



RESEARCH ARTICLE

DApagliflozin 10 mg and Vildagliptin 100 mg SR use in Cardiology Practice A real world Clinical Insight (DAa-ViNCI Study)

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ABSTRACT

Background: Diabetes mellitus is a global epidemic characterized by persistently high blood sugar levels. The combination of dipeptidyl peptidase-4 inhibitors (DPP-4i) and sodium-glucose cotransporter-2 inhibitors (SGLT2i) is potentially effective in managing type 2 diabetes mellitus (T2DM). The present study analyzed the efficacy, safety, and practice patterns of the fixed-dose (FDC) of vildagliptin 100 mg and dapagliflozin 10 mg in cardiology practice.

Methods: This retrospective, non-randomized, non-comparative, multi-center study was conducted at 200 sites across India from June 2023 to March 2024. Patients of either sex, >18 years of age, diagnosed with T2DM, and who received the FDC of vildagliptin 100 mg SR and dapagliflozin 10 mg for the treatment of their condition were included. Comprehensive patient information collected from the medical records were analyzed.

Results: A total of 2,199 patients were included, with a mean age of 55.04 years. Approximately 63% of the patients were male. Hypertension (74.81%) was the most common comorbidity, followed by dyslipidemia (38.52%). The FDC of vildagliptin 100 mg SR and dapagliflozin 10 mg reduced the mean glycated hemoglobin (7.7% vs 5.8%), fasting plasma glucose (142.4 mg/dL vs 90.2 mg/dL), postprandial glucose (205.64 mg/dL vs 123.38 mg/dL) levels from baseline to 3 months. The mean systolic blood pressure decreased from 141.35 mmHg to 131.59 mmHg, and the mean diastolic blood pressure decreased from 89.65 mmHg to 84.42 mmHg following FDC therapy. Glycemic goals were achieved in 78.08% of patients. Adverse events were reported in 0.36% of patients.

Conclusion: The FDC of vildagliptin and dapagliflozin demonstrated substantial efficacy in managing T2DM and was well-tolerated, with a low incidence of adverse events.

Keywords: Adverse events, comorbidities, efficacy, fixed-dose combination, glycemic control, tolerability, type 2 diabetes mellitus.

Introduction

Diabetes mellitus is a global epidemic characterized by persistently high blood sugar levels.¹ The global prevalence of diabetes was 536.6 million (10.5%) in 2021, and it is projected to reach 783.2 million (12.2%) by 2045.²

Type 2 diabetes mellitus (T2DM) is associated with several physiological abnormalities collectively known as the "ominous octet." These include increased hepatic glucose synthesis, decreased insulin sensitivity, increased insulin secretion, increased lipolysis, increased glucagon secretion, increased renal glucose reabsorption, and dysregulated neurotransmitter modulation.³ However, diabetes is no longer a standalone metabolic disorder—it is intricately linked with cardiovascular (CV) complications from the very onset. Patients with diabetes often present with early CV risk factors such as hypertension and dyslipidemia, setting the stage for progressive vascular damage. The traditional approach of addressing cardiovascular risks only after overt complications emerge is no longer viable. Instead, a paradigm shift towards early, comprehensive intervention is crucial.⁴

Managing diabetes with a focus on early CV risks can significantly alter disease trajectories. Evidence suggests that timely glycemic control combined with CV risk reduction strategies can prevent major adverse cardiovascular events (MACE) and improve long-term outcomes.⁴ The role of novel therapeutic options, such as Fixed-Dose Combinations (FDCs) that address both hyperglycemia and CV risk factors, is becoming increasingly important in this strategy.

In patients with T2DM, fixed-dose combinations (FDC) have proven to be more effective than their individual components.⁵ When taking oral anti-diabetic medications in combination, 58% of participants in an Indian study chose FDC.⁶ The combination of dipeptidyl peptidase-4 (DPP-4) and sodium-glucose cotransporter-2 (SGLT2) inhibitors is potentially effective.⁷ Sodium-glucose cotransporter-2 inhibitors lower blood sugar levels by increasing glucose excretion through urine, without impacting

insulin secretion or action. Dipeptidyl peptidase-4 inhibitors improve glucose control by inhibiting the degradation of active incretin hormones, which boosts insulin secretion and reduces glucagon levels.⁸ Together, these medications address at least six of the eight elements of the "ominous octet".

Among DPP-4 inhibitors, vildagliptin has been extensively researched for its clinical benefits. Its efficacy is noted for its minimal risk of hypoglycemia, lack of weight gain, and no increased risk of cardiovascular events. Both clinical trials and real-world evidence suggest that vildagliptin has a safety and tolerability profile comparable to that of a placebo.⁹

Dapagliflozin, a highly potent and reversible SGLT2 inhibitor, is the main transporter for glucose absorption in the gut. It effectively controls blood sugar levels and reduces blood pressure and body weight, whether used alone or in combination with other antihyperglycemic drugs. Dapagliflozin has attracted attention for its benefits in patients with established atherosclerotic cardiovascular disease or multiple cardiovascular risk factors, offering glycemic control, cardioprotection, and potentially renal protection, while generally maintaining a favorable tolerability profile.^{10,11}

The complementary mechanisms of action of these two drug classes render them suitable treatment options for combination therapy with any glucose-lowering agents, including insulin.¹² However, there is a scarcity of data evaluating the efficacy, safety, and tolerability of the combination of vildagliptin and dapagliflozin in patients with T2DM within the Indian settings. Therefore, this real-world study was conducted to analyze the efficacy, safety, and practice patterns of the FDC of vildagliptin 100 mg and dapagliflozin 10 mg in cardiology practice.

Materials and methods

STUDY DESIGN AND ETHICAL CONSIDERATION

This retrospective, non-randomized, non-comparative, multi-center study was conducted at 200 sites across India from June 2023 to March 2024. The study was

conducted in compliance with the principles of the Declaration of Helsinki. The study protocol received approval from the ACEAS Independent Ethics Committee (Registration no. ECR/281/Indt/GJ/2017).

INCLUSION CRITERIA AND EXCLUSION CRITERIA

Patients of either sex, above 18 years of age, diagnosed with T2DM, and who received the FDC of vildagliptin 100 mg and dapagliflozin 10 mg for the treatment of their condition were included in the study. Additionally, the inclusion criteria required that the treating physician agreed to provide information regarding the participant's treatment. Patients with incomplete data files or with any condition not suitable for inclusion, as indicated by the investigator's discretion were excluded from the study.

SAMPLE SIZE

The estimated sample size was approximately 4,000 patients with T2DM.

DATA COLLECTION

Comprehensive patient information, including demographic characteristics, treatment duration, comorbidities, concomitant medications, and adverse events was collected from medical records authenticated by the treating physicians. The collected data were then entered into the case report forms and analyzed.

STUDY ENDPOINTS

The endpoint of the study was to determine the number and percentage of patients receiving the FDC of vildagliptin 100 mg and dapagliflozin 10 mg; the number and percentage of patients of various age groups receiving the FDC of vildagliptin 100 mg and dapagliflozin 10 mg; the duration of FDC of vildagliptin 100 mg and dapagliflozin 10 mg therapy; the duration of comorbidities; compliance with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg; adverse events reported in last 1-year related to FDC therapy; efficacy and safety parameters including quality of life (adherence and lack of side effects).

STATISTICAL ANALYSIS

Data were analyzed using the Statistical Package for Social Sciences (SPSS) software, version 28. Descriptive analysis was used to present the study outcomes. Continuous variables were described as mean and standard deviation (SD), whereas categorical variables were described as numbers and percentages.

Results

A total of 2,199 patients were included in the study, with a mean age of 55.04 years. The majority of the patients (62.62%) were male. Among the study population, 62.94% of patients were in the 40-60 years age group, followed by 27.47% in the 60-80 years age group. The mean systolic blood pressure (SBP) of the patients was 139.31 mmHg, and the mean diastolic blood pressure (DBP) was 88.15 mmHg. The mean (SD) duration of treatment with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg was 8.07 (3.0) months. Hypertension (74.81%) was the most common comorbidity, followed by dyslipidemia (38.52%), coronary artery disease (CAD, 14.60%), and stroke/transient ischemic attack (TIA, 5.23%). The mean (SD) durations of hypertension and dyslipidemia were 44.85 (39.04) and 40.49 (35.00) months, respectively (Table 1).

Glycemic parameters of the patients from baseline to 3 months are presented in table 2. The mean (SD) HbA1c level decreased from 7.7% (3.1) at baseline to 5.8% (2.88) at 3 months. Similarly, the mean (SD) fasting plasma glucose (FPG) level decreased from 142.4 (88.4) mg/dL at baseline to 90.2 (62.44) mg/dL at 3 months; the mean (SD) postprandial glucose (PPG) decreased from 205.64 (128.0) mg/dL at baseline to 123.38 (89.15) mg/dL at 3 months.

Physician's global assessments are illustrated in Figure 1a and 1b. About 38.88% of physicians reported that the FDC of vildagliptin 100 mg and dapagliflozin 10 mg showed good tolerability, while 35.01% reported very good tolerability. Additionally, 38.06% of physicians observed good efficacy, while 35.29% reported very good efficacy.

Table 1: Demographic characteristics of patients

Parameters	Number of patients (N=2199)
Age (years)	55.04 (10.68)
Age groups (years), n (%)	
20-40	173 (7.87)
40-60	1384 (62.94)
60-80	604 (27.47)
>80	38 (1.73)
Gender, n (%)	
Male	1377 (62.62)
Female	822 (37.38)
Height (cm)	163.81 (9.21)
Weight (kg)	75.55 (11.32)
BMI (kg/m ²)	28.23 (4.20)
SBP (mmHg)	139.31 (12.23)
DBP (mmHg)	88.15 (6.27)
Duration of T2DM (years)	6.09 (4.26)
Duration of treatment with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg (months)	8.07 (3.00)
Comorbidity, n (%)	
Hypertension	1645 (74.81)
Dyslipidemia	847 (38.52)
CAD	321 (14.60)
Stroke/TIA	115 (5.23)
NAFLD	95 (4.32)
Retinopathy	77 (3.50)
Nephropathy	69 (3.14)
Foot ulcer	34 (1.50)
Erectile dysfunction	16 (0.73)
PAD	14 (0.64)
Other	27 (1.22)
Duration of comorbidity (months)	
Hypertension	44.85 (39.04)
Dyslipidemia	40.49 (35.00)
CAD	15.55 (21.59)
Stroke/TIA	16.63 (17.02)
NAFLD	13.24 (9.78)
Retinopathy	12.97 (14.97)
Nephropathy	13.72 (9.53)
Foot ulcer	12.09 (9.33)
Erectile dysfunction	8.74 (8.32)
PAD	14.93 (8.81)
Other	11.00 (16.68)

Data presented as mean (SD), unless otherwise specified.

BMI, body mass index; CAD, coronary artery disease; DBP, diastolic blood pressure; NAFLD, non-alcoholic fatty liver disease; PAD, peripheral artery disease; SBP, systolic blood pressure; T2DM, type 2 diabetes mellitus; TIA, transient ischemic attack.

Table 2: Glycemic parameters from baseline to 3 months

	HbA1c (%) (N=2198)		FPG (mg/dL) (N=2187)		PPG (mg/dL) (N=2174)	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
Baseline	7.7 (3.10)	7.57, 7.83	142.4 (88.4)	138.7, 146.1	205.64 (128.0)	200.28, 211
1st month			110.84 (82.6)	107.38, 114.3	156.91 (118.16)	151.97, 161.85
2nd month			96.52 (72.64)	93.48, 99.56	134.5 (103.17)	130.19, 138.81
3rd month	5.8 (2.88)	5.68, 5.92	90.2 (62.44)	87.59, 92.81	123.38 (89.15)	119.65, 127.11

CI, confidence interval; FPG, fasting plasma glucose; HbA1c, glycated hemoglobin; PPG, postprandial glucose; SD, standard deviation.

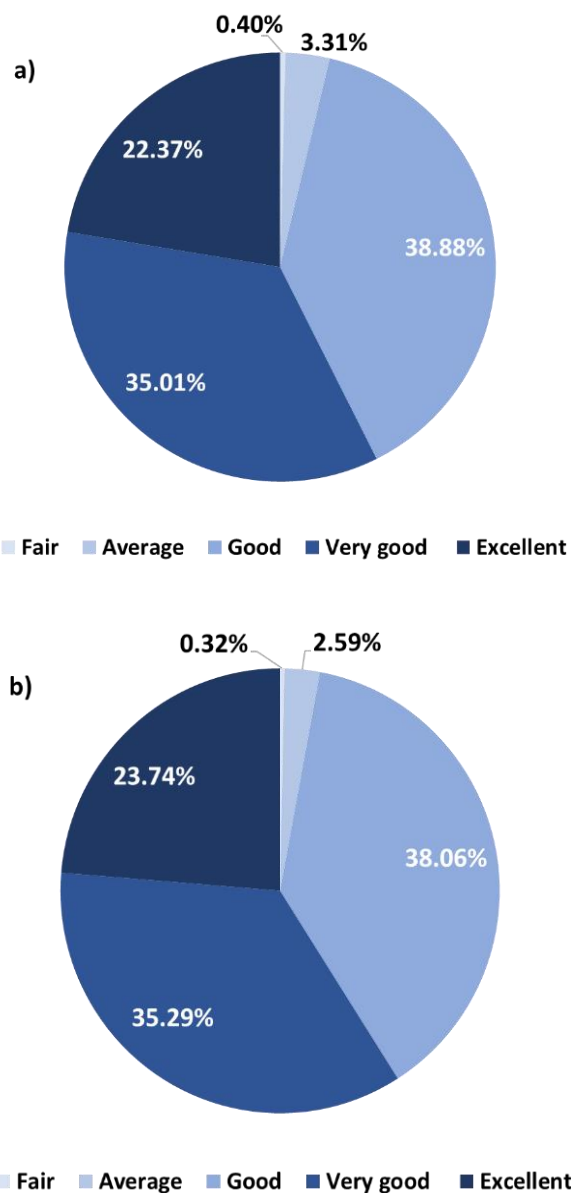


Figure 1: Physician's global assessments a) Physician's global evaluation of tolerability, b) Physician's global evaluation of efficacy

Only eight (0.36%) patients reported adverse events, with urinary tract infection (UTI) affecting three patients (0.13%). Other adverse events included hypotension, photosensitivity, fungal phimosi, moderate hypoglycemia, and hypersensitivity, each occurring in one patient (0.05%). Of the 1,315 patients (59.8%) who experienced weight loss, 708 (32.2%) lost 0-2 kg, 508 (23.1%) lost 2-4 kg, and 99 (4.5%) lost more than 4 kg.

A total of 1,717 (78.08%) patients achieved their glycemic goal with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg (Table 3).

The blood pressure change following the FDC of vildagliptin 100 mg and dapagliflozin 10 mg therapy

is represented in Figure 2. The mean (SD) SBP decreased from 141.35 (12.60) mmHg to 131.59 (10.38) mmHg, and the mean (SD) DBP decreased from 89.65 (7.37) mmHg to 84.42 (5.78) mmHg after the FDC therapy.

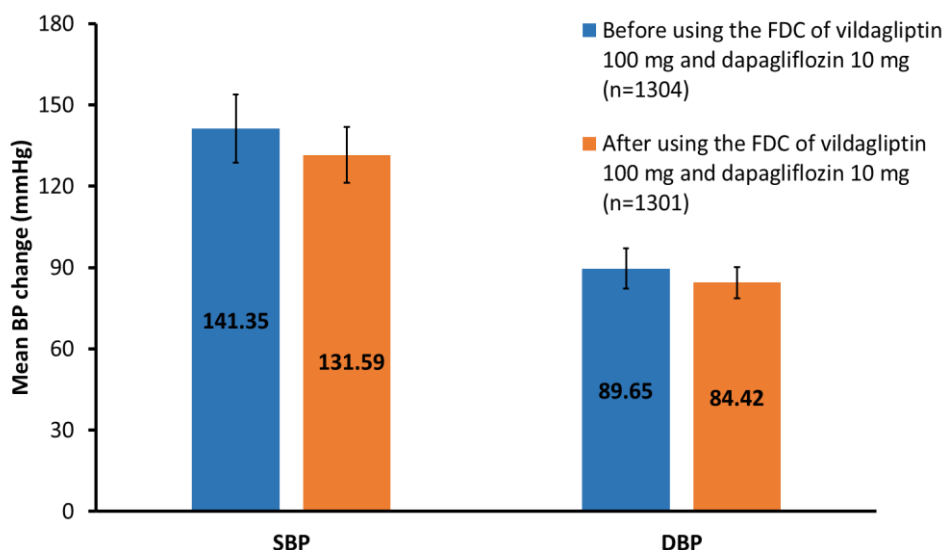
The compliance issues with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg are presented in Figure 3. Issues with treatment adherence were noted in 641 (29.15%) patients, mainly due to lack of exercise (14.46%), followed by dietary non-compliance (13.42%), and failure to follow home-based glucose monitoring as advised (11.51%).

Table 3: Glycemic goal with FDC of vildagliptin 100 mg and dapagliflozin 10 mg

Glycemic goal achieved with the FDC of vildagliptin and dapagliflozin	Number of patients (N=2199)
Yes	1717 (78.08)
No	482 (21.92)

Table 4: At which HbA1c level treatment started

	HbA1c (%)				
	<7	7-8	8-9	9-10	>10
Biguanides	5 (0.23)	65 (2.96)	69 (3.14)	59 (2.6)	13 (0.59)
Sulfonylureas	4 (0.18)	40 (1.82)	68 (3.09)	64 (2.91)	12 (0.55)
T2Z	1 (0.05)	9 (0.41)	22 (1.00)	25 (1.14)	4 (0.18)
AGI	0	3 (0.14)	3 (0.14)	5 (0.23)	3 (0.14)
GLP-1 agonist	1 (0.05)	10 (0.45)	5 (0.23)	5 (0.23)	8 (0.36)
Data presented as n (%). AGI, alpha-glucosidase inhibitors; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; T2Z, thiazolidinediones.					



BP, blood pressure; DBP, diastolic blood pressure; FDC, fixed-dose combination; SBP, systolic blood pressure.

Figure 2: Blood pressure change post-medication

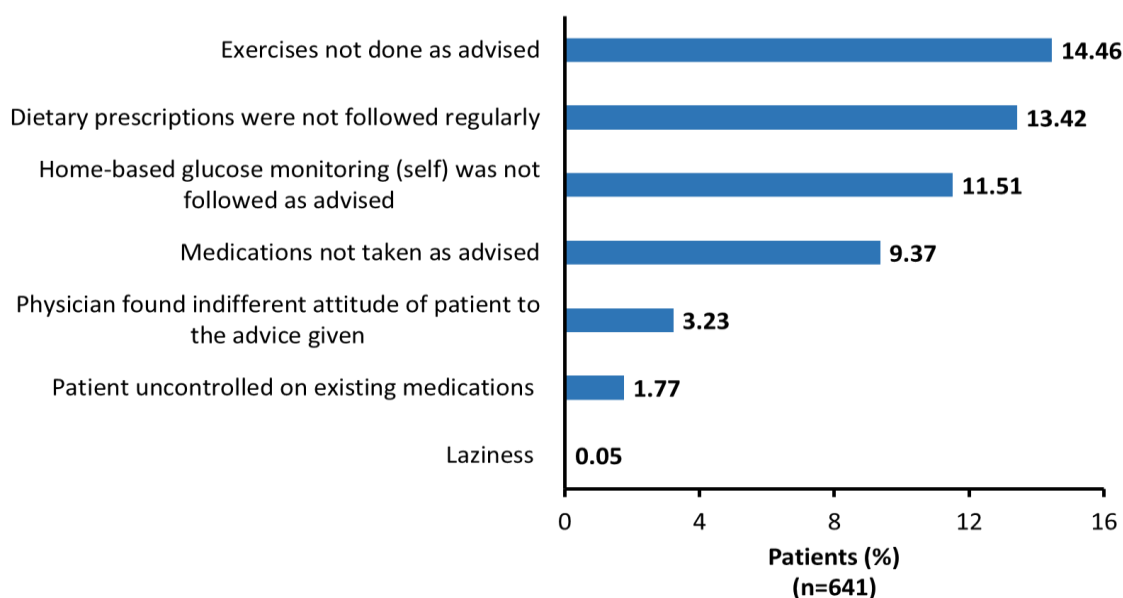


Figure 3: Compliance issues with the FDC of vildagliptin 100 mg and dapagliflozin 10 mg

Discussion

Managing T2DM requires navigating a complex landscape to achieve optimal glycemic control. Effective management often involves combination therapy, which uses antidiabetic drugs with complementary mechanisms of action. This approach addresses multiple pathophysiological defects and can lead to an additive reduction in HbA1c levels.¹³ However, there is a scarcity of real-world data from India evaluating the efficacy, safety, and tolerability of the combination of vildagliptin and dapagliflozin in patients with T2DM.

The present study revealed that most patients with T2DM in India, visiting cardiologists, fall within the age group of 40–60 years, highlighting a predominance of T2DM among middle-aged Indian adults. This finding aligns with a survey in which 90% of clinicians also reported that most T2DM patients in India are aged 40–60 years.¹⁴ However, global evidence suggests a rising trend of early-onset T2DM, particularly among adolescents and young adults in countries with low-middle and middle sociodemographic indexes.¹⁵ Recent studies emphasize the growing prevalence of T2DM among young Indian adults aged 20–40 years.¹⁶⁻¹⁹

The present study identified hypertension as the most common comorbidity among patients with T2DM, followed by dyslipidemia, CAD, and stroke/transient ischemic attack. This finding is consistent with the expert opinion on the use of vildagliptin in Indian patients with diabetes mellitus, where most clinicians reported hypertension (71.4%) as the prevalent comorbidity, followed by dyslipidemia (22.1%), ischemic heart disease (3.7%), and hypothyroidism (2%).²⁰

In this study, most patients achieved their glycemic goals using the FDC of vildagliptin 100 mg and dapagliflozin 10 mg. This suggests that this combination might be an effective treatment strategy for glycemic control in T2DM patients, offering a better chance of achieving and maintaining the desired HbA1c levels, a critical indicator of long-term blood glucose control. These findings are supported by an expert opinion-based consensus, where over 80% of clinical experts concurred that the vildagliptin-dapagliflozin FDC is an appealing treatment option for a broad range of Indian T2DM patients. The consensus underscored the potential of this combination therapy to enhance diabetes management outcomes in the Indian population.²¹ The current study highlights a notable decrease in mean HbA1c levels from baseline to 3 months, reinforcing the effectiveness of various combination therapies for T2DM. In a randomized clinical trial, the combination of saxagliptin and dapagliflozin achieved an HbA1c level of <7% in 41% of patients by week 24, demonstrating substantial glycemic control.²² Fixed-dose combinations of dapagliflozin with linagliptin or vildagliptin produced even more pronounced reductions in HbA1c over 16 weeks.²³ Several studies also corroborate that the combination of DPP-4 and SGLT2 inhibitor showed significant changes in HbA1c levels from baseline.^{22,26}

In the present study, the majority of physicians reported that the FDC of vildagliptin 100 mg and dapagliflozin 10 mg demonstrated good efficacy and tolerability. This aligns with phase III trial findings, which indicated that the combination had no severe

adverse effects and was well tolerated.²³ The majority of experts (82%) view the vildagliptin-dapagliflozin FDC as an appealing treatment option for T2DM due to the complementary mechanisms of action of DPP-4 inhibitors and SGLT2 inhibitors.²¹

Conclusion

The management of diabetes must evolve beyond glycemic control to encompass the broader spectrum of cardiovascular risk. Early intervention in patients with diabetes and associated risk factors like hypertension and dyslipidemia is not just beneficial—it is imperative. Delaying treatment allows silent yet progressive vascular damage to take hold, increasing the likelihood of severe complications such as heart attacks and strokes.

By adopting a proactive, multifaceted approach that integrates advanced therapeutic options—such as Fixed-Dose Combinations (FDCs) targeting both glycemia and cardiovascular health—clinicians can significantly improve patient outcomes. The FDC of vildagliptin 100 mg and dapagliflozin 10 mg demonstrated substantial efficacy in managing T2DM, with significant improvements in glycemic control and blood pressure. The combination was well-tolerated with a low incidence of adverse events. These findings support the utility of the FDC of vildagliptin 100 mg and dapagliflozin 10 mg in real-world clinical practice in the Indian context.

Conflict of interest:

There are no conflicts of interest. Dr. Sona Warriar is an employee of USV Pvt Ltd.

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