



## PHYSICIAN-REPORTED EXPERIENCE WITH DAPAGLIFLOZIN IN TYPE 2 DIABETES: EVIDENCE FROM SOUTHERN INDIA

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**Article History:** Received: 11.09.2025 Revised: 24.10.2025 Accepted: 26.12.2025

### Abstract

**Background:** Type 2 diabetes mellitus (T2DM) is associated with microvascular and macrovascular complications, contributing substantially to the global disease burden. This study aimed to evaluate the real-world safety, efficacy, and prescribing patterns of dapagliflozin in T2DM management to support tailored diabetes care.

**Methods:** This questionnaire-based study included a 12-item questionnaire that evaluated physicians' perspectives and prescribing patterns related to dapagliflozin, with a specific focus on their last 10 patients with T2DM.

**Results:** A total of 251 physicians from southern India participated. Nearly half (44.22%) reported initiating dapagliflozin in 3-5 of their last 10 elderly patients ( $\geq 65$  years). Dapagliflozin was most commonly preferred for patients with CKD (28.69%), followed by those with poor glycemic control or cardiovascular disease (27.49%). Adherence was high with 62.55% noting that 9-10 patients continued therapy for at least six months, cost was the main reason for discontinuation (41.43%). Most physicians (37.45%) reported no major concerns in elderly patients. Among female patients, 0-2 out of 10 experienced urinary tract infections (52.99%). Nearly half (47.01%) felt their patients were very satisfied with dapagliflozin. Cardiovascular protection (33.07%) and glycemic control (29.08%) were the main reasons for prescribing, and metformin was the most common add-on therapy (59.36%). Physicians also reported glycemic efficacy comparable to other sodium-glucose co transporter 2 (SGLT2) inhibitors (42.23%) and cardiovascular benefits comparable to glucagon-like peptide-1 (GLP-1) receptor agonists (49.40%). Most (55.38%) expressed a high likelihood of prescribing it in the future.

**Conclusion:** Physicians prefer dapagliflozin as an effective agent for both monotherapy and combination therapy in T2DM management.

**Keywords:** Glycemic control, sodium-glucose cotransporter 2, cardioprotective, adverse events, combination.

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**DOI:** <https://doi.org/10.22376/ijlpr.v16i1.2027>

### INTRODUCTION

Type 2 diabetes mellitus (T2DM) represents about 96% of all diabetes cases and is a major non-communicable chronic disease that poses a serious threat to human health [1,2]. Currently, diabetes affects approximately 589 million individuals worldwide, and this number is projected to rise to 853 million by 2050 [3]. The worldwide rise in T2DM is evident in India, where cases increased from 32 million in 2000 to 101 million today [1], making the country with 17.78% of the global population and 101 million T2DM patients,

the second largest contributor to the global diabetes burden at 14% [4].

Chronic hyperglycemia contributes to multi-organ damage, notably microvascular (retinopathy, nephropathy, neuropathy) and macrovascular complications [5,6]. Optimal glycemic control reduces the risk of micro and macrovascular complications and becomes the cornerstone of T2DM management [7]. Management of diabetes in older patients is challenging owing to the clinical heterogeneity, multiple comorbidities, and diversity of living situations and fewer than 50% of those aged  $\geq 65$  years achieve HbA1c  $< 7.0\%$  and the hypoglycaemia risk remains high in these patients even with the oral monotherapy and combination therapy [8,9].

Metformin remains the first-line monotherapy, and is used as a monotherapy or in combination with other

glucose-lowering therapies owing to its efficacy, safety and affordability [10]. Despite its proven efficacy, metformin monotherapy is often associated with inadequate glycemic control [11], while growing evidence supports early initiation of sodium-glucose co-transporter (SGLT2) inhibitors and glucagon-like peptide (GLP-1) receptor agonists for cardiovascular benefit [12].

Multiple randomised controlled trials, including Dapagliflozin Effect on Cardiovascular Events-Thrombolysis in Myocardial Infarction 58 (DECLARE-TIMI 58) and Dapagliflozin and Prevention of Adverse Outcomes in Heart Failure (DAPA-HF), reported that dapagliflozin significantly reduced cardiovascular deaths or hospitalisation for heart failure [13]. In clinical trials, dapagliflozin has exhibited a favorable safety profile with urinary tract infections (UTI) and genital mycotic infections as the most common adverse events and rare occurrences of diabetic ketoacidosis [14,15]. Combination therapy of dapagliflozin with other antihyperglycemic agents, such as dipeptidyl peptidase-4 inhibitors or sulfonylureas, has demonstrated effective glycemic control in well-designed phase 3 and phase 4 clinical trials [16].

According to the post-hoc analysis of cardiovascular outcome trials and real-world evidence, a combination of sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists is associated with metabolic benefits and a decrease in major adverse cardiovascular events [17]. The present study aims to evaluate the physician's perspective, prescribing patterns and clinical outcomes of dapagliflozin and its combination therapy with other antihyperglycemic agents in routine practice in Southern India. By evaluating the real-world efficacy and safety, this study aims to contribute to the patient-tailored diabetes care and support clinical decision making.

## METHODS

### *Study design*

This questionnaire-based study was conducted among physicians involved in the management of T2DM to evaluate their perspectives and prescribing patterns regarding the use of dapagliflozin in their clinical practice in the Southern India. Participation in the study was entirely voluntary, and the study procedures, along with the data analysis, ensured the anonymity and confidentiality of the respondents. All study-related findings and data presented in this report were based on expert opinion. The ethical approval was obtained from the independent Ethics Committee. All the findings and the data presented in this report are derived from the expert opinions provided by the physicians.

### *Study questionnaire*

The study questionnaire was designed based on clinical guidelines, existing literature and expert opinions. It consisted of a total of 12 questions that focused on the rationale for prescribing dapagliflozin, its real-world effectiveness, safety profile and comparative evaluation

of patient eligibility and adherence. The questionnaire further explored key areas such as the primary reason for initiating the therapy, patient demographics, eligibility criteria, adherence patterns, comparative insights with other glucose-lowering therapies, and future clinical recommendations. Physicians were asked to respond based on their last 10 patients treated with dapagliflozin.

### *Inclusion and exclusion criteria*

The study included healthcare professionals (HCPs) with clinical experience in managing T2DM and who had prescribed dapagliflozin to their patient. Participants with no recent dapagliflozin prescriptions, or unwilling to participate in the study were excluded.

### *Data collection*

The physicians, 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 physicians through online platforms.

### *Data analysis*

The responses of the physicians were entered into Microsoft Excel, and the descriptive statistics like percentages, were utilized to present the data.

## RESULTS

A total of 251 physicians from southern India were included in this study. The majority of physicians (44.22%) reported that from the past 10 patients, 3-5 patients were elderly i.e.,  $\geq 65$  years), when dapagliflozin therapy was initiated. Most physicians (28.69%) preferred dapagliflozin in patients with CKD and diabetes, while a similar proportion (27.49%) of physicians preferred dapagliflozin therapy in patients with poor glycemic control and established cardiovascular disease, followed by a very small number of physicians (16.33%) preferring dapagliflozin therapy in patients with obesity and diabetes (16.33%) (Table 1).

A majority of physicians (62.55%) reported that, among their last 10 patients, 9-10 patients were adherent to dapagliflozin therapy for at least 6 months, while 24.30% reported that 6-8 patients maintained adherence for the same duration. A higher proportion (41.43%) of physicians identified cost as the most common reason for discontinuation of dapagliflozin therapy, while around 25.90% cited adverse events, such as genital infections and dehydration, as the most common reasons for discontinuation in their patients. Most physicians (37.45%) reported no major concerns in elderly patients receiving dapagliflozin, while approximately 30.28% noted an increased risk of dehydration (Figure 1). Higher proportion of physicians (52.99%) reported that among their last 10 female patients on dapagliflozin, only 0-2 patients reported urinary tract infection post-initiation, whereas 29.88% reported that 3-5 patients did (Figure 2). Most physicians (47.01%) reported that their patients were very satisfied with dapagliflozin, while 37.85% noted a satisfied response (Table 1).

About 33.07% of physicians cited cardiovascular protection as the primary reason for prescribing dapagliflozin, while 29.08% cited glycemic control. A majority of physicians (59.36%) reported metformin as the most commonly prescribed drug in combination with dapagliflozin, followed by DPP-4 inhibitors (18.73%), sulphonylureas (13.55%), and insulin (8.37%). About 42.23% of physicians reported that dapagliflozin is equally effective as other SGLT2 inhibitors for glycemic control. In contrast, 41.43% of physicians reported that dapagliflozin is more effective compared to other SGLT2 inhibitors for glycemic control (Table 1).

A majority of physicians (49.40%) described that dapagliflozin is equally effective as GLP-1 receptor agonists in terms of cardiovascular benefits, while about 23.90% of physicians reported that dapagliflozin is less effective than GLP-1 receptor agonists in terms of cardiovascular benefits. Most physicians (55.38%) stated that they are very likely to prescribe dapagliflozin to T2DM patients in the future, based on their clinical experience (Table 1).

Table 1. Responses of the physicians on dapagliflozin use and comparative effectiveness in patients with T2DM.

Parameters	Response of physicians (N=251)
<b>Elderly patients (≥65 years) among the last 10 T2DM patients</b>	
0-2	49 (19.52)
3-5	111 (44.22)
6-8	69 (27.49)
9-10	22 (8.76)
<b>Preferred patient profile</b>	
Patients with CKD and diabetes	72 (28.69)
Patients with poor glycemic control	69 (27.49)
Patients with established cardiovascular disease	69 (27.49)
Patients with obesity and diabetes	41 (16.33)
<b>Patient adherence to dapagliflozin therapy for at least six months</b>	
0-2 patients	11 (4.38)
3-5 patients	22 (8.76)
6-8 patients	61 (24.30)
9-10 patients	157 (62.55)
<b>Reason for dapagliflozin discontinuation</b>	
Cost or affordability issues	104 (41.43)
Adverse events (e.g., genital infections, dehydration)	65 (25.90)
Patient preference	54 (21.51)
Lack of glycemic control	28 (11.16)
<b>Patient satisfaction with dapagliflozin</b>	
Very satisfied	118 (47.01)
Satisfied	95 (37.85)
Neutral	28 (11.16)
Dissatisfied	10 (3.98)

<b>The primary reason for the dapagliflozin prescription</b>	
Cardiovascular protection	83 (33.07)
Glycemic control	73 (29.08)
Renal protection	60 (23.90)
Weight reduction	35 (13.94)
<b>Combination of dapagliflozin and other glycemic control drugs</b>	
Metformin	149 (59.36)
DPP-4 inhibitors	47 (18.73)
Sulphonylureas	34 (13.55)
Insulin	21 (8.37)
<b>Comparison of dapagliflozin with other SGLT2 inhibitors</b>	
More effective	104 (41.43)
Equally effective	106 (42.23)
Less effective	29 (11.55)
Not sure	12 (4.78)
<b>Comparison of dapagliflozin with GLP-1 receptor agonists for cardiovascular benefits</b>	
More effective	49 (19.52)
Equally effective	124 (49.40)
Less effective	60 (23.90)
Not sure	18 (7.17)
<b>Prescription of dapagliflozin to future T2DM patients</b>	
Very likely	139 (55.38)
Somewhat likely	79 (31.47)
Neutral	26 (10.36)
Unlikely	7 (2.79)
Data presented as n (%) DPP-4, dipeptidyl peptidase; GLP-1, glucagon-like-peptide; SGLT2, sodium-glucose cotransporter 2; T2DM, type 2 diabetes mellitus.	

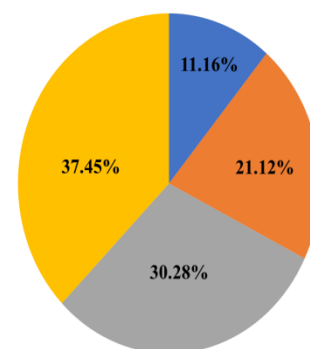


Figure 1: Primary concerns in elderly patients on dapagliflozin (N=251)

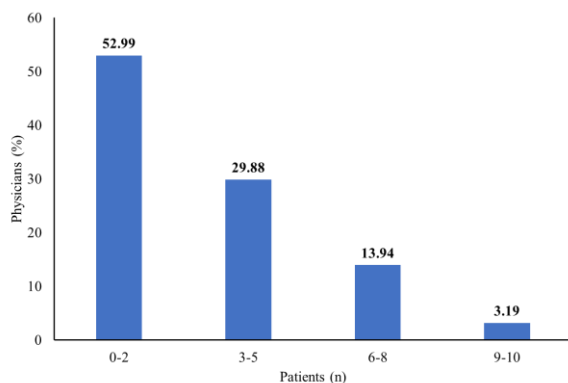


Figure 2: Urinary tract infection post-initiation of dapagliflozin in females (N=251)

## DISCUSSION

The present study highlights the real-world insights into the effectiveness and utilization of dapagliflozin in the management of T2DM. In the present study, nearly half of the physicians reported that among the past 10 patients, dapagliflozin was initiated in 3-5 elderly patients, indicating substantial level of prescribing in the elderly population. Most of the physicians preferred dapagliflozin in patients with poor glycemic control, CKD and cardiovascular disease. The study findings align with the findings of the prior studies. In the Dapagliflozin and Prevention of Adverse Outcomes in Chronic Kidney Disease (DAPA-CKD) trial, dapagliflozin significantly reduced the risk of a sustained  $\geq 50\%$  decline in estimated glomerular filtration rate (eGFR), progression to end-stage renal disease, or death, demonstrating robust renoprotective benefits irrespective of T2DM status [18]. Similarly, the DAPA-HF trial confirmed its cardioprotective effects in patients with heart failure, with or without diabetes [19]. A majority of physicians reported that, out of their last 10 patients, 9-10 patients were adherent to dapagliflozin therapy for at least 6 months, indicating better patient compliance. A large number of physicians suggested that cost was the most common reason for discontinuation, followed by adverse events like genital infections and dehydration. Another study reported similar results, wherein the patients discontinued the treatment with the SGLT2 inhibitor drug due to cost issues or patient complaints on side effects like constipation and hypoglycemia [20]. Additionally, the DELIVER trial reported that renal adverse events caused the discontinuation of dapagliflozin in 2.5% of patients [21].

In the present study, most physicians reported no major concerns in elderly patients on dapagliflozin. This finding aligns with a previous study, in which dapagliflozin treatment for up to 104 weeks was well tolerated in older patients [22]. In the current study significant proportion of physicians opined that only 0-2 of 10 female patients reported UTI post-initiation of dapagliflozin. This finding aligns with real-world evidence from the previous study, which reported a higher risk of UTIs and genital mycotic infections in female patients using dapagliflozin [15]. A majority of physicians reported that patients were highly satisfied

with dapagliflozin therapy. Another study by Nakajima H, et al. reported improved satisfaction among T2DM patients receiving dapagliflozin therapy [23]. In the present study, a large number of physicians identified cardiovascular protection as the primary reason for prescribing dapagliflozin. These study findings are consistent with other studies wherein *dapagliflozin therapy showed cardiovascular benefits* [24, 25]. A significant proportion of physicians reported metformin as the most commonly prescribed drug in combination with dapagliflozin followed by DPP-4 inhibitors, sulphonylureas and insulin. This finding aligns with another real-world study that reported the combination of dapagliflozin and metformin improved glycemic parameters, supporting metformin as an appropriate add-on therapy to dapagliflozin [26]. Yet another study indicated that a fixed dose combination of dapagliflozin and metformin maybe preferred as an initial therapy [27].

A majority of physicians reported that dapagliflozin has glycemic control efficacy comparable to that of other SGLT2 inhibitors, while a similar proportion believed it offers similar efficacy. A study by Velusamy S, et al. in Indian patients with T2DM demonstrated comparable efficacy between dapagliflozin and empagliflozin in achieving effective glycemic control [28]. In the present study, a large number of physicians reported equivalent efficacy of dapagliflozin and GLP-1 receptor agonists in conferring cardiovascular benefits. This finding aligns with another study, which reported comparable cardiovascular benefits from SGLT2 inhibitors and GLP-1 receptor agonists [29]. Most physicians expressed a strong likelihood of prescribing dapagliflozin to patients with T2DM in the future, based on their clinical experience with the therapy. This finding aligns with an Indian study that emphasised a strong preference for dapagliflozin in the management of T2DM [30].

## LIMITATIONS

This study possesses a few limitations. The small sample size limits the generalizability of the results. Since the study was restricted to physicians from southern India, the findings may not reflect the practices across the broader physician population. Also, the prescribing practices and comorbidities could differ across various regions. The findings are solely based on the self-reported clinical perspectives, which may introduce response bias. Additionally, the questionnaire may not have captured all relevant aspects of the subject matter.

## CONCLUSION

The study reported favorable clinical experience with dapagliflozin as both monotherapy and in combination therapy in Southern India, demonstrating its glycemic, cardiovascular and renal benefits along with a tolerable safety profile, thereby highlighting its role in current and future management of T2DM.

## CONFLICT OF INTEREST

None

## FUNDING

The study was funded by Lloyd Healthcare Pvt. Ltd., Mumbai.

## ACKNOWLEDGEMENT

None

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