Survey Report

Perception Mapping of Physicians on Therapeutic Usage of Dapagliflozin in Indian Patients with Type 2 Diabetes Mellitus in Real-life Scenario

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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1 INTRODUCTION

Type 2 Diabetes Mellitus (T2DM), also known as non-insulin dependent diabetes, is characterized by insulin resistance and has become a serious health issue in children over the past two decades [1]. In 2021, an estimated 537 million people worldwide have diabetes, a figure expected to rise to 643 million by 2030 and 783 million by 2045 [2]. The primary drug treatments for type II diabetes mellitus include insulin secretagogues, biguanides, insulin sensitizers, alpha-glucosidase inhibitors, incretin mimetics, amylin antagonists, and sodium-glucose co-transporter-2 (SGLT2) inhibitors [3].

Dapagliflozin, a selective SGLT2 inhibitor, has emerged as a promising therapeutic option in T2DM management, demonstrating benefits beyond glycemic control. The DECLARE-TIMI 58 trial, a landmark study involving 17,160 patients, established dapagliflozin's cardiovascular safety and efficacy, showing significant reductions in hospitalization for heart failure and cardiovascular death in patients with T2DM [4]. Furthermore, the DAPA-CKD trial demonstrated remarkable renoprotective effects, reducing the risk of kidney failure, death from cardiovascular causes, or hospitalization for heart failure in patients with chronic kidney disease, with or without T2DM [5].

The multifaceted benefits of dapagliflozin extend to weight management and blood pressure control, making it an attractive option for T2DM patients with multiple cardiovascular risk factors. The DAPA-HF trial demonstrated that these benefits persist even in patients without diabetes, suggesting a mechanism of action independent of glucose control [6]. Recent meta-analyses have confirmed the consistent cardiovascular and renal benefits across different patient populations, strengthening the evidence base for its use in clinical practice [7].

In the Indian context, where cardiovascular complications remain a leading cause of mortality in T2DM patients, the role of dapagliflozin becomes particularly relevant. Therefore, this survey study aims to systematically assess physician perspectives on dapagliflozin use in Indian T2DM patients, focusing on real-world application, decision-making factors, and perceived benefits and challenges to optimize patient care and outcomes.

2 RATIONALE OF THE STUDY

While clinical trials confirm dapagliflozin's effectiveness in managing T2DM, its real-world application in India remains underexplored. The unique challenges of managing T2DM in India—stemming from diverse patient profiles, socioeconomic factors, and healthcare variations—make it crucial to understand physician perspectives on its use. Translating guidelines into practice often reveals gaps due to differences in patient selection, therapy initiation, and long-term treatment decisions. Understanding how physicians prioritize dapagliflozin's benefits, such as cardiovascular protection and renal health, is essential for aligning real-world practices with evidence-based recommendations.

This survey will document Indian physicians' experiences with dapagliflozin in T2DM, aiming to identify barriers, highlight practice patterns, and guide context-appropriate clinical support. Insights gained may help bridge the gap between trial data and actual practice, contributing to improved patient outcomes in India.

3 OBJECTIVES

To assess the perception, practice patterns, and clinical experiences of Indian physicians regarding the use of Dapagliflozin in the treatment of T2DM.

4 METHODS

This study was a cross-sectional, questionnaire-based survey that assessed the perceptions, practices, and clinical experiences of Indian physicians regarding the use of dapagliflozin in managing T2DM. A structured questionnaire was distributed to a representative sample of endocrinologists, diabetologists, and general practitioners across India who routinely treat T2DM patients. The questionnaire captured data on the prevalence of T2DM and associated cardiovascular risk factors, prescribing patterns of SGLT2 inhibitors, primary therapeutic goals, and observed cardiovascular outcomes with dapagliflozin. It also examined factors influencing initiation, continuation criteria for patients with reduced kidney function, and long-term safety perceptions. The data provided insights into real-world dapagliflozin use and aimed to inform future guidelines and best practices for T2DM management.

Physicians were identified and invited to participate through professional networks and medical associations. Participants received detailed information prior to participation.

The 11-question survey was administered electronically, and responses were collected and securely stored. Statistical analysis was conducted to summarize findings and identify key trends, with results compiled into a comprehensive report. Findings were planned for sharing through scientific publications or presentations at conferences. The target sample size for this study was 100 Indian physicians. Physicians practicing in India who regularly treated T2DM patients and had experience with dapagliflozin use were included, provided they were willing to give informed consent and complete the survey. Physicians who did not treat T2DM, had no experience with dapagliflozin, or declined to participate were excluded, as were incomplete questionnaires.

Data were analyzed using descriptive and inferential statistics. Descriptive statistics summarized demographic information and response frequencies, while inferential statistics, such as chi-square tests or logistic regression, explored associations between physician characteristics and their perceptions and prescribing behaviors.

4 RESULTS

A total of 85 HCPs participated in the survey. Below is the summary of the responses.

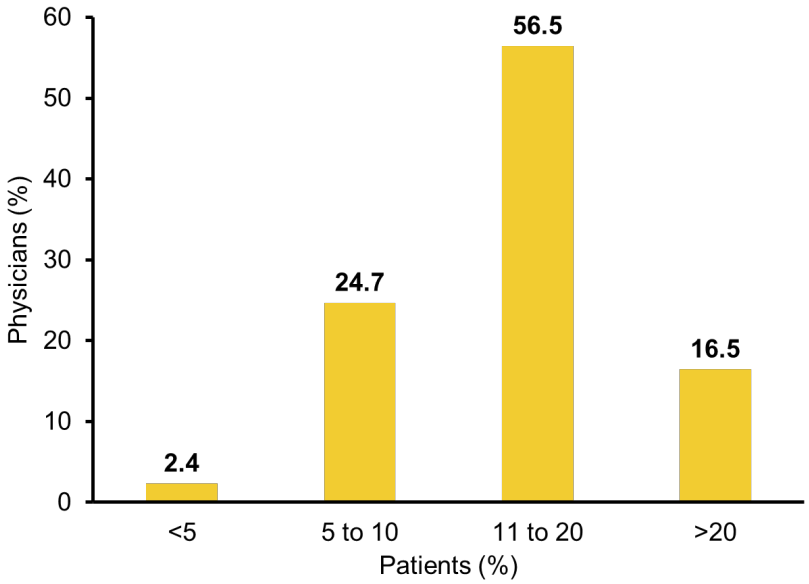
Question 1: In your practice, what is the approximate percentage of type 2 diabetes mellitus (T2DM) patients?

A. <5%

B. 5-10%

C. 11-20%

D. >20%



- The largest group of physicians (56.5%) encountered 11–20% of their patients with type 2 diabetes mellitus in clinical practice.
- A notable proportion of physicians (24.7%) reported that 5–10% of their patients had T2DM during clinical practice.
- A smaller group (16.5%) reported that more than 20% of their patients had T2DM.
- A very small group (2.4%) indicated that less than 5% of their patients were diagnosed with T2DM.

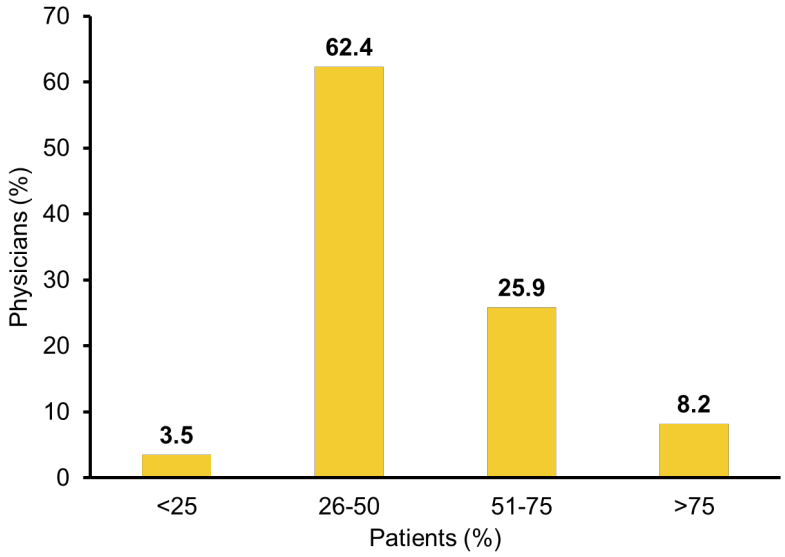
Question 2: In your clinical practice, what is the approximate percentage of type 2 diabetes mellitus (T2DM) patients having Multiple Cardiovascular (CV) risk factors?

A. <25%

B. 26-50%

C. 51-75%

D. >75%

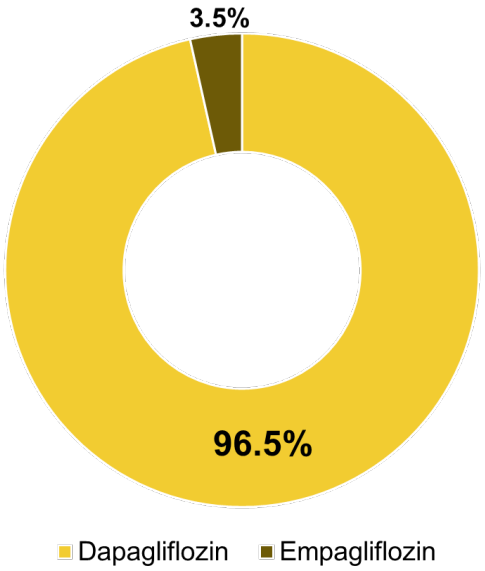


- The majority of physicians (62.4%) observed that 26-50% of T2DM patients had cardiovascular (CV) risk factors in clinical practice.
- 25.9% of physicians reported that 51-75% of T2DM patients had CV risk factors in clinical practice.
- A notable group (8.2%) of physicians reported that more than 75% of T2DM patients had CV risk factors in clinical practice.
- Around 3.5% of physicians reported that less than 25% of T2DM patients had CV risk factors in clinical practice.

Question 3: Which SGLT2i do you commonly prescribe for T2DM patients?

A. Dapagliflozin

B. Empagliflozin



- The largest proportion of physicians (96.5%) commonly prescribed dapagliflozin, an SGLT2i, for T2DM patients.
- Empagliflozin, an SGLT2i, was commonly prescribed for T2DM patients by 3.5% of physicians.

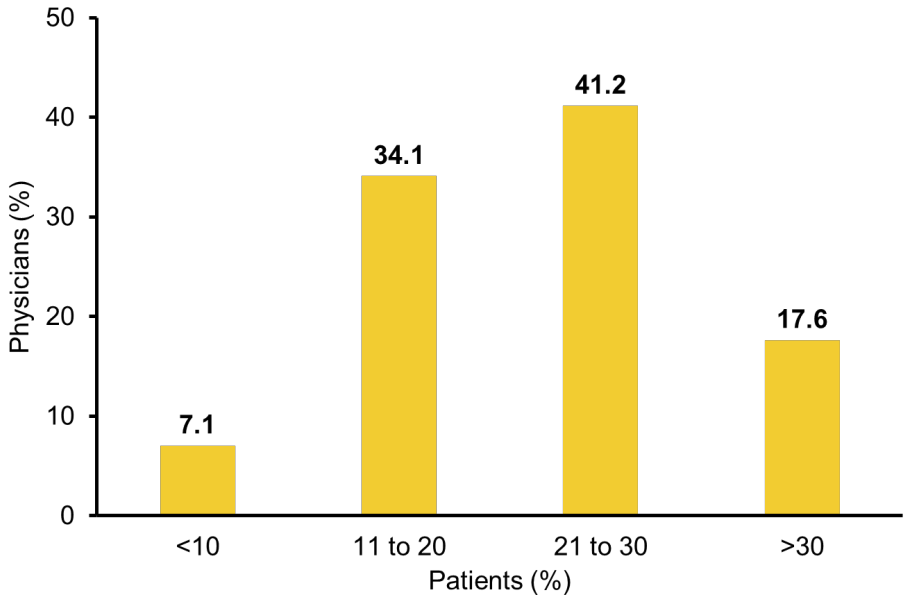
Question 4: In your clinical experience, what percentage of Diabetic patients are prescribed with Dapagliflozin therapy?

A. <10%

B. 11-20%

C. 21-30%

D. >30%



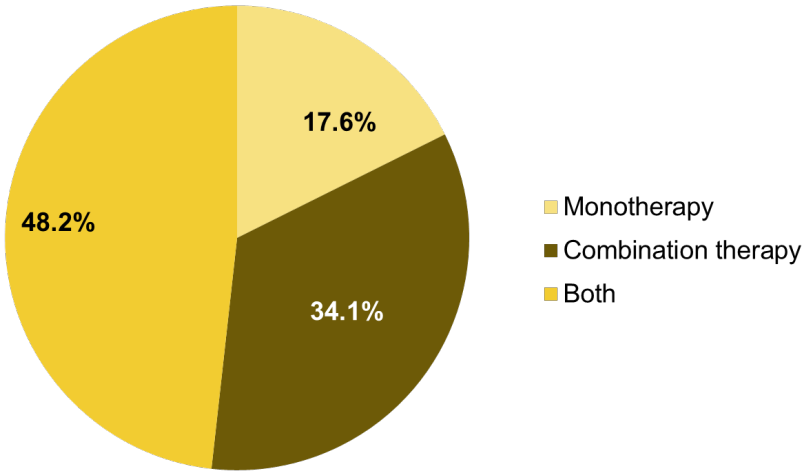
- In clinical practice, 41.2% of physicians prescribed dapagliflozin therapy for 21-30% of diabetic patients.
- A significant portion (34.1%) of physicians prescribed dapagliflozin therapy for 11-20% of diabetic patients.
- Around 17.6% of physicians prescribed dapagliflozin therapy for more than 30% of diabetic patients.
- Approximately 7% of physicians prescribed dapagliflozin therapy for fewer than 10% of diabetic patients.

Question 5: Do you prescribe Dapagliflozin as monotherapy or in combination with other antidiabetic drugs?

A. Monotherapy

B. Combination therapy

C. Both



- A significant portion (48.2%) of physicians prescribed dapagliflozin as monotherapy or in combination with other antidiabetic drugs in clinical practice.
- Approximately 34.5% of physicians prescribed dapagliflozin as monotherapy or in combination with other antidiabetic drugs in clinical practice.
- A small portion (17.6%) of physicians prescribed dapagliflozin as monotherapy or in combination with other antidiabetic drugs in clinical practice.

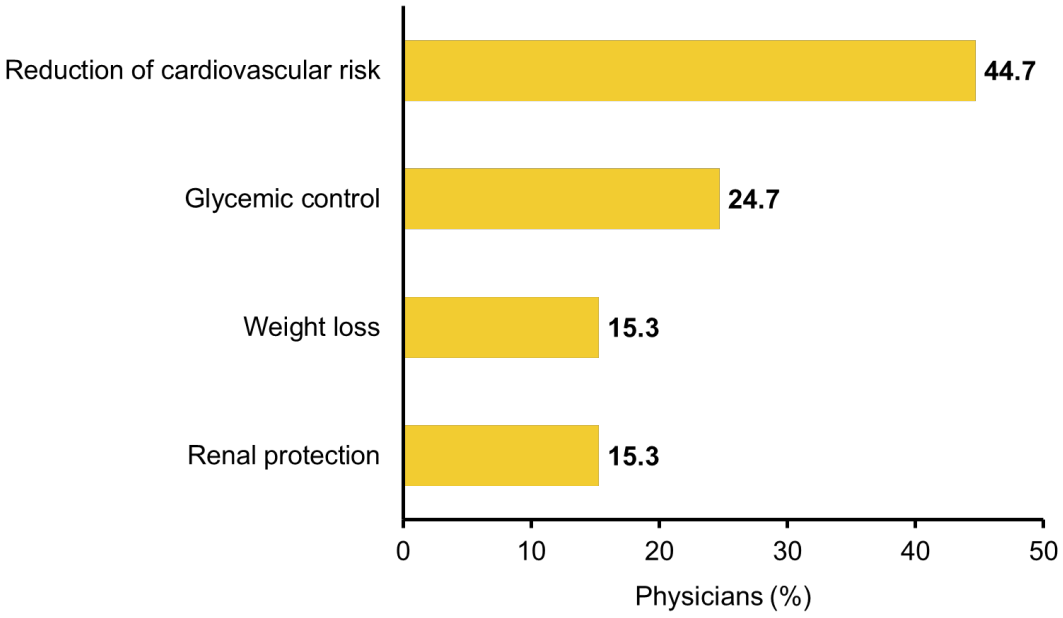
Question 6: What is your primary goal in prescribing Dapagliflozin to your T2DM patients? (Can mark more than 1 option, if required)

A. Glycemic control

B. Weight loss

C. Reduction of cardiovascular risk

D. Renal protection



- Reduction of cardiovascular risk was the primary goal prescribed by 44.7% of physicians for T2DM patients.
- Around 24.7% of physicians prescribed glycemic control as the primary goal for T2DM patients.
- 15.3% of physicians prescribed weight loss as the primary goal for T2DM patients.
- Renal protection was the primary goal prescribed by 15.3% of physicians for T2DM patients.

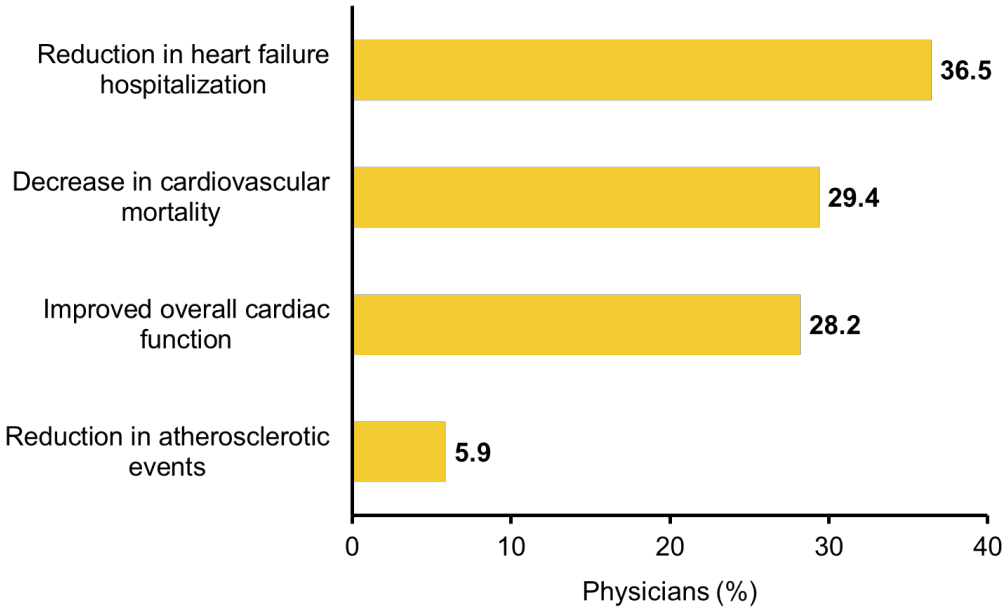
Question 7: Which cardiovascular outcome(s) improvements do you observe with the use of Dapagliflozin? (Can mark more than 1 option, if required)

A. Reduction in heart failure hospitalization

B. Decrease in cardiovascular mortality

C. Improved overall cardiac function

D. Reduction in atherosclerotic events



- A significant portion (36.5%) of physicians reported a reduction in heart failure hospitalizations as an outcome observed with the use of dapagliflozin.
- A total of 29.4% of physicians reported a decrease in cardiovascular mortality as the cardiovascular outcome observed with the use of dapagliflozin.
- Improved overall cardiac function was the cardiovascular outcome reported by 28.2% of physicians in clinical practice.
- A reduction in atherosclerotic events was the cardiovascular outcome reported by 5.9% of physicians in clinical practice.

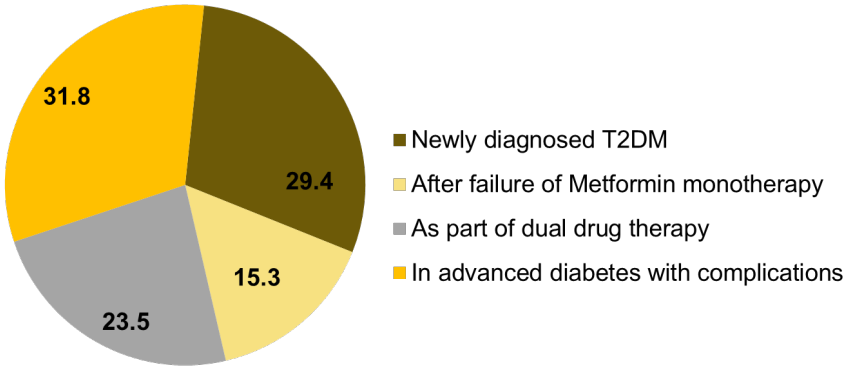
Question 8: At what stage of T2DM do you typically initiate Dapagliflozin treatment in your patients?

a. Newly diagnosed T2DM

b. After failure of Metformin monotherapy

c. As part of dual drug therapy

d. In advanced diabetes with complications

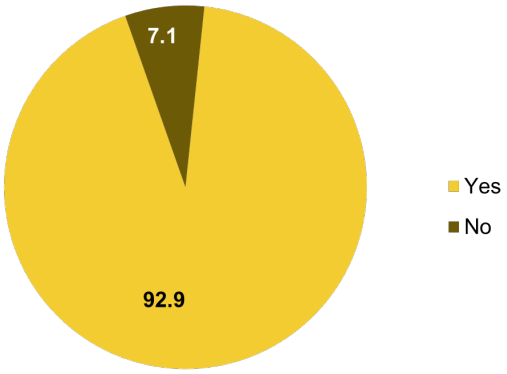


- In advanced diabetes with complications, 31.8% of physicians reported initiating dapagliflozin treatment for their patients with T2DM.
- For newly diagnosed T2DM, 29.4% of physicians reported initiating dapagliflozin treatment for their patients.
- As part of dual-drug therapy, 23.5% of physicians reported initiating dapagliflozin treatment for their patients with T2DM.
- After failure of metformin monotherapy, 15.3% of physicians reported initiating dapagliflozin treatment for their patients with T2DM.

Question 9: Do you consider continuing Dapagliflozin, if the eGFR of a T2DM patients falls below 25 mL/min/1.73 m2 while receiving treatment to reduce the risk of eGFR decline, ESKD, CV death and hHF?

A. Yes

B. No



- A majority (92.9%) of physicians reported continuing dapagliflozin if the eGFR of a T2DM patient falls below 25 mL/min/1.73 m² while receiving treatment to reduce the risk of eGFR decline, ESKD, CV death, and hHF.
- Around 7.1% of physicians reported discontinuing dapagliflozin if the eGFR of a T2DM patient falls below 25 mL/min/1.73 m² while receiving treatment to reduce the risk of eGFR decline, ESKD, CV death, and hHF.

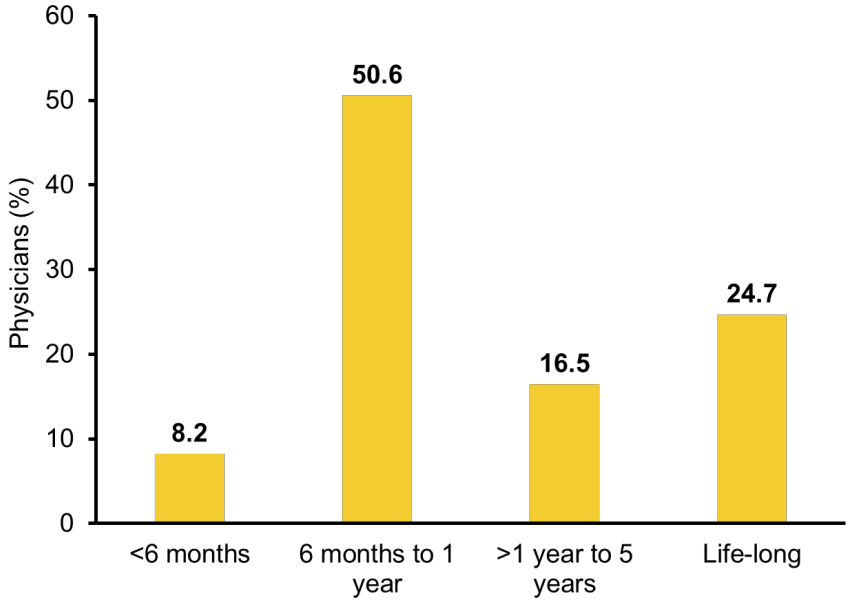
Question 10: As per your opinion, what can be the average duration of Dapagliflozin Therapy in T2DM patients with CV risk?

A. Less than 6 months

B. 6 months to 1 year

C. >1 year to 5 years

D. Life-long



- The majority (50.6%) of physicians reported a duration of less than 6 months to 1 years for dapagliflozin therapy in T2DM patients with CV risk.
- A significant portion (24.7%) of physicians reported a life-long duration for dapagliflozin therapy in T2DM patients with CV risk.
- A duration of more than 1 year to 5 years for dapagliflozin therapy in T2DM patients with CV risk was reported by 16.5% of physicians.
- A small portion (8.2%) of physicians reported a duration of less than 6 months for dapagliflozin therapy in T2DM patients with CV risk.

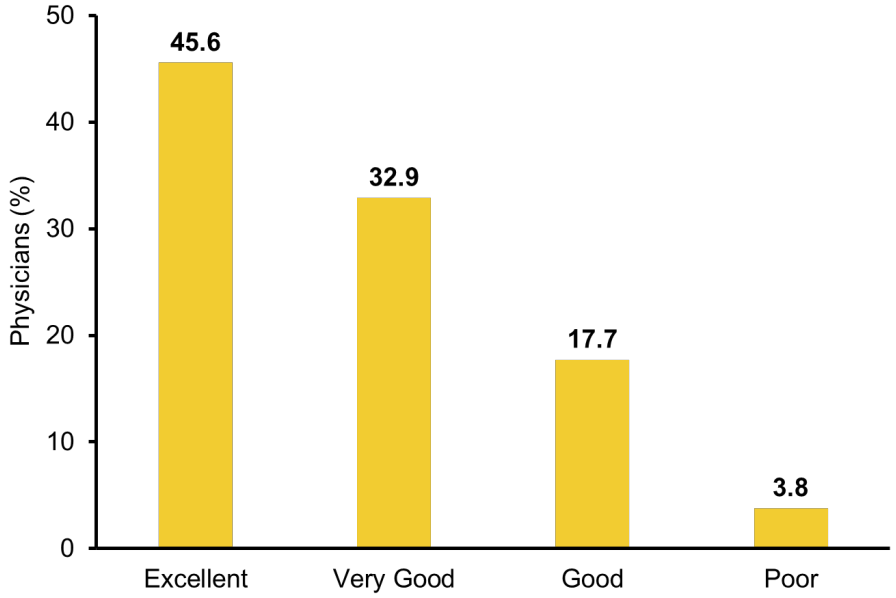
Question 11: In your opinion, how is the long-term safety profile of Dapagliflozin Therapy in T2DM patients with CV risk?

A. Excellent

B. Very Good

C. Good

D. Poor



- An excellent long-term safety profile of dapagliflozin therapy in T2DM patients with CV risk was reported by 45.6% of physicians.
- A very good long-term safety profile of dapagliflozin therapy in T2DM patients with CV risk was reported by 32.9% of physicians.
- A good long-term safety profile of dapagliflozin therapy in T2DM patients with CV risk was reported by 17.7% of physicians.
- A poor long-term safety profile of dapagliflozin therapy in T2DM patients with CV risk was reported by 3.8% of physicians.

5 SUMMARY

The data highlights physician practices and observations regarding T2DM and the use of dapagliflozin, an SGLT2 inhibitor. Most physicians (56.5%) encountered 11–20% of patients with T2DM in their practice, while smaller groups reported encountering 5–10% (24.7%), more than 20% (16.5%), or less than 5% (2.4%). Additionally, 62.4% of physicians observed that 26–50% of T2DM patients had CV risk factors, with 25.9% reporting 51–75%, and 8.2% reporting more than 75%. Only 3.5% observed CV risk factors in less than 25% of their T2DM patients. Dapagliflozin was the preferred SGLT2i for 96.5% of physicians, while 3.5% prescribed empagliflozin. Physicians commonly prescribed dapagliflozin for 21–30% (41.2%) or 11–20% (34.1%) of their diabetic patients, with fewer prescribing it for more than 30% (17.6%) or less than 10% (7%). It was used as monotherapy or in combination by 48.2% of physicians. The primary treatment goals included reducing CV risk (44.7%), glycemic control (24.7%), weight loss (15.3%), and renal protection (15.3%). Clinical outcomes observed with dapagliflozin included reductions in heart failure hospitalizations (36.5%), CV mortality (29.4%), and improvements in overall cardiac function (28.2%), while 5.9% reported reductions in atherosclerotic events.

Dapagliflozin was initiated for advanced T2DM with complications by 31.8% of physicians, for newly diagnosed cases by 29.4%, as part of dual-drug therapy by 23.5%, and after metformin failure by 15.3%. Most physicians (92.9%) continued dapagliflozin even if the patient's eGFR dropped below 25 mL/min/1.73 m², while 7.1% discontinued it. Regarding therapy duration, 50.6% reported prescribing dapagliflozin for less than six months, 24.7% for life, and 16.5% for 1–5 years. Long-term safety was rated as excellent (45.6%), very good (32.9%), or good (17.7%), with only 3.8% reporting poor safety. In summary, dapagliflozin is widely utilized for T2DM patients, primarily for reducing CV risks, with notable benefits observed in cardiac outcomes and a favorable long-term safety profile.

6 DISCUSSION

The data provides a comprehensive overview of physician practices and clinical observations in managing T2DM, with a focus on the use of dapagliflozin, an SGLT2 inhibitor. Most physicians (56.5%) encounter T2DM in 11–20% of their patients, suggesting that managing this condition forms a significant aspect of routine clinical practice. Smaller groups reported T2DM prevalence rates of 5–10% (24.7%) and more than 20% (16.5%), with only 2.4% encountering it in less than 5% of their patients. These figures highlight the pervasive nature of T2DM across diverse patient populations. Moreover, CV risk factors were identified in a substantial proportion of T2DM patients, with the majority of physicians (62.4%) observing these in 26–50% of cases, further underscoring the intersection of metabolic and cardiovascular health challenges in diabetic care.

Dapagliflozin emerged as the overwhelmingly preferred SGLT2 inhibitor, prescribed by 96.5% of physicians, while empagliflozin was used by only 3.5%. Physicians commonly prescribed dapagliflozin to 21–30% (41.2%) or 11–20% (34.1%) of their diabetic patients, reflecting its widespread acceptance. However, 17.6% of physicians prescribed it to more than 30% of their patients, while 7% limited its use to fewer than 10%. Dapagliflozin was utilized either as monotherapy or in combination therapy in nearly half (48.2%) of cases, with its appeal rooted in its multifunctional benefits. The primary therapeutic goals for prescribing dapagliflozin included reducing cardiovascular risk (44.7%), glycemic control (24.7%), weight loss (15.3%), and renal protection (15.3%). This highlights its versatility in addressing various complications associated with T2DM.

In terms of clinical outcomes, physicians reported significant improvements linked to dapagliflozin use. These included reductions in heart failure hospitalizations (36.5%) and cardiovascular mortality (29.4%), along with improved overall cardiac function (28.2%). A smaller proportion (5.9%) noted reductions in atherosclerotic events. These findings emphasize dapagliflozin's role in addressing critical CV and cardiac outcomes in T2DM patients. Initiation of dapagliflozin therapy was most common in advanced diabetes with complications (31.8%), newly diagnosed T2DM cases (29.4%), as part

of dual-drug therapy (23.5%), and after metformin failure (15.3%), indicating its flexibility across various stages of disease progression.

When faced with declining kidney function (eGFR below 25 mL/min/1.73 m²), 92.9% of physicians continued dapagliflozin, reflecting confidence in its renal benefits, while only 7.1% opted to discontinue treatment. The duration of dapagliflozin therapy varied, with half of the physicians (50.6%) prescribing it for less than six months, while 24.7% prescribed it for life, and 16.5% for one to five years. These patterns suggest individualized approaches to therapy based on patient profiles and risk assessments.

Physicians generally rated the long-term safety profile of dapagliflozin favorably, with 45.6% describing it as excellent, 32.9% as very good, and 17.7% as good. Only a small minority (3.8%) reported poor safety outcomes, reinforcing the drug's reliability in long-term use. In summary, dapagliflozin is widely utilized for its cardiovascular, glycemic, renal, and weight-management benefits, with significant outcomes reported in routine clinical practice. Its versatility, safety, and efficacy make it a cornerstone in the management of T2DM patients with and without complications.

7 CLINICAL RECOMMENDATIONS

- Identify and address CV risk factors, present in 26–50% of T2DM patients, as reported by 62.4% of physicians.
- Prioritize therapies like dapagliflozin for patients at risk of CV and renal complications, given its efficacy in reducing heart failure hospitalizations (36.5%) and CV mortality (29.4%).
- Dapagliflozin is widely prescribed (96.5%) for T2DM management. It can be initiated after metformin failure (15.3%) or for newly diagnosed patients (29.4%).
- Tailor dapagliflozin therapy to address specific goals, such as CV risk reduction (44.7%), glycemic control (24.7%), weight loss (15.3%), or renal protection (15.3%).
- A majority of physicians (50.6%) suggest therapy durations of less than six months for CV risk management, while 24.7% recommend lifelong treatment.
- Long-term safety is supported, with 45.6% and 32.9% of physicians reporting excellent or very good profiles, respectively.
- Dapagliflozin therapy should be continued even if eGFR declines below 25 mL/min/1.73 m^2, as per 92.9% of physicians, to mitigate risks of end-stage kidney disease and CV mortality.
- Employ dapagliflozin as monotherapy or alongside other antidiabetic drugs, leveraging its effectiveness in multi-drug regimens (48.2%).

8 CONSULTING OPINION

Management of T2DM should prioritize a comprehensive approach addressing both glycemic control and associated CV and renal risks. Based on physician-reported practices, a significant portion of T2DM patients (26–50%) exhibit CV risk factors, underscoring the importance of early intervention. Dapagliflozin, an SGLT2 inhibitor, has emerged as a cornerstone therapy, widely prescribed by 96.5% of physicians. Its benefits include a reduction in heart failure hospitalizations, observed by 36.5% of physicians, and a decrease in CV mortality (29.4%). Furthermore, it contributes to weight loss and renal protection, meeting diverse therapeutic goals.

Dapagliflozin therapy is versatile, being utilized in newly diagnosed cases (29.4%), after failure of metformin monotherapy (15.3%), and as part of dual or combination therapy (23.5%). While its use is tailored to patient-specific needs, the majority of physicians emphasize its utility in reducing CV risks, a primary goal for 44.7% of clinicians. Most physicians (50.6%) recommend therapy durations of less than six months for managing CV risks, although lifelong therapy may be warranted in some cases. The long-term safety profile of dapagliflozin is robust, with 78.5% of physicians rating it as excellent or very good. Importantly, 92.9% of physicians recommend continuing therapy even when eGFR declines below 25 mL/min/1.73 m^2, highlighting its role in mitigating end-stage kidney disease and CV mortality.

In clinical practice, dapagliflozin demonstrates notable efficacy when used as monotherapy or in combination with other agents. It addresses glycemic control, weight management, and renal protection while reducing CV risks. Its widespread adoption underscores its importance in achieving holistic T2DM management, ensuring improved patient outcomes across varying disease stages and comorbid conditions. This data reinforces dapagliflozin’s role as a pivotal therapeutic agent in T2DM care.

9 MARKET OPPORTUNITIES

The rising prevalence of T2DM globally presents significant market opportunities for innovative therapies like dapagliflozin. With a notable proportion of physicians reporting that 11–20% of their patients have T2DM and many observing CV risk factors in over 50% of cases, the need for therapies addressing both glycemic control and comorbidities is critical. Dapagliflozin, an SGLT2 inhibitor, stands out with its dual benefits in diabetes management and cardiovascular protection, creating a broad scope for adoption in clinical practice.

Physician-reported data highlights dapagliflozin's widespread prescription, with 96.5% of clinicians favoring it. Its ability to reduce heart failure hospitalizations, improve cardiac function, and decrease CV mortality aligns with the growing demand for therapies that address the complications of T2DM. Furthermore, its renal protective properties, evidenced by its continued use in patients with declining eGFR, strengthen its positioning in the nephrology segment. This expands its potential market among patients with advanced diabetes and those at risk of end-stage kidney disease.

The versatility of dapagliflozin in treatment regimens, from monotherapy to combination therapy, adds to its appeal. Physicians report using it for newly diagnosed patients, those with complications, and after metformin failure, creating opportunities for increased penetration across various stages of T2DM management. Additionally, its safety profile, endorsed as excellent or very good by the majority of physicians, enhances its credibility and marketability.

As the focus on value-based care intensifies, dapagliflozin's proven outcomes in reducing hospitalizations and long-term complications make it a cost-effective option, appealing to healthcare systems and payers. With increasing awareness of the importance of cardiovascular and renal health in diabetes care, dapagliflozin is well-positioned to capture a growing share of the diabetes therapeutic market, addressing unmet needs and improving patient outcomes.

10 MARKET POSITIONING

Dapagliflozin occupies a leading position in the T2DM treatment market, driven by its unique ability to address glycemic control alongside CV and renal comorbidities. As an SGLT2 inhibitor, it has garnered widespread adoption, with 96.5% of physicians prescribing it in clinical practice. Its positioning as a multifaceted therapeutic agent aligns with the evolving needs of T2DM management, particularly in patients with high CV and renal risks. One of dapagliflozin's key differentiators is its efficacy in reducing heart failure hospitalizations, an outcome reported by 36.5% of physicians, and its ability to decrease cardiovascular mortality, noted by 29.4%. These benefits place it at the forefront of T2DM therapies that go beyond glucose-lowering to deliver comprehensive health benefits. Additionally, its renal protective effects, highlighted by its continued use in patients with eGFR levels below 25 mL/min/1.73 m², enhance its appeal among nephrologists and endocrinologists. These attributes make dapagliflozin particularly attractive for managing advanced diabetes cases and patients with complications, a segment that represents a significant portion of the T2DM population.

Dapagliflozin's versatility further strengthens its market position. It is widely prescribed across different patient profiles, including newly diagnosed cases (29.4%), advanced diabetes with complications (31.8%), and post-metformin failure (15.3%). Its utility in both monotherapy and combination regimens (used by 48.2% of physicians) broadens its application across various stages of T2DM. The therapy also aligns with diverse treatment goals, such as cardiovascular risk reduction (44.7%), glycemic control (24.7%), weight management (15.3%), and renal protection (15.3%).

Safety and tolerability are critical factors in T2DM management, and dapagliflozin excels in this area. With 78.5% of physicians rating its long-term safety profile as excellent or very good, it has a strong reputation for reliability. This enhances patient adherence and positions dapagliflozin as a preferred choice among healthcare providers.

Moreover, dapagliflozin's cost-effectiveness and demonstrated ability to reduce hospitalizations and long-term complications make it appealing to healthcare systems and payers. Its established role in delivering improved outcomes and addressing

unmet needs in T2DM management solidifies its market leadership. Dapagliflozin is poised to maintain its competitive edge in a growing market by continuing to meet the complex demands of T2DM care while ensuring patient and provider satisfaction.

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