

# Survey Report

## **Therapeutic Usage of Vildagliptin + Dapagliflozin Combination in Current Clinical Scenario in India**

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

Diabetes mellitus is a chronic metabolic disorder that is increasingly becoming a major global health challenge, affecting millions of individuals worldwide. India is currently the diabetes capital of the world, with an estimated 77 million people living with the condition [1]. Uncontrolled diabetes is associated with numerous long-term complications, including cardiovascular disease, retinopathy, neuropathy, and nephropathy. These conditions can significantly diminish quality of life and cause early death. Consequently, managing diabetes effectively is essential to prevent these complications and improve overall health outcomes [1]. Effective management of diabetes mellitus requires a comprehensive approach that includes lifestyle modifications, pharmacotherapy, and sometimes insulin therapy. This strategy aims to achieve and maintain glycemic control while reducing the risk of associated complications [2]. Despite the availability of various treatment, many patients continue to struggle with achieving and sustaining optimal glycemic control, often failing to reach target glycated hemoglobin (HbA1c) levels [3].

In recent years, the combination of Vildagliptin and Dapagliflozin has emerged as a promising treatment option due to its complementary mechanisms of action and potential synergistic benefits. A recent network meta-analysis demonstrated that adding Vildagliptin and Dapagliflozin to metformin monotherapy offers superior efficacy in long-term diabetes management compared to other antidiabetic medications [4].

Dapagliflozin works by inhibiting the sodium-glucose co-transporter 2 (SGLT2) in the kidneys, preventing the reabsorption of glucose from the filtered urine back into the bloodstream. This action leads to increased excretion of glucose in the urine, thereby lowering blood glucose levels. Importantly, dapagliflozin's mechanism of action does not rely on pancreatic  $\beta$  cell function or affect insulin sensitivity [5].

On the other hand, vildagliptin, among the DPP-4 inhibitors, has undergone extensive clinical research due to its clinical effectiveness. Its efficacy profile, minimal risk of hypoglycemia, avoidance of weight gain, and lack of increased cardiovascular event risk have established Vildagliptin as a valuable anti-diabetes medication [6].

Combining Vildagliptin and Dapagliflozin aims to improve glycemic control beyond monotherapy by leveraging their complementary mechanisms. This dual therapy not only targets hyperglycemia effectively but also provides potential benefits in weight management, blood pressure regulation, and reducing cardiovascular risks. These advantages are crucial for managing the prevalent insulin resistance and related metabolic challenges in the Indian population [7].

Understanding the real-world clinical outcomes and challenges associated with this combination therapy is crucial for optimizing treatment strategies and improving patient outcomes in the management of T2DM in India.

Therefore, this study aims to evaluate the therapeutic usage of the Vildagliptin and Dapagliflozin combination among Indian physicians managing patients with T2DM. By employing a cross-sectional, questionnaire-based approach, the study seeks to explore prescribing patterns, perceived efficacy, safety considerations, and the challenges associated with this regimen in real-life clinical settings.

## **2 RATIONALE OF THE STUDY**

The rationale for this study was to understand the preferences and practices of Indian physicians regarding the combination therapy of Vildagliptin and Dapagliflozin in T2DM management. By investigating their perspectives and experiences, the study aims to identify potential barriers and facilitators to the adoption of this combination therapy in clinical practice, ultimately optimizing treatment outcomes for patients.

The purpose of this study was to gather insights into the usage of the Vildagliptin + Dapagliflozin combination among Indian physicians treating patients with T2DM inadequately controlled on dual combination therapy.

## **3 STUDY OBJECTIVE**

The primary objective of this study was to assess the perspectives, prescribing patterns, and experiences of Indian physicians regarding the usage of the Vildagliptin + Dapagliflozin combination in T2DM patients inadequately controlled on dual combination therapy.

#### **4 METHODS**

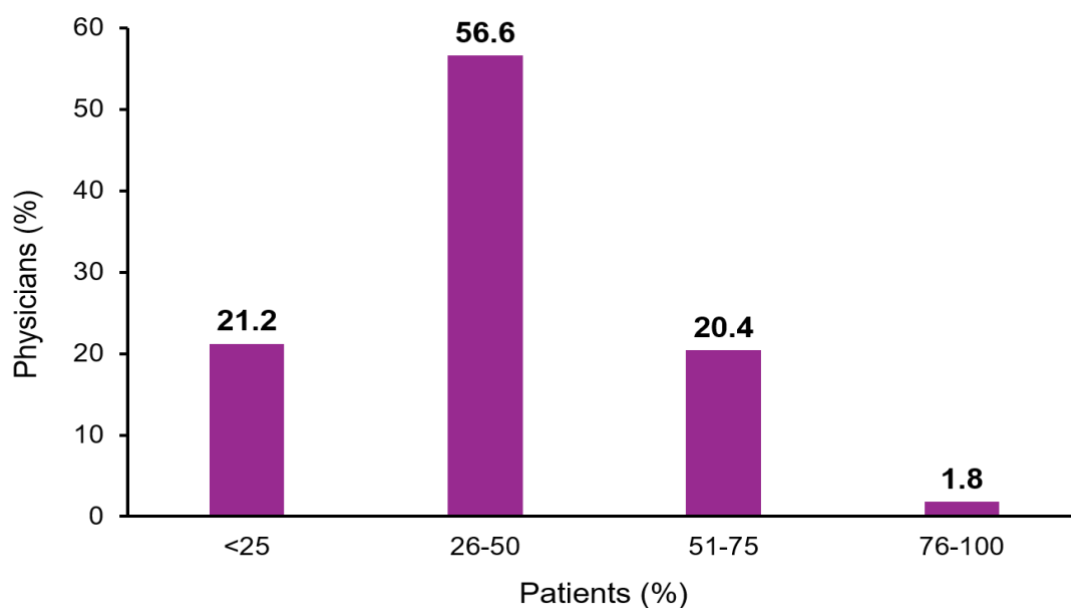
The survey methodology for evaluating the therapeutic usage of the Vildagliptin + Dapagliflozin combination in the clinical scenario of Type 2 Diabetes Mellitus (T2DM) in India involves a structured approach. Initially, a cross-sectional study design will be employed, targeting Indian physicians who manage T2DM patients. These physicians will be recruited through professional networks, medical associations, and hospital affiliations, ensuring a diverse and representative sample. After obtaining informed consent electronically, participants will complete a detailed questionnaire. This questionnaire will cover demographics, clinical experience, prescribing practices, and their perceptions of the Vildagliptin + Dapagliflozin combination therapy. Key areas of interest include the percentage of newly diagnosed T2DM cases, the need for combination therapy, patient profiles suitable for DPP4i + SGLT2i therapy, and the effectiveness and place of the Vildagliptin + Dapagliflozin combination in different patient populations, including those with obesity, hypertension, and cardiovascular risk. Data will be collected anonymously to ensure confidentiality and analyzed using descriptive statistics to identify trends and insights. This methodical approach will provide a comprehensive understanding of the current clinical practices and opinions regarding the Vildagliptin + Dapagliflozin combination in managing T2DM in India.

## 5 RESULTS

A total of 113 HCPs participated in the survey. Below is the summary of the responses.

**Question 1:** In your Diabetes practice, what is the percentage of newly diagnosed cases with type 2 diabetes mellitus (T2DM)?

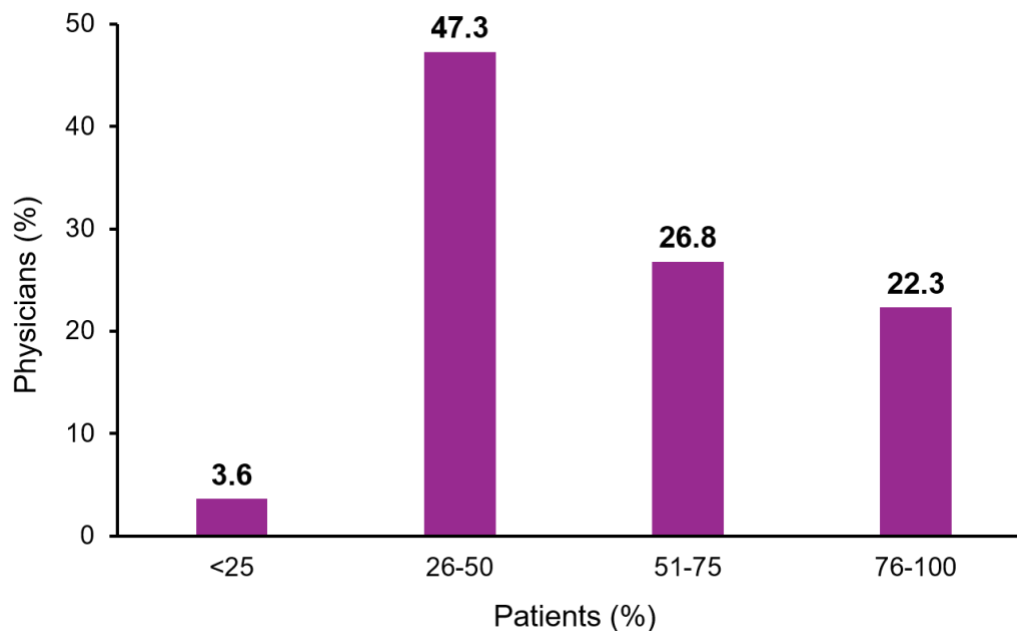
Options	Number of physicians (N=113)
<25%	24 (21.2)
26-50%	64 (56.6)
51-75%	23 (20.4)
76-100%	2 (1.8)
Data presented as n (%).	



- Majority of physicians (51.2%) see 26 to 50% of newly diagnosed cases with type 2 diabetes mellitus (T2DM).
- A significant portion (21.2%) observed less than 25% of newly diagnosed cases with T2DM and similarly 20.4% physician noted 51-75% cases.
- A small group (1.8%) see's 76-100% cases of newly diagnosed T2DM.

**Question 2:** As per your opinion, what percentage of patients with T2DM require combination therapy to achieve the target glycaemic control effectively?

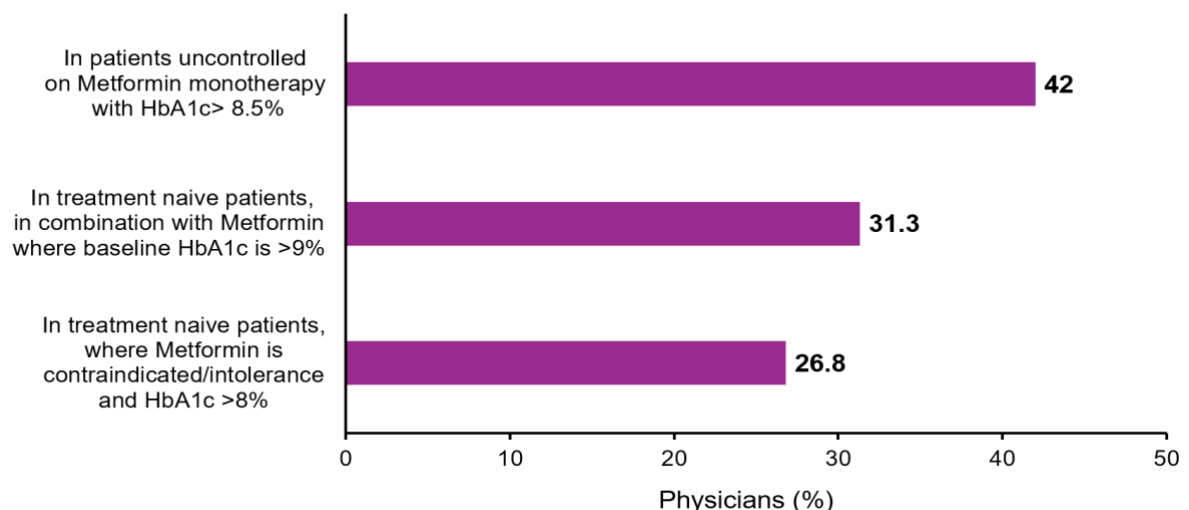
Options	Number of Physicians (N=112)
<25%	6 (3.6)
26-50%	53 (47.3)
51-75%	30 (26.8)
76-100%	25 (22.3)
Data Presented as n (%).	



- According to 47.3% physicians, 26-50% of patients with T2DM require combination therapy to achieve the target glycaemic control effectively.
- Approximately 26.8% and 22.3% of physicians observed 51-75% and 76-100% patients respectively need combination therapy to achieve the target glycaemic control effectively.
- Small portion (3.6%) noted that only less than 25% cases of T2DM requires combination therapy to achieve the target glycaemic control effectively in T2DM cases.

**Question 3:** In which patient profile would you consider initiating a combination therapy with DPP4i + SGLT2i for T2DM management?

Options	Number of Physicians (N=112)
In treatment naive patients, where Metformin is contraindicated/intolerance and HbA1c >8%.	30 (26.8)
In treatment naive patients, in combination with Metformin where baseline HbA1c is >9%.	35 (31.3)
In patients uncontrolled on Metformin monotherapy with HbA1c> 8.5%.	47 (42.0)
Data Presented as n (%).	

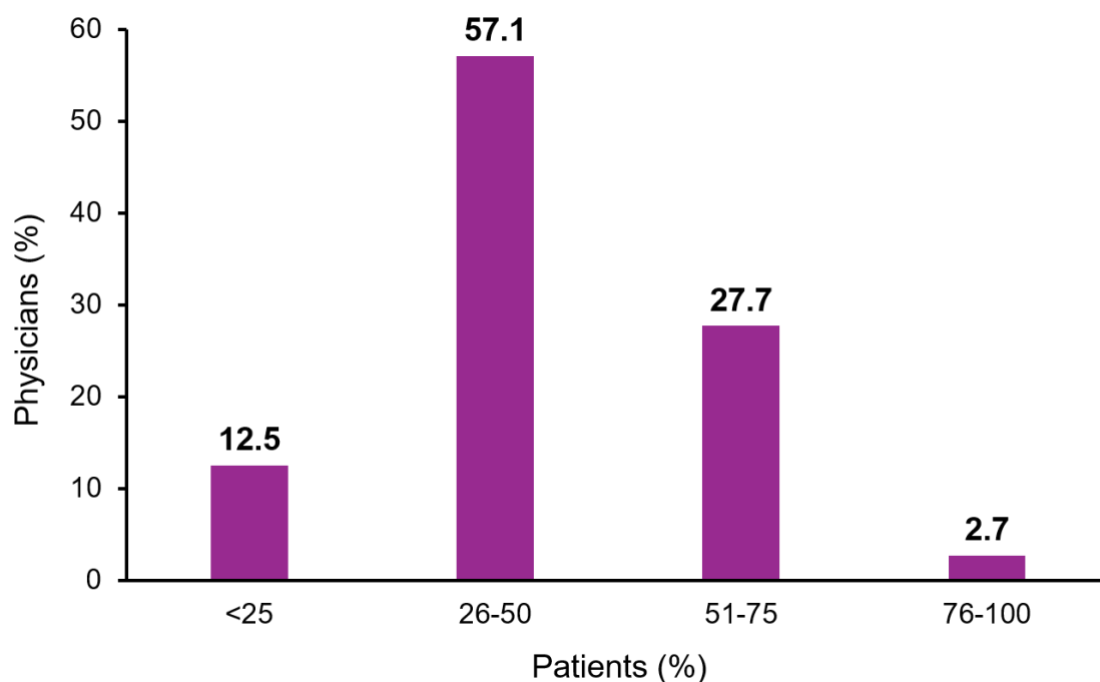


- Physicians around 42% believes that patients uncontrolled on metformin monotherapy with HbA1c>8.5% should consider initiating a combination therapy with DPP4i + SGLT2i for T2DM management.
- Approximately 31.3% physicians observed treatment naive patients in combination with metformin with baseline HbA1c>9% mostly initiates combination therapy with DPP4i + SGLT2i for T2DM management.
- Around 26.8% physicians considers observed treatment naive patients contraindicated with metformin with baseline HbA1c>8% requires combination therapy with DPP4i + SGLT2i for T2DM management.



**Question 4:** In your clinical experience, what percentage of diabetic patients are prescribed Vildagliptin + Dapagliflozin?

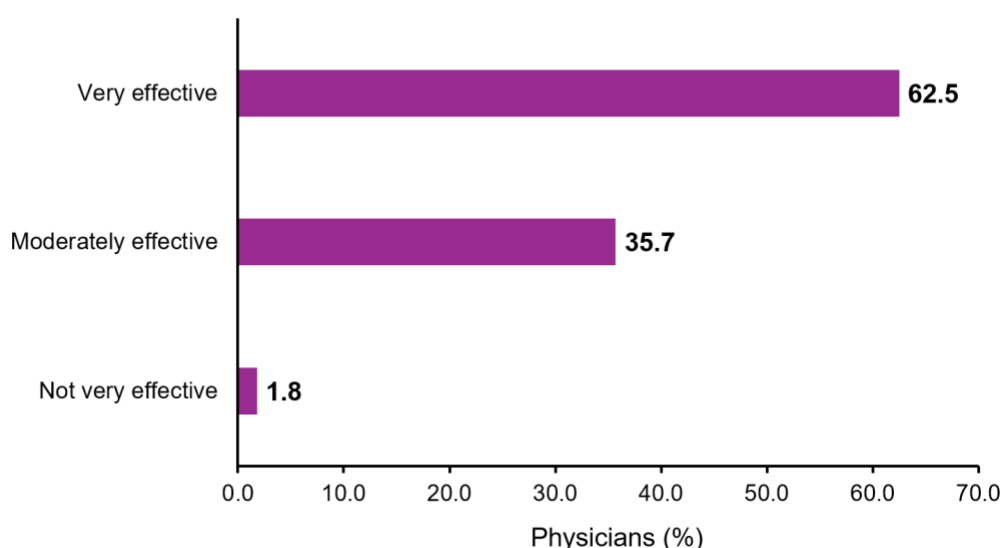
Options	Number of Physicians (N=112)
< 25	14 (12.5)
26 to 50	64 (57.1)
51 to 75	31 (27.7)
76 to 100	3 (2.7)
Data presented as n (%).	



- Majority of physicians (57.1%) prescribes Vildagliptin + Dapagliflozin to around 26-50% diabetic patients
- Approximately 12.5% and 27.7% of physicians prescribes Vildagliptin + Dapagliflozin around less than 25% and 51-75% patients respectively suffering from diabetes.
- Small portion of physician around 2.7% physicians prescribes Vildagliptin + Dapagliflozin to 76-100% diabetic patient.

**Question 5:** In your opinion, how effective is the Vildagliptin + Dapagliflozin combination in managing Diabetes in the Indian patient population?

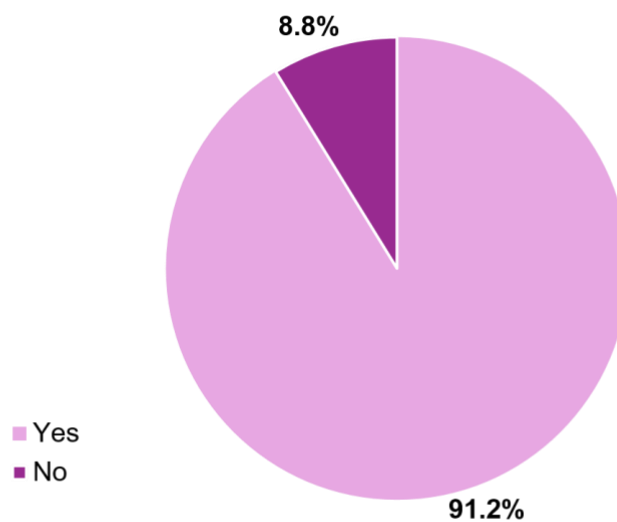
Options	Number of Physicians (N=112)
Very effective	70 (62.5)
Moderately effective	40 (35.7)
Not very effective	2 (1.8)
Data Presented as n (%).	



- Majority of the physicians (62.5%) believes that Vildagliptin + Dapagliflozin combination is very effective in managing diabetes in the Indian patient population.
- Approximately 35.7% physicians observed that Vildagliptin + Dapagliflozin combination is moderately effective in managing diabetes in the Indian patient population.
- According to 1.8% of the physicians considers Vildagliptin + Dapagliflozin combination as not very effective in managing diabetes in the Indian patient population.

**Question 6:** Do you see the place of Vildagliptin + Dapagliflozin in Newly diagnosed T2DM patients?

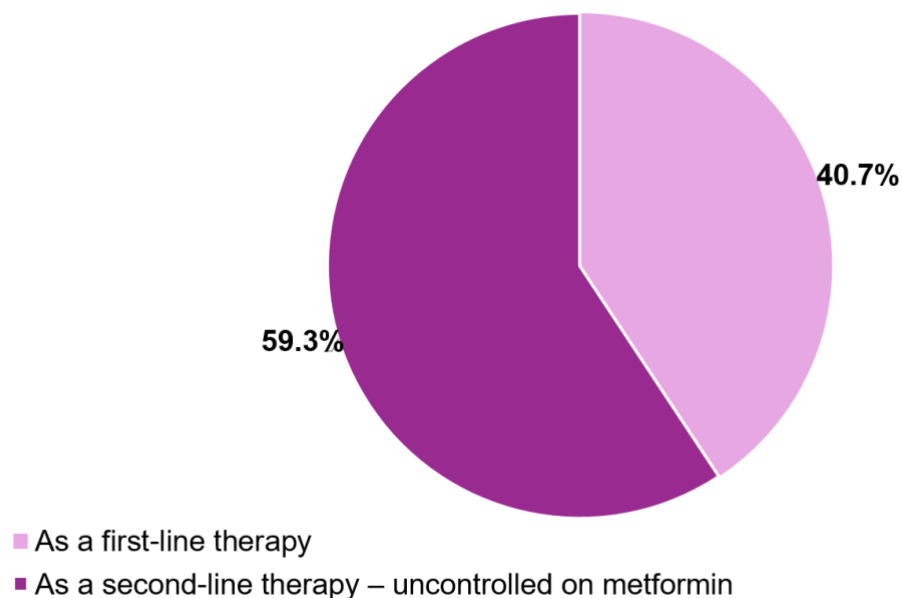
Options	Number of Physicians (N=113)
Yes	103 (91.2)
No	10 (8.8)
Data Presented as n (%).	



- Majority of the physicians (91.2%) see the place of Vildagliptin + Dapagliflozin in newly diagnosed T2DM patients while only small portion of physician around 8.8% do not see the place of Vildagliptin + Dapagliflozin.

**Question 7:** Where do you see the place of Vildagliptin + Dapagliflozin FDC in obese people with T2DM?

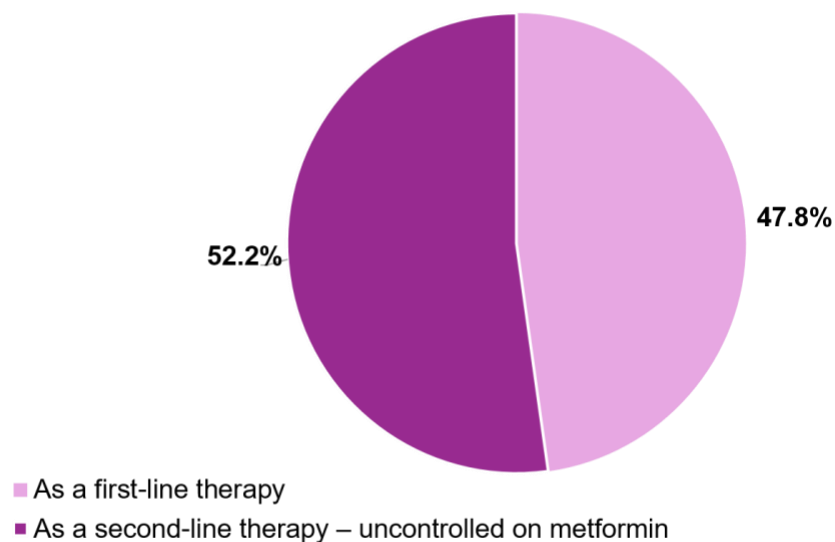
Options	Number of Physicians (N=113)
As a first-line therapy	46 (40.7)
As a second-line therapy – uncontrolled on metformin	67 (59.3)
Data Presented as n (%).	



- Majority of physicians (59.3%) see Vildagliptin + Dapagliflozin FDC as the second line therapy with uncontrolled on metformin.
- Approximately 40.7% physicians believed Vildagliptin + Dapagliflozin FDC as the first line therapy in diabetic patients.

**Question 8:** In people with T2DM and Hypertension, where do you see the place of Vildagliptin + Dapagliflozin FDC?

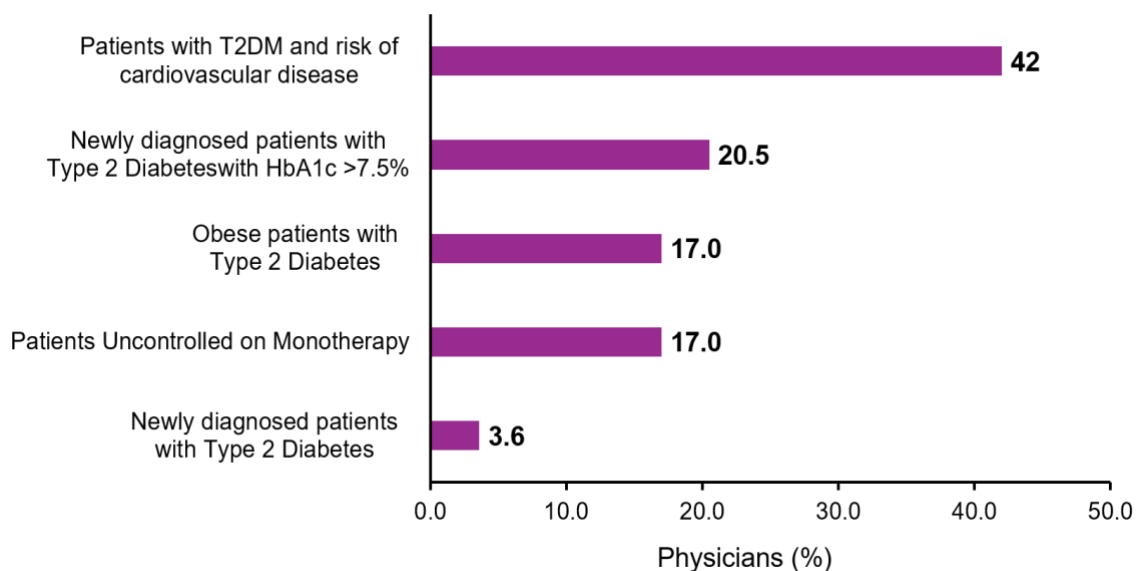
Options	Number of Physicians (N=113)
As a first-line therapy	54 (47.8)
As a second-line therapy – uncontrolled on metformin	59 (52.2)
Data Presented as n (%).	



- In clinical practice of majority of physicians (52.2%) observed Vildagliptin + Dapagliflozin FDC as a second line therapy with uncontrolled metformin in people with T2DM and hypertension.
- Approximately 47.8% physician believes Vildagliptin + Dapagliflozin FDC as a first-line therapy for patients with T2DM along with hypertension.

**Question 9:** In which patient population would the combination Vildagliptin and Dapagliflozin be preferred?

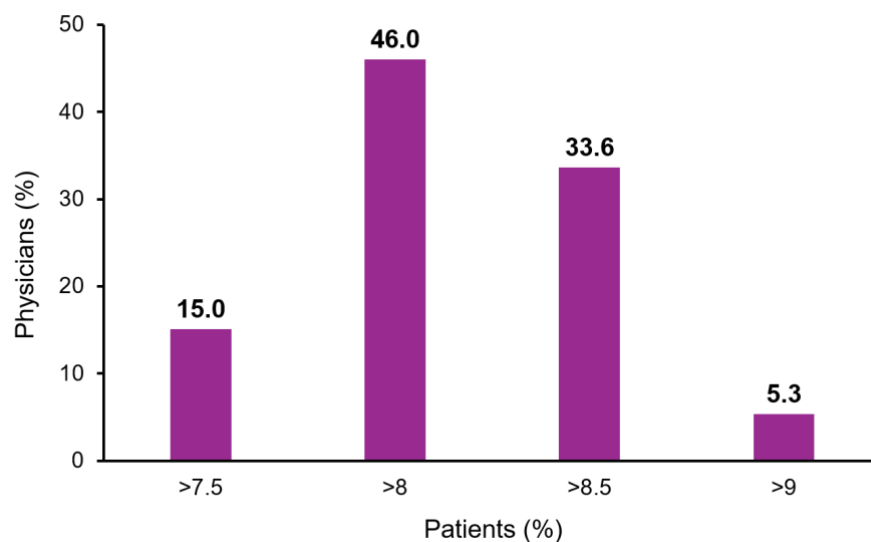
Options	Number of Physicians (N=112)
Newly diagnosed patients with Type 2 Diabetes	4 (3.6)
Newly diagnosed patients with Type 2 Diabetes with HbA1c >7.5%	23 (20.5)
Obese patients with Type 2 Diabetes	19 (17.0)
Patients uncontrolled on monotherapy	19 (17.0)
Patients with T2DM and risk of cardiovascular disease	47 (42.0)
Data Presented as n (%).	



- According to 42% of physicians, the combination Vildagliptin and Dapagliflozin would be preferred in patients with T2DM and risk of cardiovascular disease.
- Around 20.5% physicians observed that the combination Vildagliptin and Dapagliflozin is preferred in newly diagnosed patients with type 2 Diabetes with HbA1c >7.5%.
- Two sets of 175 physicians each believes that combination Vildagliptin and Dapagliflozin is given to obese patients with type 2 diabetes and Patients uncontrolled on monotherapy.
- Small portion of physicians (3.6%) prefers the newly diagnosed patients with type 2 diabetes for the treatment of Vildagliptin and Dapagliflozin combination.

**Question 10:** In people with T2DM who are on two oral antidiabetic drugs and uncontrolled, at what HbA1c level would you consider initiating a Vildagliptin + Dapagliflozin FDC?

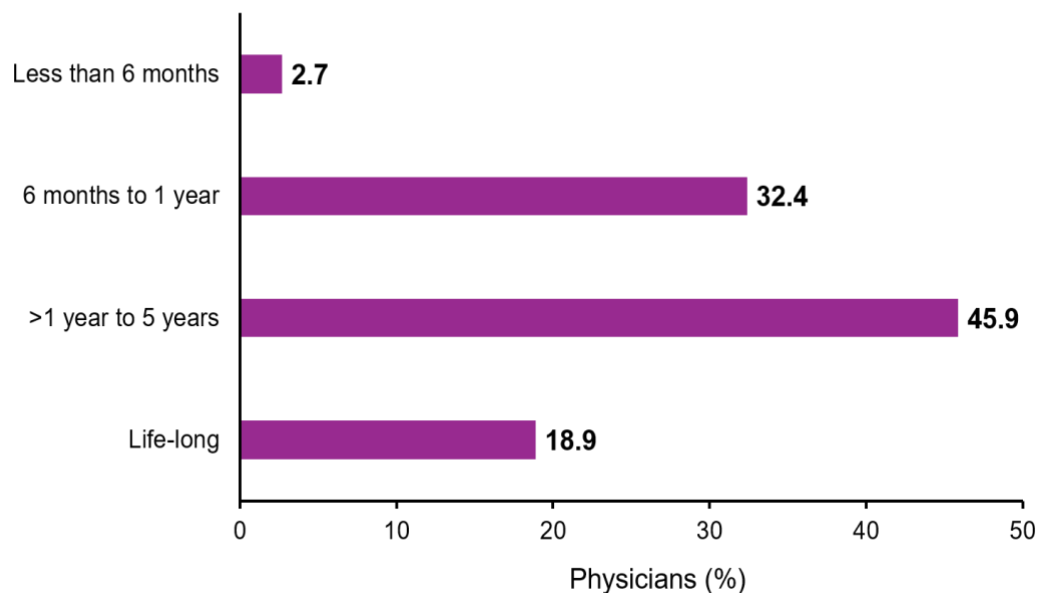
Options	Number of Physicians (N=113)
>7.5%	17 (15.0)
>8%	52 (46.0)
>8.5%	38 (33.6)
>9%	6 (5.3)
Data Presented as n (%).	



- Around 46% physicians observed that patients with T2DM who are on two oral antidiabetic drugs and uncontrolled, more than 8% HbA1c level was considered for initiating Vildagliptin + Dapagliflozin FDC.
- According to 33.6% of physicians, more than 8.5% HbA1c level was needed to initiate Vildagliptin + Dapagliflozin FDC in patients with T2DM who are on two oral antidiabetic drugs and uncontrolled.
- Physicians around 7.5% are considering HbA1c level more than 7.5% to start the Vildagliptin + Dapagliflozin FDC and similarly 5.3% physicians consider more than 9% HbA1c levels in patients with T2DM who are on two oral antidiabetic drugs and uncontrolled.

**Question 11:** As per your opinion, what can be the average duration of Vildagliptin + Dapagliflozin Therapy in Diabetes with multiple CV risk factors?

Options	Number of Physicians (N=113)
Less than 6 months	3 (2.7)
6 months to 1 year	36 (32.4)
>1 year to 5 years	51 (45.9)
Life-long	21 (18.9)
Data Presented as n (%).	

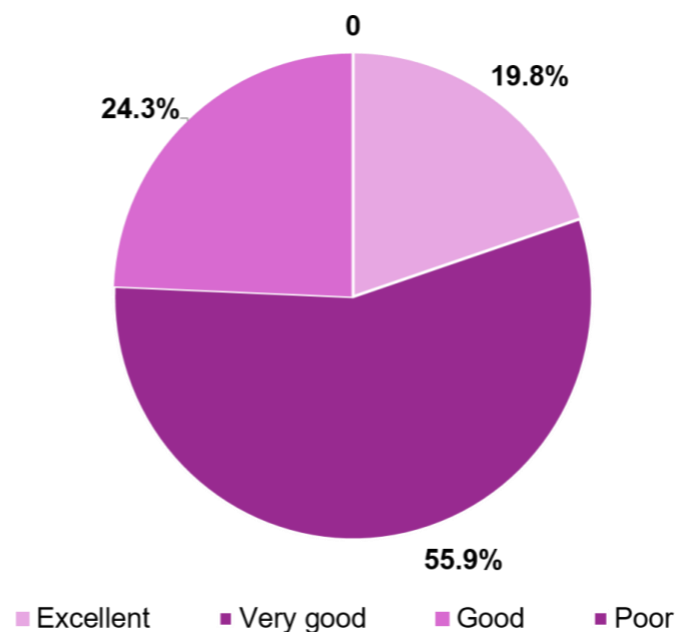


- According to 45.9% of physicians more than 1 to 5 year can be the average duration of Vildagliptin + Dapagliflozin therapy in diabetes with multiple CV risk factors.
- Approximately 32.4% physicians observed the average duration to be around 6 months to 1 year for Vildagliptin + Dapagliflozin therapy in diabetes with multiple CV risk factors.
- Lifelong therapy may be needed of Vildagliptin + Dapagliflozin in diabetes with multiple CV risk factors according to 18.95 of physicians.
- Small portion of physicians around 2.7% supports less than 6 months as the average duration for Vildagliptin + Dapagliflozin therapy in diabetes with multiple CV risk factors.



**Question 12:** As per your opinion, how is the clinical effectiveness of Vildagliptin + Dapagliflozin combination therapy in newly diagnosed T2DM patients?

Options	Number of Physicians (N=113)
Excellent	22 (19.8)
Very good	62 (55.9)
Good	27 (24.3)
Poor	0
Data Presented as n (%).	



- As per the majority of physicians (55.9%) Vildagliptin + Dapagliflozin combination therapy resulted in very good effectiveness in newly diagnosed T2DM patients.
- Around 24.3% physicians observed good effectiveness of Vildagliptin + Dapagliflozin combination therapy in newly diagnosed T2DM patients.
- Approximately 19.8% physicians believed excellent effect of Vildagliptin + Dapagliflozin combination therapy in newly diagnosed T2DM patients.
- No one noted poor effect of Vildagliptin + Dapagliflozin combination therapy in newly diagnosed T2DM patient.

## 6 SUMMARY

The majority of physicians (51.2%) report seeing 26-50% of newly diagnosed cases with type 2 diabetes mellitus (T2DM), while 21.2% see less than 25%, and 20.4% see 51-75% of cases. A small group (1.8%) sees 76-100% of newly diagnosed T2DM cases. Regarding combination therapy, 47.3% of physicians indicate that 26-50% of their T2DM patients require it to achieve target glycemic control, with 26.8% observing the need in 51-75% of patients, and 22.3% in 76-100% of patients. A smaller portion (3.6%) notes less than 25% of cases requiring combination therapy. Physicians around 42% believe that patients uncontrolled on metformin monotherapy with HbA1c > 8.5% should initiate combination therapy with DPP4i + SGLT2i, and 31.3% observe treatment-naïve patients with baseline HbA1c > 9% also requiring this combination therapy. Moreover, 26.8% consider this combination necessary for treatment-naïve patients contraindicated with metformin and HbA1c > 8%. A majority of physicians (57.1%) prescribe Vildagliptin + Dapagliflozin to 26-50% of diabetic patients, with 12.5% and 27.7% prescribing it to less than 25% and 51-75% of patients, respectively. Only 2.7% prescribe it to 76-100% of patients. Most physicians (62.5%) find the combination very effective in managing diabetes in the Indian patient population, while 35.7% consider it moderately effective, and only 1.8% find it not very effective. Additionally, 91.2% of physicians see the place of Vildagliptin + Dapagliflozin in newly diagnosed T2DM patients. As a second-line therapy, 59.3% of physicians recommend Vildagliptin + Dapagliflozin FDC for patients uncontrolled on metformin, with 40.7% believing it suitable as a first-line therapy. In practice, 52.2% observe its use as a second-line therapy in T2DM and hypertension cases, while 47.8% consider it a first-line option. Physicians also prefer the combination for patients with T2DM and cardiovascular disease risk (42%), newly diagnosed T2DM with HbA1c > 7.5% (20.5%), obese patients (20.5%), and those uncontrolled on monotherapy (20.5%). About 46% of physicians initiate Vildagliptin + Dapagliflozin FDC in patients on two oral antidiabetic drugs and uncontrolled with HbA1c > 8%, while 33.6% require HbA1c > 8.5%, and smaller portions consider HbA1c > 7.5% or > 9%. The average duration of therapy varies, with 45.9% indicating 1-5 years, 32.4% suggesting 6 months to 1 year, 18.95% supporting lifelong therapy, and 2.7% recommending less than 6 months. Effectiveness in newly diagnosed T2DM patients is noted as very good by 55.9% of physicians, good by 24.3%, and excellent by 19.8%, with no reports of poor effect.

## 7 DISCUSSION

The survey results provide an in-depth look into the clinical practices and perceptions of physicians regarding the management of newly diagnosed Type 2 Diabetes Mellitus (T2DM) patients, with a particular focus on the utilization of the Vildagliptin + Dapagliflozin combination therapy. The majority of physicians (51.2%) reported seeing 26-50% of newly diagnosed T2DM cases, while a significant portion (21.2%) observed less than 25% of such cases, and 20.4% noted 51-75% of cases. Only a small group (1.8%) saw 76-100% of newly diagnosed T2DM cases. For achieving target glycemic control, 47.3% of physicians indicated that 26-50% of their T2DM patients required combination therapy, with 26.8% and 22.3% noting that 51-75% and 76-100% of their patients, respectively, needed such therapy. A smaller portion (3.6%) reported that less than 25% of T2DM cases required combination therapy. Regarding the initiation of combination therapy, about 42% of physicians recommend starting DPP4i + SGLT2i combination therapy for patients uncontrolled on metformin monotherapy with HbA1c levels greater than 8.5%. Furthermore, 31.3% of physicians tend to initiate combination therapy in treatment-naïve patients with baseline HbA1c levels over 9%, while 26.8% consider this therapy for patients contraindicated with metformin and baseline HbA1c levels above 8%. Vildagliptin + Dapagliflozin is widely prescribed, with 57.1% of physicians using it for 26-50% of diabetic patients, and 62.5% of physicians believe it to be very effective for managing diabetes in the Indian patient population. The combination is viewed as an effective second-line therapy for patients uncontrolled on metformin by 59.3% of physicians, with 42% preferring it for patients at risk of cardiovascular disease. The majority of physicians (55.9%) observed very good effectiveness in newly diagnosed T2DM patients using this combination therapy, reinforcing its importance and efficacy in clinical practice.

The survey highlights the significant role and effectiveness of the Vildagliptin + Dapagliflozin combination therapy in managing newly diagnosed T2DM patients, emphasizing its use as both a second-line therapy and a primary option for those with high HbA1c levels or cardiovascular risks.

## **8 CLINICAL RECOMMENDATIONS**

- For patients with Type 2 Diabetes Mellitus (T2DM), combination therapy is often required to achieve target glycaemic control, particularly in those uncontrolled on metformin monotherapy with HbA1c levels greater than 8.5%. In such cases, initiating a combination therapy with DPP4 inhibitors (DPP4i) and SGLT2 inhibitors (SGLT2i) is recommended.
- This approach is also suitable for treatment-naïve patients with baseline HbA1c levels over 9% and for those contraindicated with metformin with baseline HbA1c over 8%. Vildagliptin + Dapagliflozin is a commonly prescribed combination for 26-50% of diabetic patients and is considered very effective by a majority of physicians.
- It is particularly preferred as a second-line therapy for patients uncontrolled on metformin, and for those with T2DM and hypertension or cardiovascular risk factors.
- The therapy duration can vary, but it is often needed for more than 1-5 years, and in some cases, lifelong therapy may be necessary. This combination has shown very good effectiveness in newly diagnosed T2DM patients.

## **9 CONSULTANT OPINION**

The majority of physicians frequently encounter a significant proportion of newly diagnosed cases of type 2 diabetes mellitus (T2DM). Many of these physicians recognize the necessity for combination therapy to achieve optimal glycemic control in their patients. While some patients might manage with monotherapy, a notable number require the integration of therapies such as DPP4 inhibitors and SGLT2 inhibitors, especially when initial treatments fail to meet glycemic targets. Vildagliptin combined with Dapagliflozin has emerged as a popular and effective treatment option, with most physicians observing substantial benefits in glycemic control and cardiovascular risk reduction in their patients. This combination is particularly favored for patients with additional complications such as hypertension and obesity. The therapeutic duration for this combination therapy varies, with many physicians advocating for its use over extended periods, including lifelong treatment for those with multiple cardiovascular risk factors. The consensus among physicians indicates that this combination therapy is

highly effective, demonstrating significant improvements in managing newly diagnosed T2DM patients.

## **10 MARKET OPPORTUNITIES**

- With a significant number of newly diagnosed T2DM cases being observed (51.2% of physicians seeing 26-50% new cases), there is a growing patient base requiring effective management strategies.
- A substantial portion of patients (47.3%) need combination therapy for effective glycemic control. This highlights a market demand for combination drugs like Vildagliptin + Dapagliflozin.
- Physicians prefer Vildagliptin + Dapagliflozin for patients uncontrolled on metformin monotherapy with high HbA1c levels, and for those contraindicated with metformin. This targeted approach can enhance drug adoption among specific patient subsets.
- Majority of physicians (57.1%) prescribe Vildagliptin + Dapagliflozin to a significant portion (26-50%) of diabetic patients, indicating a strong market presence and acceptance.
- The combination is perceived as very effective by 62.5% of physicians in the Indian patient population, enhancing its market credibility and potential for widespread use.
- The combination is preferred for patients with T2DM and cardiovascular risk, offering an additional therapeutic benefit that can be a key market differentiator.
- With many physicians indicating the need for long-term therapy (1 to 5 years or lifelong), there is potential for sustained market demand and patient adherence.

## **11 MARKET POSITIONING**

- The market positioning of Vildagliptin + Dapagliflozin combination therapy in the Indian context reflects a strong preference among physicians for its effectiveness in managing type 2 diabetes mellitus (T2DM).
- It is primarily seen as a second-line treatment for patients not controlled on metformin but is also considered a first-line option by a significant number of

physicians. Its prescription ranges widely, covering newly diagnosed patients, those with cardiovascular risks, and those on multiple antidiabetic drugs.

- The combination's broad application and high efficacy ratings highlight its robust market presence and therapeutic value in managing T2DM in India.

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