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Real-world clinical and cardio-renal outcomes with Dapagliflozin in Type 2 Diabetes Mellitus: Experience from routine practice

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Abstract
Background: Type 2 diabetes mellitus (T2DM) is a progressive condition that often requires combination therapy for optimal control. Dapagliflozin offers complementary glycaemic, metabolic, and cardiovascular benefits when combined with other oral antidiabetic agents. This study aimed to assess healthcare professionals' (HCPs) real-world experience with dapagliflozin-based regimens in Indian patients with T2DM, with a focus on glycaemic improvement, metabolic outcomes, and treatment tolerability.
Methods: A questionnaire-based observational survey was conducted among 401 HCPs across India, including endocrinologists, diabetologists, and general physicians. A structured 24-item questionnaire captured data on patient characteristics, glycaemic response, HbA1c and fasting blood glucose (FBG) improvement, cardiovascular and renal benefits, weight changes, lipid profile changes, adverse events, and discontinuation patterns based on the last 10 patients treated. Descriptive statistics were used, and results were expressed as percentages.
Results: Most HCPs reported that the majority of their managed patients were between 41 and 60 years of age, with overweight and obesity frequently observed. Dapagliflozin was frequently initiated in patients with HbA1c 8.1-9.0%, and 48.88% observed HbA1c target achievement in at least 9-10 patients. An HbA1c reduction of 1.1-1.5% and FBG improvement of 31-50 mg/dL were commonly reported. Dapagliflozin provided additional benefits, including blood pressure reduction, improvement in heart failure symptoms, slowed CKD progression, and favourable changes in lipid parameters. Weight loss of >2 kg over 3 months was frequently noted. Adverse events were minimal, with genital infections being the most common, and most HCPs (66.83%) reported no therapy discontinuation.
Conclusion: Dapagliflozin-based regimens are effective, well tolerated, and widely used in Indian T2DM patients, offering consistent improvements in glycaemic control, cardio-renal parameters, and metabolic outcomes. These real-world insights support their clinical utility and safety, though larger long-term studies are needed.

Keywords: Type 2 diabetes mellitus, dapagliflozin, cardio-renal outcomes

Introduction

Type 2 diabetes mellitus (T2DM) is a metabolic, heterogeneous disease characterised by loss of islet β-cell function and impaired insulin secretion associated with insulin resistance and metabolic syndrome [1]. Globally, the prevalence of diabetes continues to rise at an alarming rate, with approximately 589 million adults aged 20-79 years (about one in nine adults) currently living with the disease in 2024, as reported by the International Diabetes Federation Diabetes Atlas; this number is projected to reach 643 million by 2030 [2]. India accounts for more than 77 million people with diabetes, ranking second worldwide and highlighting the urgent public health implications in this region [3]. The rising prevalence of T2DM is driven by a combination of genetic susceptibility, advancing age, obesity, sedentary lifestyles, unhealthy diets, urbanisation, and stress [4]. Chronic hyperglycemia progressively damages multiple organ systems, leading to both microvascular complications, such as retinopathy, nephropathy, and neuropathy, and macrovascular complications, including coronary artery disease, stroke, and peripheral arterial disease, as well as serious outcomes like chronic kidney disease (CKD), heart failure (HF), and lower-limb amputations [5].

Lifestyle modifications, including weight reduction, dietary adjustments, and increased physical activity, play a vital role alongside pharmacological therapy in the management of T2DM. Regular monitoring of glycemic status, heart function, and kidney function further supports optimal treatment outcomes [6, 7]. When pharmacologic therapy is required, metformin remains the first-line agent, with adjunctive medications including sulfonylureas, dipeptidyl peptidase-4 (DPP) inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, and sodium-glucose cotransporter-2 (SGLT2) inhibitors [6, 8]. Some patients may not tolerate metformin due to adverse effects such as diarrhoea (occurring in approximately 10% of users) or renal impairment, in which case SGLT2 inhibitors are recommended as suitable alternatives [6].

The SGLT2inhibitors work by inhibiting renal glucose reabsorption in the proximal tubules, thereby lowering plasma glucose levels independently of insulin secretion while also promoting natriuresis, weight loss, and blood pressure reduction [9, 10]. Clinical trials such as DECLARE-TIMI 58, DAPA-HF, and DAPA-CKD have demonstrated the cardiorenal protective effects of dapagliflozin, showing significant improvements in CKD progression, reductions in

hospitalisations for cardiorenal complications, and enhancements in overall quality of life and survival [11].

Dapagliflozin is generally well tolerated; common side effects include urinary tract infections, genital mycotic infections, and increased urination. Hypoglycemia is uncommon unless combined with insulin or insulin secretagogues [12]. Meta-analyses confirm its favourable risk-benefit ratio, particularly when used in combination regimens to achieve better glycaemic control and reduce glucose variability [13]. Overall, long-term data support its favourable safety and risk-benefit profile across diverse patient populations, including those with HF or CKD. Overall, dapagliflozin represents a significant advancement in T2DM management by offering combined glycemic control and multisystem cardio-renal benefits, solidifying its role as a cornerstone in comprehensive diabetes care [14, 15]. The present study provides insights from healthcare professionals (HCPs) on the use of dapagliflozin-based regimens for Indian patients with T2DM, evaluating glycemic efficacy, metabolic benefits, cardiovascular and renal outcomes, safety profile, and overall treatment decision in a real-world clinical setting.

Methods

Study design

This questionnaire-based study was designed to evaluate the real-world use of dapagliflozin-based regimens in the management of T2DM in Indian patients. All study-related findings and data presented in this report were based on healthcare professionals' expert opinions, focusing on glycemic outcomes, cardio-renal benefits, metabolic effects, safety, and treatment decisions.

Study questionnaire

The study questionnaire was designed based on clinical guidelines, existing literature, and experts' opinions. It included 24 questions focusing on patient characteristics, efficacy outcomes, cardio-renal benefits, metabolic effects, and safety observations in patients with T2DM treated with dapagliflozin-based regimens. Areas covered included patient demographics, glycemic control, HbA1c and fasting blood glucose improvement, cardiovascular and renal outcomes, weight changes, adverse events, and management of side effects. The questionnaire focused on the last 10 patients treated by healthcare professionals. The study protocol was approved by the independent ethics committee (ACEAS - Independent Ethics Committee; Date of approval: 07 March 2025).

Data collection method

The HCPs participating in the study were provided with a concise overview of the study's nature and the process for completing the questionnaire. The questionnaire was given to HCPs through online platforms.

Data analysis

Responses to questions were entered into Microsoft Excel. Descriptive analysis was performed, and the outcome was presented as percentages.

Results

A total of 401 HCPs participated in the study. The majority of HCPs (37.91%) reported that patients most commonly belonged to the 41-50 years age group, followed by 51-60 years (35.91%). Regarding body mass index (BMI), most patients were categorised as overweight (41.40%) or obese (30.92%), while a smaller proportion were within the normal weight range (13.22%) (Table 1).

Physicians shared their real-world experiences from the last 10 patients treated with dapagliflozin, focusing on glycemic outcomes and treatment decisions in individuals with T2DM managed with dapagliflozin-based regimens. Most HCPs (37.91%) reported that dapagliflozin was initiated in patients with baseline HbA1c levels between 8.1-9.0%, followed by 7.0-8.0% (34.91%). Nearly half of the respondents (42.89%) observed noticeable glycemic improvement within 2-4 weeks of therapy initiation. Metformin was the most frequently prescribed concomitant agent with dapagliflozin (58.60%), followed by DPP-4 inhibitors (18.45%) and sulfonylureas (13.47%). Furthermore, a considerable proportion of HCPs (48.88%) reported that 9-10 out of their last 10 patients achieved the target HbA1c level (<7%) following dapagliflozin therapy (Table 2). In addition, most HCPs (37.91%) observed an HbA1c reduction of 1.1-1.5% after three months of dapagliflozin therapy, while another 26.43% noted reductions of 0.5-1.0% or above 1.5%. Regarding fasting blood glucose (FBG), 37.66% of HCPs reported an improvement of 31-50 mg/dL, and 25.44% observed improvements exceeding 50 mg/dL (Figure 1).

According to 43.39% of HCPs, 26-50% of their patients had a prior history of cardiovascular disease (CVD), whereas only a small proportion (8.98%) indicated that 76-100% of their patients had a history of CVD. Regarding HF before initiating dapagliflozin, around 48.63% of HCPs reported that 0-25% of their patients had a prior history, and 23.69% observed a prevalence of 26-50% (Figure 2). Among hypertensive diabetic patients, 43.89% of HCPs reported that dapagliflozin reduced blood pressure by 5-10 mmHg, while 21.95% observed reductions greater than 10 mmHg. With respect to HF symptoms, 44.64% of HCPs reported improvement in 9-10 patients, whereas only 7.23% noted improvement in 0-2 patients. The most commonly reported cardiovascular benefit was reduced hospitalisation for HF (40.40%), followed by improved blood pressure control (31.42%). In terms of peripheral edema, nearly half of HCPs (49.88%) reported frequent improvement in 4-7 patients, while 38.65% noted occasional improvement in 1-3 patients (Table 2).

Regarding renal outcomes, 43.64% of HCPs reported an initial mild reduction in eGFR with subsequent stabilization, while 37.41% observed a marked improvement in proteinuria. Among patients with CKD, 43.39% of HCPs reported that dapagliflozin therapy slowed disease progression, while only 5.74% observed worsening renal function. In terms of weight management, 36.16% of HCPs indicated that 9-10 patients experienced a weight loss of more than 2 kg after 3 months of dapagliflozin therapy, with the average reduction ranging from 2-4 kg in 40.15% of patients. Beyond glycemic control, 31.67% of HCPs observed decreased triglyceride levels, and 29.68% reported improvements in high-density lipoprotein cholesterol (HDL) (Table 2).

The safety outcomes of dapagliflozin therapy, as reported by HCPs, indicate a generally favourable tolerability profile. Genital infections were the most commonly reported adverse event (28.18%), followed by dehydration (13.47%). Regarding therapy discontinuation, the majority of HCPs

(66.83%) reported that none of their patients discontinued dapagliflozin due to adverse effects. For the management of genital infections, most HCPs (69.08%) treated patients with antifungal or antibacterial therapy while continuing dapagliflozin. In terms of hydration status, 57.36% of HCPs reported mild fluid loss with stable electrolytes, while 22.94% observed no effect. Diabetic ketoacidosis was rare, with 65.34% of HCPs reporting that it never occurred and only 2.24% noting more than three cases (Table 3).

Table 1: Demographic characteristics of patients with T2DM treated with dapagliflozin

Parameter	Response of HCPs (N=401)
Common age group	
30-40 years	54 (13.47)
41-50 years	152 (37.91)
51-60 years	144 (35.91)
Above 60 years	51 (12.72)
Frequent BMI category	
Normal weight (BMI <25)	53 (13.22)
Overweight (BMI 25-29.9)	166 (41.40)
Obese (BMI 30-34.9)	124 (30.92)
Severely obese (BMI ≥35)	58 (14.46)

Data represented as n (%).
BMI, body mass index.

Table 2: Glycemic control, treatment trends, and cardiorenal-metabolic outcomes observed with dapagliflozin therapy in patients with T2DM

Parameter	Response of HCPs (N=401)
Glycemic profile and treatment patterns	
Common HbA1c range before starting dapagliflozin	
<7.0%	40 (9.98)
7.0-8.0%	140 (34.91)
8.1-9.0%	152 (37.91)
Above 9.0%	69 (17.21)
Time to significant glycaemic improvement after starting dapagliflozin	
Within 1 week	99 (24.69)
2-4 weeks	172 (42.89)
5-8 weeks	81 (20.20)
Above 8 weeks	49 (12.22)
Most common combination therapy prescribed with dapagliflozin	
Metformin	235 (58.60)
Insulin	38 (9.48)
Sulfonylureas	54 (13.47)
DPP-4 inhibitors	74 (18.45)
Patients achieving target HbA1c (<7%) after dapagliflozin initiation	
0-2 patients	30 (7.48)
3-5 patients	64 (15.96)
6-8 patients	111 (27.68)
9-10 patients	196 (48.88)
Cardiovascular outcomes	
Impact on blood pressure in hypertensive diabetic patients	
No change	49 (12.22)
Reduced by <5 mmHg	88 (21.95)
Reduced by 5-10 mmHg	176 (43.89)
Reduced by >10 mmHg	88 (21.95)
Improvement in heart failure symptoms	
0-2 patients	29 (7.23)
3-5 patients	98 (24.44)
6-8 patients	95 (23.69)
9-10 patients	179 (44.64)
Most common cardiovascular benefit	
Reduced hospitalisation for heart failure	162 (40.40)
Improved blood pressure control	126 (31.42)
Lower incidence of major adverse cardiac events	83 (20.70)
No noticeable cardiovascular benefits	30 (7.48)
Reduction in peripheral edema	
Never	46 (11.47)
Occasionally (1-3 patients)	155 (38.65)

Frequently (4-7 patients)	200 (49.88)
Very often (8-10 patients)	0 (0)
Renal and metabolic outcomes	
Effect on kidney function	
No effect	54 (13.47)
Mild reduction in eGFR initially, then stabilisation	175 (43.64)
Significant improvement in proteinuria	150 (37.41)
Worsening renal function	22 (5.49)
Patients experiencing weight loss (>2 kg) after 3 months	
0-2 patients	36 (8.98)
3-5 patients	80 (19.95)
6-8 patients	140 (34.91)
9-10 patients	145 (36.16)
Average weight loss observed	
<2 kg	62 (15.46)
2-4 kg	161 (40.15)
4-6 kg	155 (38.65)
>6 kg	23 (5.74)
Effect of dapagliflozin in CKD patients	
No change	81 (20.20)
Slowed progression of CKD	174 (43.39)
Improved albuminuria	123 (30.67)
Worsened renal function	23 (5.74)
Common metabolic effects apart from glycemic control	
Reduced triglycerides	127 (31.67)
Improved HDL cholesterol	119 (29.68)
Increased LDL cholesterol	27 (6.73)
No metabolic effects	28 (6.98)

Data represented as n (%).

BP, blood pressure; CV, cardiovascular; CKD, chronic kidney disease; DPP-4, dipeptidyl peptidase-4; HbA1c, glycated haemoglobin; HCPs, healthcare professionals; HF, heart failure; MACE, major adverse cardiac events.

Table 3: Safety profile of dapagliflozin therapy among patients with T2DM

Parameter	**Response of HCPs (N=401)**
Most common adverse event reported	
Genital infections	113 (28.18)
Dehydration	54 (13.47)
Hypoglycemia	29 (7.23)
None	205 (51.12)
Patients who discontinued Dapagliflozin due to side effects	
0 patients	268 (66.83)
1-2 patients	91 (22.69)
3-4 patients	30 (7.48)
Above 5 patients	12 (2.99)
Management approach for genital infections	
Discontinuation of Dapagliflozin	39 (9.73)
Antifungal/antibacterial treatment while continuing Dapagliflozin	277 (69.08)
Dose reduction	40 (9.98)
Switching to another SGLT2 inhibitor	45 (11.22)
Effect on hydration status	
No effect	92 (22.94)
Increased dehydration risk in elderly	54 (13.47)
Mild fluid loss with stable electrolytes	230 (57.36)
Severe dehydration requiring intervention	25 (6.23)
Incidence of diabetic ketoacidosis	
Never	262 (65.34)
Rarely (1 case)	91 (22.69)
Occasionally (2-3 cases)	39 (9.73)
Frequently (Above 3 cases)	9 (2.24)

Data represented as n (%).

DKA, diabetic ketoacidosis; HCPs, healthcare professionals.

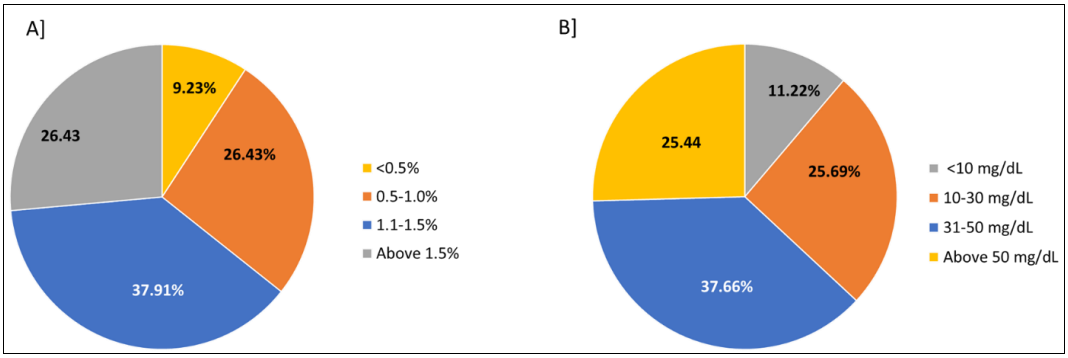

Fig 1: Glycaemic outcomes observed after dapagliflozin therapy
A] Patients with average HbA1c reduction after three months of dapagliflozin therapy
B] Patients with improvement in fasting blood glucose levels following dapagliflozin therapy

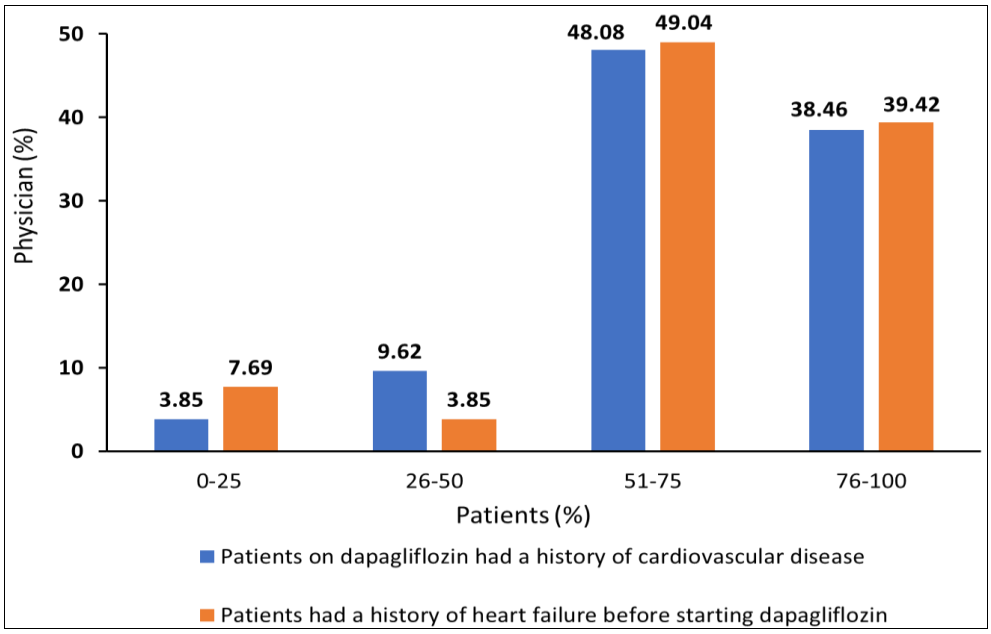

Fig 2: Proportion of patients with cardiovascular disease and heart failure among those prescribed dapagliflozin

Discussion

The present study provides valuable insights into the real-world clinical use of dapagliflozin-based regimens, focusing on glycemic outcomes, cardio-renal benefits, metabolic effects, and safety, as reported by HCPs in the management of T2DM among Indian patients. Of the 401 participating HCPs, 37.91% reported that most patients were within the 41-50 years age group, while a considerable proportion indicated that patients were predominantly overweight (41.40%) or obese (30.92%) based on BMI. These observations align with the findings of the study by Sheikh *et al*., which reported a mean (SD) age of 53.6 (10.2) years, with 66.4% of patients aged between >40 and 60 years, and a majority (68.1%) classified as obese [16].

Most HCPs (37.91%) reported initiating dapagliflozin in patients with baseline HbA1c levels between 8.1 9.0%. Nearly half of the respondents (42.89%) observed a noticeable improvement in glycemic control within 2-4 weeks of therapy initiation. These findings are comparable to those reported by Scheerer *et al*., where patients with T2DM initiating dapagliflozin had a baseline HbA1c of 8.5 (1.5) %. A significant reduction of −0.8 (1.4) % was observed at 3 months, with greater declines noted among patients with higher baseline HbA1c (> 8%) [17]. Furthermore, a considerable proportion of HCPs (48.88%) reported that 9-10 of their patients achieved target HbA1c levels (<7%) following dapagliflozin therapy. These results are in line with findings from a population PK-PD analysis, which demonstrated that dapagliflozin therapy reduced baseline HbA1c from 6.8% (range 6.0-7.8%) to 6.5% and 6.4% with 5 mg and 10 mg dosing, respectively, indicating that most patients can achieve HbA1c levels below 7% after treatment [18]. Metformin was the most frequently prescribed concomitant agent with dapagliflozin, followed by DPP-4 inhibitors. Similar observations were reported by Hankin *et al*., where 67.6% of dapagliflozin users were prescribed metformin and 44.9% received DPP-4 inhibitors as concomitant therapy [19] In terms of FBG, 37.66% of HCPs observed an improvement in the range of 31-50 mg/dL. This observation is consistent with findings from a pivotal 2-week clinical trial that reported a mean reduction of approximately 33 mg/dL in fasting plasma glucose and about 73 mg/dL in 2-hour postprandial glucose levels [20].

Among surveyed HCPs, 43.39% reported that 26-50% of their patients had a prior history of CVD. With respect to HF, 48.63% indicated that 0-25% of their patients had a history of HF before starting dapagliflozin therapy. These trends are consistent with an Indian meta-analysis that estimated a pooled CVD prevalence of 21.1 % among patients with T2DM [21]. Likewise, data from the RED-HEART study demonstrated that over half of the patients (56.4%) had HF with reduced ejection fraction, while 22.1%

and 21.5% had preserved and mildly reduced ejection fractions, respectively [22]. Among hypertensive diabetic patients, most HCPs observed that dapagliflozin therapy reduced blood pressure by 5-10 mmHg. Similarly, Sjöström *et al*. reported in their study that dapagliflozin 10 mg/day produced a mean systolic blood pressure reduction of approximately 3.6 mmHg in hypertensive individuals [23].

A phase 3, placebo-controlled trial by McMurray *et al*. demonstrated that the incidence of hospitalisation for HF was significantly lower in the dapagliflozin group compared to placebo (hazard ratio = 0.75; 95% CI: 0.65-0.85; P < 0.001). Moreover, the dapagliflozin group showed a greater increase in the total symptom score on the Kansas City Cardiomyopathy Questionnaire (KCCQ) between baseline and month 8, indicating fewer symptoms and improved quality of life [24]. Similarly, in the DEFINE-HF trial, 42.9% of dapagliflozin-treated patients showed improvement in heart failure-related health status, as measured by the KCCQ [25]. These findings align well with the present study, wherein 44.64% of HCPs reported improvement in HF symptoms among 9-10 patients, while only 7.23% noted improvement in 0-2 patients. The most commonly reported cardiovascular benefit was reduced hospitalisation for HF (40.40%), followed by improved BP control (31.42%). Regarding peripheral oedema, nearly half of HCPs (49.88%) observed frequent improvement in 4-7 patients. The CV outcomes of the present study are consistent with the findings of Borrelli *et al*., who reported that after 12 weeks of dapagliflozin therapy, there was an improvement in sodium and volume overload, along with a reduction in nighttime systolic blood pressure (SBP) by −3.0 mmHg. Additionally, the proportion of patients achieving the nighttime SBP goal (<110 mmHg) increased from 18.0% to 27.0% [26].

In the current study, 43.64% of HCPs reported an initial mild decline in eGFR followed by subsequent stabilisation, with dapagliflozin shown to slow CKD progression in a substantial proportion of patients. These findings are in line with those of Jongs *et al*., who observed that nearly half of patients (49.4%) treated with dapagliflozin experienced an acute eGFR reduction of >10% within the first two weeks, followed by a slower long-term decline compared with placebo, highlighting dapagliflozin's renal protective effects [27]. The DAPA-CKD trial similarly showed that dapagliflozin delayed kidney failure by an estimated 6.6 years and reduced the risk of sustained eGFR decline, end-stage kidney disease, and kidney or CV death [25]. For weight management, 36.16% of HCPs reported that several patients lost more than 2 kg within 3 months, with average reductions of 2-4 kg in 40.15% of cases. These results align with Bolinder *et al*., who observed a placebo-corrected mean weight loss of 2.08 kg with dapagliflozin 10 mg daily, with 26.2% achieving ≥5% weight loss [28]. Beyond glycemic control, several HCPs observed reductions in triglyceride levels and reported improvements in HDL cholesterol. Similar results were noted by Calapkulu *et al*., where patients receiving dapagliflozin therapy for 6 months showed decreases in total cholesterol (−17.6 mg/dL), LDL cholesterol (−13.4 mg/dL), and triglycerides (−25.9 mg/dL), along with modest increases in HDL cholesterol. These results suggest that dapagliflozin not only improves glycemic parameters but also exerts favourable effects on lipid metabolism, contributing to its broader cardiometabolic benefits [29].

Genital infections were the most commonly observed adverse event with dapagliflozin therapy, followed by dehydration. These results are consistent with the findings of Unnikrishnan *et al*., who reported urogenital infections in 4.1-5.7% of patients and vulvovaginal mycotic infections in 8.5-10.8% of women, while dehydration occurred in fewer than 3% of cases [30]. Most HCPs indicated that no patients discontinued therapy due to adverse effects, consistent with Kim *et al*., who found a discontinuation rate of 8.96%, largely due to unexpected causes such as elevated blood glucose or weight gain [31]**.** In the present survey, most HCPs treated genital infections with antifungal or antibacterial agents without interrupting dapagliflozin, supporting continued therapy. Regarding hydration, over half of HCPs noted mild fluid loss with stable electrolytes, indicating minimal clinical concern. Diabetic ketoacidosis (DKA) was rare, with a large proportion of HCPs reporting no cases. The DAPA-KETO study similarly showed DKA occurred less frequently with dapagliflozin than with other SGLT2 inhibitors (odds ratio = 0.91; 95% CI 0.87-0.96) [32]. Overall, HCP-reported outcomes indicate that dapagliflozin is well tolerated, with manageable side effects and a low risk of serious complications, supporting its favourable safety profile in real-world practice.

Conclusion

The findings show that dapagliflozin-based regimens are effective, well-tolerated, and widely used in routine clinical practice for Indian patients with T2DM. Most healthcare professionals reported meaningful improvements in HbA1c, fasting glucose levels, blood pressure, weight, and cardiorenal parameters, with very few therapy discontinuations. The therapy demonstrated additional benefits in HF symptom relief, slowing CKD progression, and improving lipid profiles. These insights reinforce the clinical value and safety of dapagliflozin across diverse patient profiles, supporting its role as a key component of comprehensive diabetes management. However, larger long-term studies are warranted to further validate these real-world findings.

Conflict of interest: None

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