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Experts' perspective on the prescription of dapagliflozin for treating T2DM patients in Indian settings

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Abstract
Objective: To gather expert opinions on the clinical use and prescription practices of dapagliflozin for managing type 2 diabetes mellitus (T2DM) in Indian settings.
Methodology: This cross-sectional study was conducted using a 23-item, multiple-response questionnaire to collect insights from specialists experienced in managing T2DM in routine clinical practice in India. The study included questions on current prescription practices, clinical observations, preferences, and experiences related to dapagliflozin use in T2DM treatment. Descriptive statistics were used to analyze the data, and categorical variables were presented as percentages to provide a clear understanding of their distribution.
Results: This study included 446 clinicians, of whom 47% reported dapagliflozin as the most commonly used SGLT2 inhibitor, while 45% favored empagliflozin. A majority (53.51%) preferred dapagliflozin as an add-on to DPP4 inhibitors to achieve targeted glycemic control. Among the participants, 58% stated that their decision to prescribe dapagliflozin for heart failure with preserved ejection fraction (HFpEF) or reduced ejection fraction (HFrEF) was based on the patient's profile. Regarding glycemic control, 52% observed an HbA1c reduction of 1 to 1.5% after three months of treatment with SGLT2 inhibitors. Approximately 42% of respondents highlighted the pleiotropic benefits of SGLT2 inhibitors, including reductions in cardiovascular death and heart failure hospitalization, improved glycemic control with weight loss, and a lower risk of kidney disease progression and cardiovascular events. In terms of blood pressure management, 64% of clinicians reported a systolic blood pressure reduction of 5 to 10 mmHg with dapagliflozin 10 mg. Nearly 52% of participants preferred the fixed-dose combination of dapagliflozin and linagliptin for various patient groups, including elderly individuals, diabetics with obesity and cardiac complications, and those with obesity and renal complications.
Conclusion: This study highlights dapagliflozin as a widely preferred treatment for T2DM management in India, offering benefits in glycemic control, cardiovascular and renal health, and blood pressure reduction. The preference for its combination with linagliptin further underscores its clinical utility.

Keywords: Type 2 diabetes, dapagliflozin, glycemic control, blood pressure, chronic kidney disease

Introduction

Diabetes mellitus is a major global health challenge with an alarming increase in prevalence. Type 2 diabetes mellitus (T2DM) is the most common form, accounting for over 90% of diabetes cases worldwide [1]. According to the 10th edition of the Diabetes Atlas, diabetes prevalence among individuals aged 20-39 increased from 2.9% in 2013 to 3.8% in 2021. By 2045, the number of individuals with diabetes is expected to reach 700 million, impacting around 11% of the global population [2, 3].

The rising burden of diabetes is particularly concerning in India, often referred to as the diabetes capital of the world. T2DM affects 4.2% of individuals aged 20-39 years, and in 2019, approximately 77 million people in India were living with diabetes, predominantly T2DM. This number is expected to surpass 134 million by 2045. India has the second-highest diabetes burden globally, following China, making it a critical public health challenge [4].

Despite ongoing efforts, many individuals with T2DM in India struggle to achieve optimal glycemic control, with over half unable to attain the target HbA1c level of ≤7% [5]. While

metformin remains the first-line therapy, disease progression often necessitates additional agents. However, tolerability challenges and side effects can impact adherence, leading to therapy failure and the need for alternative treatment options.

The introduction of novel treatments, particularly sodium-glucose co-transporter 2 (SGLT2) inhibitors, has expanded second-line options. These agents enhance glucose excretion through urine, offering significant cardiometabolic benefits [6, 7]. Unlike traditional therapies, SGLT2 inhibitors act independently of insulin secretion, blocking glucose reabsorption in the kidneys and enhancing urinary glucose excretion. This mechanism helps lower blood glucose levels while also promoting weight loss and reducing blood pressure, with a minimal risk of hypoglycaemia [8].

Among these, dapagliflozin, a selective SGLT2 inhibitor, has emerged as a valuable addition to T2DM treatment. It effectively reduces HbA1c and fasting plasma glucose levels and can be used as monotherapy or in combination with other antidiabetic agents. Beyond glycemic control, dapagliflozin provides cardiovascular and renal benefits, making it a preferred choice for comprehensive diabetes management. Given its multiple advantages, understanding prescribing patterns and clinical perspectives is essential for optimizing T2DM treatment strategies [9, 10]. This study aims to explore clinicians' perspectives and prescription trends of dapagliflozin in the management of T2DM in Indian settings.

Methodology

A cross-sectional study was conducted among clinicians specialized in managing T2DM in the major Indian cities from June 2024 to December 2024.

Questionnaire

The questionnaire booklet titled DERIVE (Dapagliflozin and combinations in Diabetes Management: Expert Perspective Study) was sent to the doctors who were interested in participating in this study. The DERIVE study comprised 23 questions covering current feedback, prescription practices, clinical observations, and specialists' experiences in T2DM management. The study was performed after obtaining approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

Participants

An invitation was sent to professionals across India based on their expertise and experience in treating T2DM in the month of March 2024 for participation in this Indian survey. About 456 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. They were instructed to complete the survey alone and not consult their colleagues. Written informed consent was obtained from all the participants prior to the study.

Statistical analysis

The data were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear insight into their distribution. The frequency of occurrence and the corresponding percentages were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, graphs and pie charts were created using Microsoft Excel 2019 (version 16.0.17928.20114).

Results

This study included 456 clinicians, of whom 54% reported that the urban population is generally aware of diabetes as a medical condition and its consequences. Approximately 57% of experts stated that 11-20% of young individuals (<45 years) newly diagnosed with diabetes already have at least one diabetes-related complication. More than half (56.14%) of clinicians identified overweight T2DM individuals with cardiovascular risk factors as the most common subgroup of patients with uncontrolled glycemic levels who experience diabetic complications. A majority (60.96%) of participants reported that cardiovascular (CV) complications are the most frequently observed in young, uncontrolled T2DM patients. Additionally, 48% of clinicians estimated that 11-20% of young diabetic patients have comorbid cardiac dysfunction.

Around 40% of participants stated that fewer than 10% of young diabetic patients have comorbid renal dysfunction. According to 46% of respondents, poor compliance with diet and exercise, medication adherence, and follow-up visits are the most common challenges in managing T2DM. Approximately 47% of participants preferred dapagliflozin as the most commonly used SGLT2 inhibitor, while 45% identified empagliflozin as their preferred choice (Fig. 1).

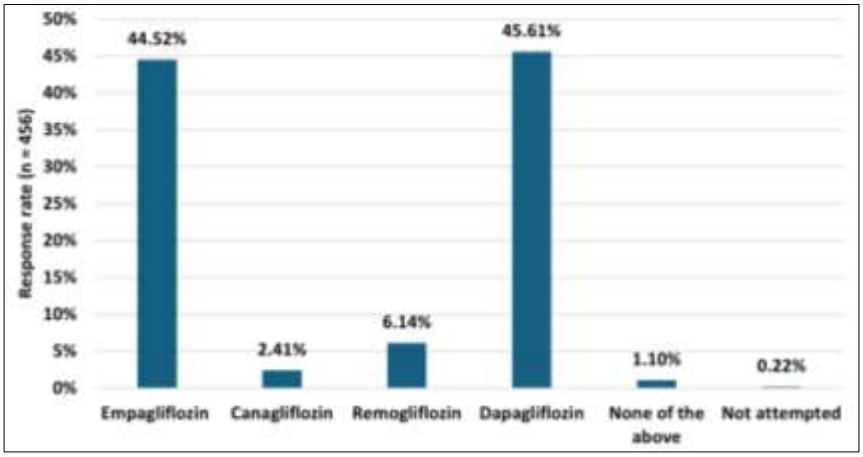

Fig 1: Distribution of response to the most commonly used SGLT2 inhibitor in routine settings

According to 49% of participants, on average, 26-40% of patients required the addition of an SGLT2 inhibitor each month to achieve glycemic targets. Around 49% of respondents stated that with recent advancements in oral antidiabetic drugs (OADs), such as dipeptidyl peptidase-4 (DPP4) inhibitors and SGLT2 inhibitors, insulin usage has decreased by 25-50%. The majority of participants (53.51%) preferred adding dapagliflozin as an add-on to DPP4 inhibitors to achieve targeted glycemic control (Fig. 2).

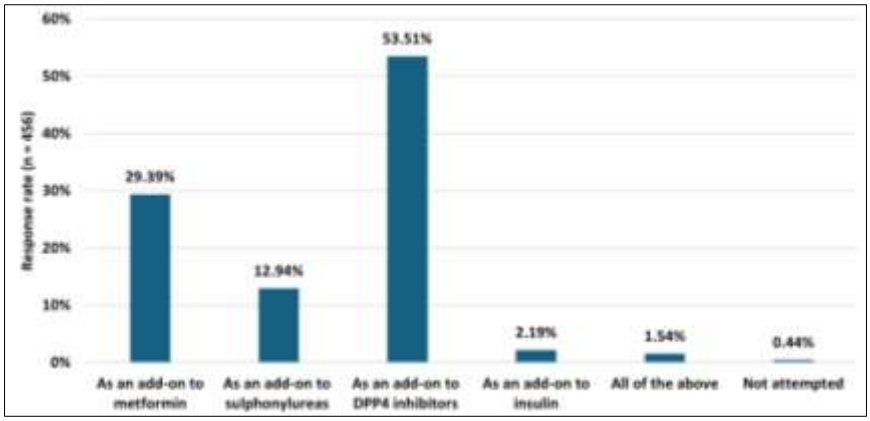

Fig 2: Distribution of response to the referred therapy category for adding dapagliflozin to achieve targeted glycemic control

Approximately 27% of clinicians stated that the aids to achieve glycemic control are a key factor influencing the decision to prescribe dapagliflozin over other medications for cardiometabolic and renal disorders. Meanwhile, 26% indicated that practitioners consider multiple benefits, including pleiotropic effects, weight neutrality, and a favorable pharmacokinetic profile, when making prescribing decisions. More than half (55.48%) of participants reported that they regularly monitor patients on dapagliflozin for potential side effects or complications.

According to 33% of participants, approximately 3-5% of patients reported experiencing genital infections after receiving dapagliflozin. The majority (58.33%) stated that their decision to prescribe dapagliflozin for heart failure with preserved ejection fraction (HFpEF) or reduced ejection fraction (HFrEF) depends on the patient's profile (Fig. 3).

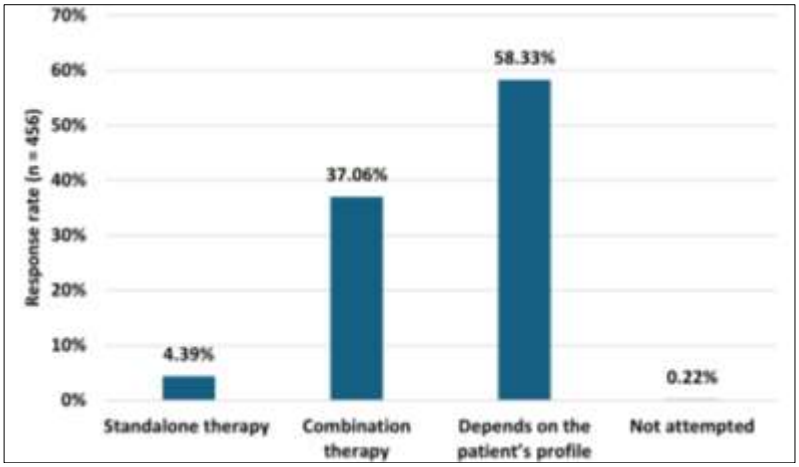

Fig 3: Distribution of responses to the clinicians' approach to prescribing dapagliflozin for HFpEF or HFrEF

About 52% of participants reported an HbA1c reduction of 1-1.5% after three months of treatment with SGLT2 inhibitors (Table 1). Nearly 42% stated that SGLT2 inhibitors offer multiple pleiotropic benefits, including a reduction in CV death and heart failure hospitalizations, improved glycemic control with weight reduction, and a lower risk of kidney disease progression and CV events (Table 2).

Around 64% of clinicians observed a 5-10 mm Hg reduction in systolic blood pressure with dapagliflozin 10 mg (Fig. 4). About 40% of participants managed the potential risk of genital mycotic infections associated with dapagliflozin through proactive education and monitoring. More than half (56.14%) indicated that 20-40% of patients require at least two additional OADs along with metformin.

Table 1: Distribution of responses to the HbA1c reduction observed with SGLT2 inhibitors after 3 months of treatment

HbA1c level	Response rate (n = 456)
1.5 to 2%	23.03%
1 to 1.5%	52.41%
0.5 to 1%	22.37%
<0.5%	1.97%
Not attempted	0.22%

Table 2: Distribution of responses to the main pleiotropic benefits of SGLT2 inhibitors noted beyond glycemic control

Pleiotropic benefits	Response rate (n = 456)
Reduces the rate of CV death and hospitalization for heart failure	31.58%
Provides effective glycemic control and reduces body weight	14.04%
Reduces the risk of progression of kidney disease, renal and CV events	12.28%
All of the above	41.89%
Not attempted	0.22%

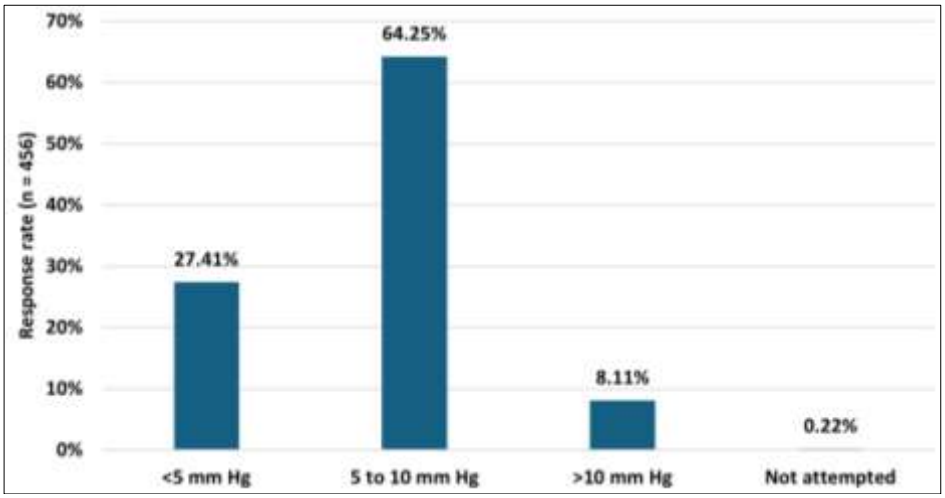

Fig 4: Distribution of responses to the HbA1c reduction observed with SGLT2 inhibitors after 3 months of treatment

As reported by 74% of participants, approximately 10-20% of diabetes mellitus patients are on linagliptin. About 52% of participants preferred using the dapagliflozin + linagliptin single-pill fixed-dose combination for various patient groups, including elderly individuals, diabetics with obesity and cardiac complications, and those with obesity and renal complications (Table 3). Additionally, 38% of clinicians noted that the key advantage of the dapagliflozin + linagliptin fixed-dose combination (FDC) is its complementary mechanism, which enhances glycemic control.

Table 3: Distribution of responses to the preferred dapagliflozin + linagliptin single-pill fixed-dose combination in different patient groups

Patient groups	Response rate (n = 456)
Elderly diabetes individuals	6.14%
Diabetics with obesity and cardiac complications	10.96%
Diabetics with obesity and renal complications	30.48%
All the above	52.19%
Not attempted	0.22%

Discussion

The study findings highlight the increasing adoption of SGLT2 inhibitors and combination therapies in routine diabetes management across Indian clinical settings. Among the participants, 47% identified dapagliflozin as their preferred SGLT2 inhibitor, while 45% favored empagliflozin. Supporting these findings, a cross-sectional study by Mehta *et al*. reported that 91% of clinicians preferred dapagliflozin for managing T2DM patients [11]. Similarly, Viswanathan and Singh emphasized dapagliflozin's efficacy in reducing HbA1c and body weight, making it a widely chosen treatment option among Indian T2DM patients [12]. Ghoshal *et al*. noted that empagliflozin is also a preferred choice for treating T2DM patients [13]. Ku *et al*. further reported that both dapagliflozin and empagliflozin significantly reduced HbA1c and fasting plasma glucose levels [14].

The current study results indicated that the majority of participants preferred adding dapagliflozin as an add-on to DPP-4 inhibitors to achieve targeted glycemic control. This finding aligns with the study by Chadha *et al*., which reported that dapagliflozin, when used as an add-on to DPP-4 inhibitors, significantly improved glycemic control in adults with T2DM [15]. Similarly, Bhattacharjee *et al*. concluded that dapagliflozin, as an add-on therapy with a DPP-4 inhibitor (sitagliptin), is both effective and safe in reducing blood glucose levels and body mass index in Indian patients with T2DM [16]. Jeong *et al*. found that the addition of dapagliflozin to a combination of a DPP-4 inhibitor (evogliptin) and metformin led to improved glycemic control and was well tolerated by the target patient population [17]. These findings reinforce the clinical value of dapagliflozin as an effective add-on therapy to DPP-4 inhibitors, offering improved glycemic outcomes and additional metabolic benefits.

Majority of the study participants indicated that their decision to prescribe dapagliflozin for HFpEF or HFrEF is influenced by the patient's profile. Similarly, McMurray *et al*. reported that among patients with heart failure and reduced ejection fraction, dapagliflozin significantly reduced the risk of worsening heart failure or CV death, regardless of the presence of diabetes [18]. Chopra *et al*. demonstrated that SGLT2 inhibitors, such as dapagliflozin, are recommended for patients with T2DM and HFrEF to reduce the risk of hospitalizations due to heart failure and cardiovascular mortality [19]. The benefits of dapagliflozin in

heart failure extend beyond glucose regulation, as it has been shown to improve left ventricular function, reduce preload and afterload, and enhance diuresis. In addition to its impact on HFrEF, dapagliflozin has demonstrated promising outcomes in HFpEF patients, as observed in the DELIVER trial [20].

Approximately 52% of the current study participants reported an HbA1c reduction of 1 to 1.5% after three months of treatment with SGLT2 inhibitors. These findings align with the FOREFRONT study conducted in Indian patients, which demonstrated that dapagliflozin treatment significantly reduced HbA1c levels. The study reported a decline from a baseline of 9.11% (±1.44) to 8.11% (±1.22) at month 3 (Δ = 1.00% ±1.01) and further to 7.62% (±1.04) at month 6 (Δ = 1.49% ±1.18), with $P < 0.001$.[12] Similarly, a meta-analysis by Monami *et al*. evaluating the short- and medium-term efficacy of SGLT2 inhibitors reported a mean HbA1c reduction of 0.63% (95% CI: 0.57-0.68) at 12 weeks [21]. Saleem *et al*. also observed significant glycemic benefits in a study of 100 T2DM patients receiving SGLT2 inhibitors as a fourth-line therapy. Their findings demonstrated an average HbA1c reduction of 0.81% at three months and 1.07% at six months ($P < 0.001$ for both) [22]. These consistent reductions highlight the sustained efficacy of SGLT2 inhibitors in improving glycemic control over time.

In the present study, the majority of participants acknowledged the multiple pleiotropic benefits of SGLT2 inhibitors, including a reduction in cardiovascular death and heart failure hospitalizations, improved glycemic control with weight reduction, and a decreased risk of kidney disease progression and CV events. Das *et al*. concluded that SGLT2 inhibitors are recommended for lowering the risk of heart failure hospitalization in patients with T2DM who have either established cardiovascular disease or are at high cardiovascular risk [23]. Similarly, Shao *et al*. found that SGLT2 inhibitors not only exert glucose-lowering effects but also provide additional benefits, such as improvements in body weight, alanine aminotransferase levels, and estimated glomerular filtration rate, potentially reducing cardiometabolic disease risks in T2DM patients [24]. Furthermore, a meta-analysis revealed that SGLT2 inhibitors were associated with a 37% reduction in the risk of kidney disease progression and a 23% lower incidence of acute kidney injury, regardless of diabetes status [25].

The present study findings indicate that clinicians observed a systolic blood pressure reduction of 5 to 10 mm Hg with dapagliflozin 10 mg. In a prospective study, Ghanim *et al*. reported that dapagliflozin administration in patients with T2DM led to both acute and long-term reductions in systolic blood pressure, accompanied by a decrease in vasoconstrictors and an increase in vasodilators [26]. Velusamy and Kumar compared dapagliflozin 10 mg and empagliflozin 10 mg as add-on therapies in T2DM management. Over 6 months, hypertensive patients experienced significant reductions in systolic blood pressure in both groups. The dapagliflozin group showed a greater reduction of 10.26 mm Hg compared to 4.2 mm Hg in the empagliflozin group [27]. Sjöström *et al*. analyzed the effect of dapagliflozin 10 mg on blood pressure in patients with T2DM. The findings indicated that dapagliflozin was associated with placebo-subtracted changes from baseline in systolic blood pressure of -3.6 mm Hg in hypertensive patients and -2.6 mm Hg in non-hypertensive patients [28].

About 52% of participants preferred using the dapagliflozin + linagliptin single-pill fixed-dose combination for all patient groups, including elderly individuals, diabetics with obesity and cardiac complications, and those with obesity and renal complications. In a cross-sectional study, 76% of clinicians favored combining linagliptin with dapagliflozin, and about 61% specifically recommended the dapagliflozin + linagliptin FDC for elderly diabetic patients with obesity and cardiac or renal complications [29]. A phase III trial by Jain *et al*. compared dapagliflozin/linagliptin FDC to linagliptin monotherapy in metformin-treated patients. The FDC group showed greater HbA1c reduction (-1.28% vs. -0.83%), along with a significant decrease in fasting and postprandial glucose and body weight. The combination was well-tolerated, with fewer adverse events [30]. In a multicenter study, Hong *et al*. reported that the dapagliflozin/linagliptin FDC group had a significantly greater HbA1c reduction than the linagliptin plus placebo group, with a mean difference of -0.88% at 24 weeks. Additionally, 44.8% of FDC-treated patients achieved HbA1c levels <7%, compared to 18.6% in the control group. The FDC was well-tolerated, with no reported cases of symptomatic hypoglycemia [31].

The study provides valuable insights into clinicians' preferences and prescribing practices for dapagliflozin in managing T2DM in Indian clinical settings. Its key strengths include a large sample size and the use of a structured, validated questionnaire to gather data from a diverse group of clinicians. However, several limitations should be considered. The study relies on expert opinion, which may introduce bias due to variations in individual clinical experience and prescribing preferences. Additionally, the survey-based methodology may not fully capture emerging treatment trends or evolving clinical evidence. Another limitation is the absence of direct patient data, as the findings are based solely on clinician perspectives rather than real-world patient outcomes. These factors should be taken into account when interpreting the results. Future research should incorporate prospective studies or real-world observational data to validate clinician-reported findings and provide a more comprehensive understanding of optimal T2DM treatment strategies in India.

Conclusion

This study emphasizes dapagliflozin as a widely preferred SGLT2 inhibitor among clinicians in India for managing T2DM, particularly as an add-on to DPP4 inhibitors. Its benefits extend beyond glycemic control, offering pleiotropic advantages such as cardiovascular and renal protection, weight reduction, and blood pressure improvement. The preference for the dapagliflozin + linagliptin FDC further underscores its clinical utility across diverse patient groups. These findings emphasize the need for further real-world studies to validate the observed trends and optimize treatment strategies for T2DM management in India.

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