are extensively used in

India to enhance patient compliance and therapeutic efficacy [14]. Nonetheless, real-world evidence concerning their use, especially for the fixed-dose combination of sitagliptin plus dapagliflozin, is limited in the Indian context. In light of these lacunae, the present study aims to analyse the usage pattern of the sitagliptin + dapagliflozin fixed-dose combination (FDC) in actual clinical practice. The results of this study can be useful for prescribers in making informed treatment decisions, enhancing glycemic and cardio-renal outcomes, and improving patient care among the Indian population with poorly controlled T2DM.

## Methodology

This was a multicentric, cross-sectional, observational study conducted across 100 clinical sites in India. Data collection was done between January 2024 and June 2024. The study was designed to evaluate the real-world utilization patterns of the FDC of Sitagliptin and Dapagliflozin 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). The study was approved by a CDSCO-registered Institutional Ethics Committee (Protocol No. NIS/2023/13). As this was a retrospective observational study using anonymised medical records, informed consent was not required.

Data of 873 patients was captured electronically through a validated electronic data capture (EDC) platform. Medical records of patients who were prescribed with FDC of Sitagliptin + Dapagliflozin by the treating physician were included in the analysis. Incomplete information or missing essential data was excluded.

The primary endpoint of this study was to evaluate the clinical use of Sitagliptin + Dapagliflozin FDC in outpatient departments in India. Secondary endpoints were evaluation of demographic data, medical history, and concomitant medications of patients treated with the FDC.

Patient data were collected from medical records and entered into an electronic data capture (EDC) system by investigator staff at each site. All site investigators were provided with standardized training in the EDC process to ensure data accuracy and consistency of entry.

## Statistical Analysis

All of the analyses were descriptive. Continuous data were reported as mean and standard deviation or median and interquartile range, depending on the data distribution. The categorical variables were

reported in frequencies and percentages. No inferential statistical testing was conducted due to the observational nature of the study.

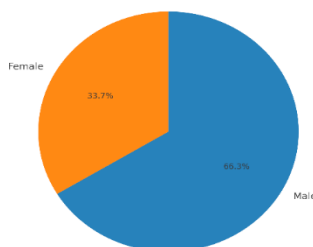
## Results

A total of 873 patients with T2DM were included in this cross-sectional analysis. The mean age of the patients was  $55.26 \pm 11.46$  years, and the average duration of diabetes was  $7.02 + 5.86$  years. The male-to-female ratio was 66% to 34%. The average body weight was  $74.25 \pm 13.79$  kg, average height  $163.05 \pm 15.70$  cm. The mean systolic blood pressure was  $141.06 \pm 19.26$  mmHg, diastolic blood pressure  $87.83 \pm 11.36$  mmHg, and mean pulse rate  $82.44 \pm 11.55$ /min. The sociodemographic profile of the study population is tabulated in (Table 1), and the overall enrolment pattern is shown in (Figure 1).

Parameter	No. of Cases (n)	Mean $\pm$ SD
Age (years)	750	$55.26 \pm 11.46$
Sex		
Male	474	66.00%
Female	255	34.00%
Weight (kg)	722	$74.25 \pm 13.79$
Height (cm)	637	$163.05 \pm 15.70$
Systolic blood pressure (mmHg)	731	$141.06 \pm 19.26$
Diastolic blood pressure (mmHg)	728	$87.83 \pm 11.36$
Pulse rate (bpm)	615	$82.44 \pm 11.55$
Respiratory Rate (breaths/min)	471	$30.40 \pm 26.86$
Duration of diabetes (years)	575	$6.79 \pm 5.29$

**Table 1:** Baseline Demographic Characteristics of the Study Population (N = 873).

Values are expressed as mean  $\pm$  Standard Deviation (SD) or n (%), unless otherwise specified.

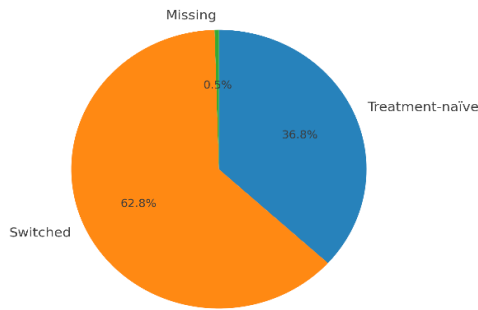


**Figure 1:** Gender distribution of study population.

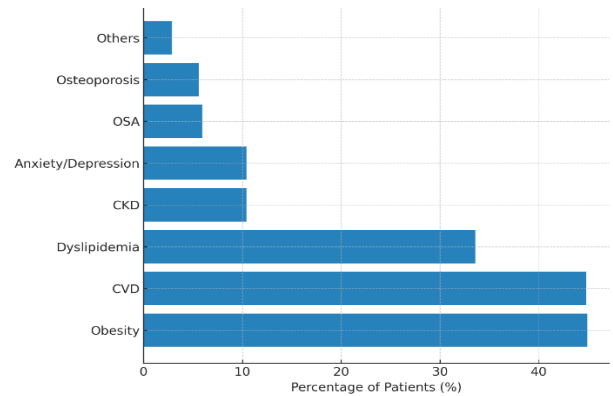
## Prescription Profile

The sitagliptin + dapagliflozin FDC was prescribed extensively in real-world clinical practice in India. Approximately 36.77% of the patients were treatment-naïve and were initiated directly on the FDC, whereas 62.77% were transitioned from previous oral antidiabetic regimens. Among FDCs used prior to switching, the most common were glimepiride + metformin, sitagliptin + metformin, glimepiride + metformin + voglibose, dapagliflozin + vildagliptin, linagliptin + dapagliflozin, and teneligliptin + dapagliflozin.

The main reasons for prescribing the FDC among switch patients were poor glycemic control on prior therapies and the occurrence of cardiovascular or metabolic comorbidities. FDC was most frequently prescribed in combination with metformin, although a large percentage was also prescribed as part of triple therapy (with sulfonylureas or other oral drugs) or in combination with insulin for more severe cases. The distribution of detailed prescription patterns is illustrated in Figure 2.



**Figure 2:** Prescription profile of patients.



**Figure 3:** Comorbidities among the study population.

In our study, the analysis of drug utilization revealed that most patients (62.77%) received various combinations of antidiabetic agents. The drugs commonly used were sitagliptin, glimepiride, canagliflozin, dapagliflozin, metformin, vildagliptin, voglibose, linagliptin, remogliflozin, insulin, empagliflozin, gliclazide, pioglitazone, repaglinide, and teneligliptin. These results are indicative of the therapeutic strategy for T2DM in real-life settings, where clinicians tend to employ combination therapy to achieve the best possible glycemic control and counter the progressive nature of the disease.

In our current investigation, a high percentage of patients with T2DM were found to have comorbid diseases. The most common comorbidity was obesity, seen in 44.90% of the study group, which was followed very closely by cardiovascular disease in 44.79% of the patients.

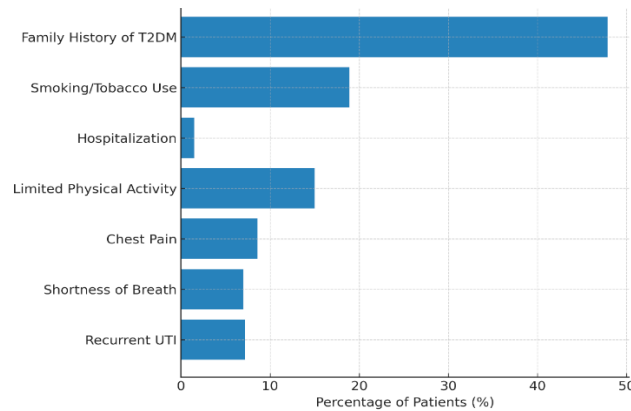
Dyslipidemia was seen in 33.56%, chronic kidney disease and anxiety/depression in 10.42% of the patients each. The less prevalent comorbidities were obstructive sleep apnea (5.96%) and osteoporosis (5.61%). Also, 2.86% of patients reported other medical conditions. These results indicate the high comorbidity burden among T2DM patients, necessitating extensive management approaches beyond glycemic control. The prevalence of comorbid conditions is represented in (Figure 3).

### Medical, Personal, and Family History

The patients' history was systematically collected to identify definitive indications related to their diabetic status. A history of recurrent Urinary Tract Infection (UTI) was noted in 63 patients (7.2%), and 61 patients (6.99%) had a history of shortness of breath. Chest pain was noted in 75 patients (8.59%), and restriction of physical activity was noted in 131 patients (15.01%). Hospitalization due to any reason in the past year was noted by 13 patients (1.49%).

165 patients (18.90%) reported a positive smoking status or a history of tobacco exposure. It emphasizes the role of modifiable lifestyle risk factors in the total disease burden of type 2 diabetes mellitus.

418 patients (47.88%) had a positive family history of diabetes, while 455 patients (52.12%) had no known familial risk. These results highlight the interaction between genetic susceptibility and environmental or lifestyle-related risk factors in the development and progression of type 2 diabetes. These results are shown in (Figure 4).



**Figure 4:** Medical, Personal, and Family History.

Among the biochemical parameters measured, there was poor glycaemic control, with mean fasting blood glucose ( $171.83 \pm 54.96$  mg/dL), postprandial glucose ( $262.81 \pm 67.71$  mg/dL), and HbA1c ( $8.28 \pm 1.25\%$ ) levels significantly above the desired values.

Renal function testing revealed a mean serum creatinine value of  $1.89 \pm 2.16$  mg/dL and a blood urea nitrogen of  $22.61 \pm 7.45$  mg/dL, with serum albumin levels maintained at  $4.86 \pm 1.59$  g/dL.

A lipid profile was abnormal in a significant number of patients, as evidenced by elevated mean triglycerides ( $187.70 \pm 91.04$  mg/dL) and LDL cholesterol ( $112.79 \pm 39.49$  mg/dL), with an average HDL cholesterol level of  $63.41 \pm 36.57$  mg/dL. These results collectively indicate suboptimal glycaemic and metabolic control among study subjects, thereby emphasizing the elevated cardiovascular and renal risk load among type 2 diabetic patients. These findings are presented in (Table 2).

Parameter	N	Range	Mean $\pm$ SD
Fasting Blood Glucose (mg/dL)	751	65 – 440	$171.83 \pm 54.96$
Postprandial Glucose (mg/dL)	756	112 – 490	$262.81 \pm 67.71$
HbA1c (%)	732	5 – 15	$8.28 \pm 1.25$
Serum Creatinine (mg/dL)	191	0.02 – 10.9	$1.89 \pm 2.16$
Serum Albumin (g/dL)	102	1.1 – 8.9	$4.86 \pm 1.59$
Blood Urea Nitrogen (mg/dL)	89	10.2 – 38.1	$22.61 \pm 7.45$
Total Cholesterol (mg/dL)	142	91 – 473	$191.45 \pm 58.23$
LDL Cholesterol (mg/dL)	145	30 – 200	$112.79 \pm 39.49$
HDL Cholesterol (mg/dL)	138	21.6 – 181	$63.41 \pm 36.57$
Triglycerides (mg/dL)	138	52.2 – 485	$187.70 \pm 91.04$

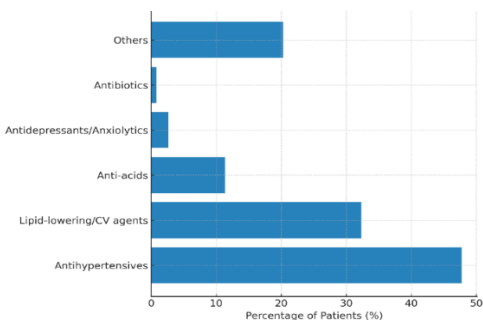
**Table 2:** Biochemical Parameters of the Study Population at the Time of Initiation of Sitagliptin + Dapagliflozin FDC.

In the current study, it was observed that a considerable number of patients needed drugs in addition to antidiabetic treatment to control concomitant comorbidities and complications. Antihypertensive drugs were prescribed to almost half (47.76%) of the patients as monotherapy or in combination due to the high incidence of hypertension in type 2 diabetes patients. Calcium channel blockers, beta blockers, Angiotensin-Converting Enzyme inhibitors, Angiotensin Receptor Blockers, and diuretics were the most commonly used medications.

Lipid-lowering treatments were given to 32.30% of patients, highlighting the high cardiovascular risk in this group. The prescriptions primarily consisted of atorvastatin, rosuvastatin, and fenofibrate, as well as fixed-dose combinations with aspirin or clopidogrel, indicating a preventive strategy aimed at reducing cardiovascular events and stroke.

Gastrointestinal drugs, especially acid-suppressive drugs, were prescribed in 11.34% of patients. The medications most commonly prescribed were proton pump inhibitors (pantoprazole, rabeprazole) and the fixed-dose combinations with prokinetics like domperidone, itopride, and levosulpiride. Psychotropic drugs, such as antidepressants and anxiolytics, were also prescribed to 2.63% of the patients, indicating the presence of mental disorders like depression and anxiety. Antibiotics were also prescribed to 0.80% of the patients, probably for acute infectious diseases.

In total, 20.27% of patients required medications for other indications, indicating that diabetes treatment is often underpinned by multiple comorbid conditions that necessitate complex treatment regimens. These facts are shown in (Figure 5).



**Figure 5:** Concomitant medication use.

### Safety Profile

The incidence of hypoglycemia over the past year showed considerable variability among participants. Out of the total cohort, 157 subjects (20.93%) reported at least one hypoglycemic episode. The number of episodes ranged from 0 to 13, with a mean of  $1.34 \pm 2.19$  and a median of 0, indicating that most individuals experienced no episodes, while a smaller subset had higher frequencies.

### Discussion

The current evidence provides valuable insights into the use of the FDC of sitagliptin and dapagliflozin in patients with T2DM in India. The FDC is very prevalent in clinical practice in patients with poor glycemic control, severe comorbidities, and those who are being switched from other oral antidiabetic treatments.

The study population was representative of the heterogeneity and

complexity of T2DM management in India, with a mean age of  $55.26 \pm 11.46$  years, a mean duration of diabetes of  $7.02 \pm 5.86$  years, and a significant burden of obesity, cardiovascular disease, and dyslipidemia. The prevalence of cardiovascular disease was high and supports the clinical imperative for agents with proven cardio-renal benefits. The use of sitagliptin (a DPP-4i) in combination with dapagliflozin (an SGLT2i) is consistent with global guideline recommendations that favor early combination therapy and prioritize drugs with organ-protective effects in high-risk patients [6,15].

The observation of a relatively high percentage of treatment-naïve patients (36.8%) being started on this FDC represents a paradigm shift towards an early combination therapy approach. This finding aligns with results from randomized trials of sitagliptin plus metformin, which demonstrated that initial combination therapy achieved greater HbA1c reductions and more durable glycemic control compared to monotherapy with either agent [10,11]. These results suggest that early dual therapy may overcome therapeutic inertia and provide more sustained benefits than stepwise treatment intensification. In addition, nearly two-thirds of patients in the present analysis changed from previous regimens, indicating robust clinician faith in the FDC's potential to treat suboptimal control with previous drugs. Comparable findings were noted in the SIDAXA study, a retrospective observational analysis of T2DM in the Indian population, which concluded that sitagliptin–dapagliflozin FDC enhanced glycemic outcomes and was well tolerated among a diverse patient population [16].

At the time of sitagliptin–dapagliflozin FDC initiation, patients demonstrated suboptimal glycaemic control, with a mean HbA1c of  $8.28 \pm 1.25\%$ , fasting blood glucose of  $171.83 \pm 54.96$  mg/dL, and post-prandial glucose of  $262.81 \pm 67.71$  mg/dL, supporting the clinical rationale for initiating combination therapy. The observed baseline glycaemic burden reinforces the need for early use of complementary mechanisms such as DPP-4 and SGLT2 inhibition to improve glycaemic outcomes in real-world Indian patients with T2DM. Compared to metformin plus DPP-4i or metformin plus SGLT2i dual therapy, sitagliptin plus dapagliflozin has shown similar or superior efficacy in reducing HbA1c, promoting weight loss, and providing cardiovascular benefits [17]. A systematic review and meta-analysis by Kim J et al. (2025) highlight the efficacy and safety of combined SGLT2i/DPP4i therapy, with a trend towards improved effectiveness of DPP4i in Asian populations. This combination therapy demonstrated additional benefits in weight reduction and blood pressure compared to DPP4i monotherapy, making it a valuable option for patients with a high metabolic burden [18].

Despite the presence of multiple pharmacological treatments, glycemic control in India is suboptimal. This may be due to the

advanced stage of the disease, a high level of comorbidities, and complex polypharmacy as observed. Most notably, hypoglycemia was experienced by almost one-quarter of patients, though the degree to which these were due to sitagliptin–dapagliflozin compared with background therapies (e.g., sulfonylureas or insulin) cannot be determined. Significantly, earlier studies, including SIDAXA, have all provided evidence that SGLT2i and DPP-4i combinations carry an extremely low risk of hypoglycemia when not combined with insulin or insulin secretagogues [18-21].

The Real DAPSI study further corroborates these observations, a retrospective real-world analysis conducted across healthcare centers in India, which assessed the effectiveness and safety of the fixed-dose combination of dapagliflozin and sitagliptin. The study included 358 patients with T2DM and demonstrated a significant reduction in mean HbA1c from 8.9% to 7.2% over a 12-week ( $p < 0.0001$ ). Substantial improvements were also noted in fasting plasma glucose (from 178.8 mg/dL to 124.0 mg/dL) and postprandial glucose (from 273.9 mg/dL to 176.0 mg/dL). Importantly, no serious adverse events were reported, reinforcing the favorable safety profile of this FDC [22]. The findings of Real DAPSI align well with our study results, collectively supporting the clinical utility of this dual-agent combination for glycemic control and highlighting its potential in routine practice among Indian patients, particularly those with comorbidities and advanced disease.

Our findings also revealed a high rate of concomitant use of antihypertensive and lipid-lowering therapies, reflecting the multifactorial cardiovascular risk management required in T2DM. This observation is consistent with previous Indian and global real-world registries, highlighting that optimal diabetes care necessitates comprehensive management of metabolic, cardiovascular, and renal risk factors, rather than focusing solely on glycemic control [18, 23,24].

Although this research provides strong descriptive information from a large, heterogeneous patient group, several limitations should be noted. Firstly, by being cross-sectional and retrospective in nature, it doesn't allow for the measurement of longitudinal outcomes such as long-term glycemic control, weight loss, or cardiovascular and renal outcomes. Secondly, the use of medical record documentation carries the risk of underreporting or incomplete capture of adverse events. Lastly, the absence of a comparator arm restricts the interpretation of relative safety or effectiveness. Together with SIDAXA [18] and Real DAPSI [24], our study builds a consistent narrative of real-world effectiveness, tolerability, and cardio-renal safety, reinforcing the rationale for considering the dapagliflozin–sitagliptin FDC in a broad spectrum of Indian patients with T2DM.

## Conclusion

This multicenter, real-world study highlights that the fixed-dose combination of sitagliptin and dapagliflozin is widely prescribed both as initial treatment for treatment-naïve subjects and as a switch therapy for inadequately controlled patients on prior regimens. The pattern of prescription indicates its increasing popularity in clinical practice among subjects with more than one comorbidity, including obesity, cardiovascular disease, and dyslipidemia.

These results suggest that sitagliptin + dapagliflozin FDCs are increasingly becoming part of standard diabetes care in India, reflecting confidence among clinicians in their use for the attainment of improved glycemic and metabolic control in various patient 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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