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Clinician's Perspectives on the use of Vildagliptin and its Fixed-Dose Combination with Metformin in the Management of Type 2 Diabetes Mellitus in India

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Abstract

Objective: To gather clinician perspectives related to the initiation and management of pharmacotherapy in type 2 diabetes mellitus (T2DM), with a particular focus on the use of vildagliptin and its fixed-dose combination (FDC) with metformin in Indian clinical settings.

Methods: This cross-sectional study was conducted among clinicians across India. The 23-item questionnaire explored various aspects of T2DM management, including demographic patterns, first-line therapy preferences, treatment adherence, perceptions of glycemic durability, and clinical experiences with vildagliptin and its sustained-release formulations. Additional questions addressed socio-economic trends in diabetes prevalence, factors contributing to non-adherence, and the role of continuous glucose monitoring. Data were analyzed using descriptive statistics.

Results: A total of 242 clinicians participated in the study. The majority (82.64%) identified the highest prevalence of diabetes in the 40–60-year age group, and 71% reported a higher occurrence among middle-income individuals. Metformin was the most commonly prescribed first-line agent (50.83%) for newly diagnosed T2DM. Approximately 46% of experts recognized dipeptidyl peptidase-4 inhibitors for their superior glycemic durability, with vildagliptin being the preferred agent among 79% of respondents. Vildagliptin was favored by 82% of clinicians for its weight-neutral effects, beta-cell preservation, and favorable side-effect profile. Nearly 76% preferred the 100 mg sustained release (SR) formulation once daily over 50 mg twice daily, citing improved patient compliance. Around 84% of respondents supported the combination of vildagliptin 100 mg SR with metformin SR for enhancing adherence.

Conclusion: The study highlights clinicians' preference for vildagliptin in the management of T2DM, particularly among middle-aged, middle-income patients in Indian settings. Once-daily dosing, favorable efficacy, and improved adherence position vildagliptin, especially in combination with metformin, as a preferred option in routine clinical practice.

Introduction

Diabetes remains one of the most widespread chronic diseases globally. The prevalence of type 2 diabetes mellitus (T2DM) is increasing rapidly due to factors such as urbanization, population aging, internal migration, and evolving lifestyles. As of 2019, approximately 463 million individuals were affected by T2DM worldwide, with this number projected to rise to 700 million by 2045. Asia accounts for nearly 60% of global T2DM cases, with China and India bearing the largest burden[1]. In India alone, prevalence varies between 2% and 25%, with 77 million cases reported in 2019, a figure expected to escalate to 134 million by 2045 [2,3]. Key risk factors include age, ethnicity, obesity, sedentary behavior, and unhealthy dietary patterns[3]. South Asians, particularly Indian populations, are more vulnerable, often developing T2DM at younger ages and lower body mass indices [1]. Major challenges in India include limited public awareness, inadequate healthcare access, and affordability of treatment [3].

Pharmacotherapy remains the cornerstone of T2DM management, with an emphasis on achieving optimal glycemic control while minimizing adverse effects. Vildagliptin, a dipeptidyl peptidase-4 inhibitor (DPP-4i), lowers blood glucose levels by inhibiting the degradation of glucagon-like peptide-1 (GLP-1), thereby enhancing its activity in both the fed and fasting states. This results in glucose-dependent stimulation of insulin secretion and suppression of glucagon release, with a low risk of hypoglycemia or weight gain. Its prolonged effect is attributed to covalent binding at the catalytic site of the DPP-4 enzyme [4]. Metformin, the first-line therapy for T2DM, primarily acts by reducing hepatic glucose production and improving peripheral insulin sensitivity through activation of adenosine monophosphate-activated protein kinase (AMPK). Additionally, it increases endogenous GLP-1 levels, influences gut glucose metabolism, and modulates the gut microbiota [5].

The combination of metformin and vildagliptin offers complementary mechanisms that enhance glycemic control without increasing the risk of hypoglycemia or weight gain [6].Metformin enhances vildagliptin's GLP–1–mediated effects, and the combination, particularly vildagliptin 50 mg twice daily with metformin, has been shown to deliver sustained clinical benefits due to vildagliptin's long-lasting enzyme inhibition [7].

This study aims to investigate clinicians' perspectives in the initiation and management of pharmacotherapy for T2DM, with a particular focus on the role of vildagliptin and its fixed-dose combination (FDC) with metformin.

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Materials and Methods

We carried out a cross-sectional study among clinicians actively engaged in routine diabetes management across India from June 2024 to December 2024. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

An invitation was sent to leading diabetologists in managing T2DM patients in the month of March 2024 for participation in this Indian survey. About 242 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. The questionnaire booklet titled VERGE (Evaluate the Vildagliptin Extended-Release Dosage and to Gather Insights from the Experts) study was sent to clinicians who were interested to participate. The VERGE study questionnaire consisted of 23 questions designed to gather clinical perspectives and experiences regarding various aspects of diabetes care. It specifically focused on addressing demographic patterns of diabetes, first-line therapy preferences, pharmacotherapy adherence, perceptions of glycemic durability, and clinical experiences with vildagliptin and its sustained-release formulations. Additional questions explored socio-economic trends in diabetes prevalence, factors contributing to treatment non-adherence, and the role of continuous glucose monitoring, with a particular emphasis on the use of vildagliptin and its FDC with metformin. Clinicians had the option to skip any questions they preferred not to answer. They were instructed to complete the questionnaire independently, without consulting their colleagues. Written informed consent was obtained from all participants before the study commenced.

Statistical Analysis

Descriptive statistical methods were used to analyse the data. Categorical variables were summarized as frequencies and percentages to represent distribution patterns. Visual representations, including pie and bar charts, were created using Microsoft Excel 2013 (version 16.0.13901.20400) to support the interpretation of the findings.

Results

The study included 242 participants, with the majority (82.64%) indicating that diabetes is more prevalent in the 40–60-year age group (Figure 1). A significant proportion (70.66%) of clinicians reported that the disease is more commonly seen among individuals belonging to the middle-income economic group in their practice (Figure 2).

Over half (51.24%) of the participants estimated that 30-40% of individuals with T2DM are likely to be non-adherent to pharmacotherapy. Approximately 68% of the experts highlighted that multiple dosing, polypharmacy, and adverse events are common causes of non-adherence to pharmacotherapy. About 37% of participants identified poor medication adherence as a key challenge when initiating pharmacotherapy in T2DM.

Around 35% of the respondents reported that they use continuous glucose monitoring (CGM) as a tool for 10% of patients when starting pharmacotherapy. About 62% of participants stated they consider glycemic status and associated complications when initiating pharmacotherapy in T2DM. More than half (50.83%) of the clinicians reported that metformin is the first-line treatment for newly diagnosed diabetes in their practice (Table 1). Around 46% noted that DPP-4i provides greater glycemic durability as monotherapy after initiating oral anti-diabetic drugs (OADs) (Figure 3).

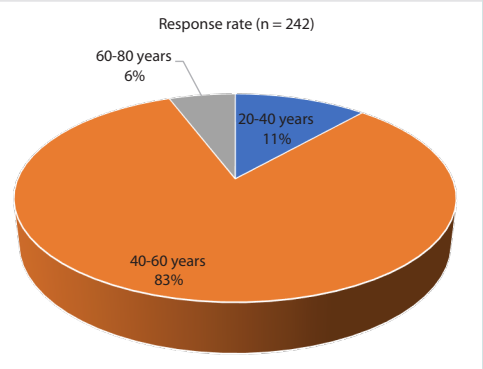

Figure 1: Distribution of responses regarding the most prevalent age group for diabetes in clinical practice

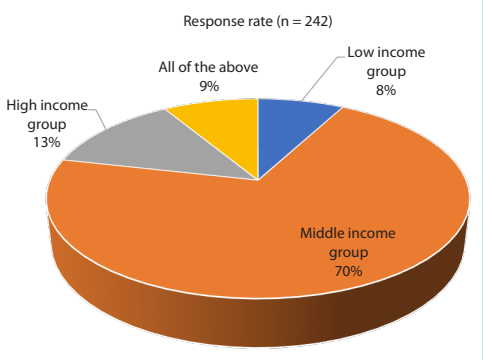

Figure 2: Distribution of responses on the prevalence of diabetes among socio-economic status groups in clinical practice

About 45% of experts reported that DPP-4 inhibitors are typically initiated after the failure of monotherapy. The majority (78.51%) preferred vildagliptin as the DPP-4 inhibitor of choice in clinical practice (Figure 4). Approximately 44% of participants indicated that 10–30% of patients in their practice are prescribed vildagliptin. Most clinicians (81.82%) favored vildagliptin over other agents due to its weight-neutral properties, ability to preserve beta-cell function, lower glycemic variability, and minimal adverse effects (Table 2).

Nearly half of the participants (49.59%) reported observing a 1–1.5% reduction in HbA1c levels following the initiation of vildagliptin in clinical practice. About 53% of respondents indicated that they prescribe vildagliptin 100 mg SR in most patients.

Approximately 76% of experts highlighted the advantages of vildagliptin 100 mg SR once daily over vildagliptin 50 mg twice daily, citing reduced dosing frequency and improved patient compliance (Table 3).

Approximately 43% of respondents reported that 11–25% of patients in their practice are started on the vildagliptin 100 mg SR + metformin SR formulation as an initiation strategy. Around 52%

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Table 1: Distribution of responses on first-line treatment for newly diagnosed diabetes in clinical practice

First line of treatment	Response rate (n = 242)
Metformin	50.83%
Dipeptidyl peptidase-4 inhibitors	37.19%
Sodium-glucose cotransporter 2 inhibitors	6.61%
Sulfonylureas	4.55%
Additionally, it adjusts based on blood glucose levels.	0.41%
It depends on the FBS and PPBS level as well as the HbA1C value	0.41%

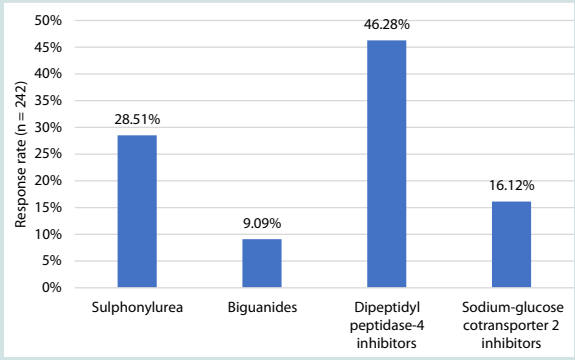

Figure 3: Distribution of responses on clinicians' perceptions of glycemic durability of OAD classes as monotherapy

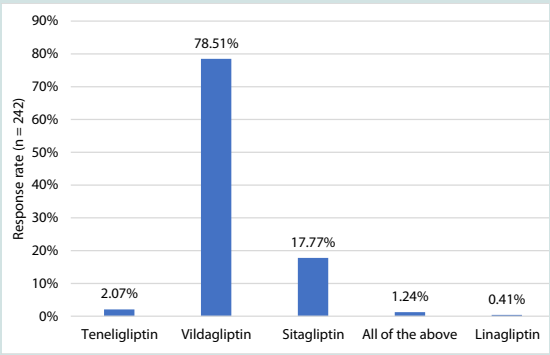

Figure 4: Distribution of responses on preferred DPP-4 inhibitor in clinical practice

Table 2: Distribution of responses on reasons for preferring vildagliptin over other agents

Reason	Response rate (n = 242)
Weight-neutral property	2.07%
Helps in preserving beta cell function	7.44%
Cause less glycemic variation	5.79%
Poses a low risk of adverse effects	2.89%
All of the above	81.82%

Table 3: Distribution of responses on perceived advantages of vildagliptin 100 mg SR once daily compared to 50 mg twice daily

Advantages	Response rate (n = 242)
Reduces dosing frequency	12.4%
Improves patient compliance	10.33%
Both the above	76.45%
No advantage	0.83%

Table 4: Distribution of responses on reasons supporting the use of vildagliptin 100 mg SR + metformin SR as an initiation strategy

Reasons	Response rate (n = 242)
Once daily advantage	6.61%
Better adherence	1.65%
Reduces pill burden	5.37%
Established efficacy and glycemic durability	2.48%
All the above	83.88%

of clinicians identified patients aged between 40 and 50 years as the preferred age group for initiating vildagliptin 100 mg SR and metformin combination therapy. The majority (83.88%) cited the benefits of once-daily dosing, improved adherence, reduced pill burden, and established glycemic efficacy as key reasons for selecting vildagliptin 100 mg SR + metformin SR as an initiation strategy (Table 4).

In day-to-day clinical practice, around 70% of participants preferred using vildagliptin 100 mg SR + metformin 500 mg SR and vildagliptin 100 mg SR + metformin 1000 mg SR combinations. About 58% of participants reported better glycemic efficacy with the FDC of vildagliptin and metformin in young, elderly, and long-standing diabetic patients.

Approximately 69% of participants observed a difference in glycemic efficacy between the twice-daily vildagliptin 50 mg immediate-release formulation and the once-daily vildagliptin 100 mg SR formulation in only a few patients. Around 63% reported a 1–1.5% reduction in HbA1c with the vildagliptin SR + metformin SR combination.

Discussion

The study provides valuable insights into the clinician's preferences and prescribing patterns of clinicians managing T2DM in Indian settings. The majority of participants reported that diabetes is most prevalent in the 40–60-year age group. Supporting this, Naveed et al. observed a significant increase in diabetes risk among individuals aged 31–60 years [8].Similarly, Awan et al. reported a 38% prevalence of diabetes in individuals aged 40 and above, with higher rates among males and those in the 50–60 age group[9].Cheng et al. reported a 75% increase in diabetes cases from 1988-1994 to 2005-2010, with middle-aged adults contributing 52.9% to this rise [10]. Mayega et al. highlighted a high prevalence of diabetes among those aged 35-60 years [11].

A significant proportion of clinicians studied reported that diabetes is more commonly observed among individuals from the middle-income socioeconomic group in their practice. Supporting this observation, Deepa et al. documented a rapid reversal of the socioeconomic gradient for diabetes risk factors in urban India, with prevalence rates converging between middle- and low-income groups [12]. Hydrie et al. highlighted that, although children in both groups exhibited, middle-income children had a significantly increased risk for diabetes [13]. Further highlighting the evolving landscape, Mailti et al. analyzed data from the NFHS-5 (2019–2021) and revealed that the age- and sex-adjusted prevalence of diabetes among adults aged 15 years and older rose from 13.1% in the poorest wealth quintile to 18.8% in the richest quintile [14].

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Over half of the study participants reported that metformin is the first-line treatment for newly diagnosed diabetes in their practice. This aligns with longstanding clinical guidelines from major organizations such as the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), which have consistently recommended metformin as the initial pharmacologic therapy for T2DM due to its proven efficacy, safety profile, and cost-effectiveness [15,16]. According to Baker et al. and Ahmad et al., metformin remains the most commonly prescribed glucose-lowering therapy (GLT) worldwide and continues to be recommended as first-line treatment for newly diagnosed T2DM. This is supported by clinical guidelines and evidence from the UK Perspective Diabetes Study (UKPDS), which demonstrated cardiovascular mortality benefits in overweight individuals treated with metformin [17,18].

Many study participants noted that DPP-4i offer greater glycemic durability as monotherapy after initiating OADs. A meta-analysis of long-term randomized controlled trials demonstrated that DPP-4 inhibitors are associated with significantly better glycemic durability compared to sulfonylureas, as evidenced by smaller increases in HbA1c levels over a 104-week treatment period. This suggests that DPP-4 inhibitors may better preserve islet β-cell function, contributing to sustained glycemic control [19]. Esposito et al. also noted that DPP-4i are effective in reducing HbA1c in the first year of treatment [20].

The majority of respondents preferred vildagliptin as their DPP-4i of choice in clinical practice. This aligns with findings from Matheiu et al., who noted that vildagliptin is among the most extensively studied DPP-4is, demonstrating strong clinical utility and safety in managing T2DM [21].Saini et al. also highlighted that vildagliptin significantly increases post-meal active plasma GLP-1 levels by 1.5 to 3 times compared to placebo. A 100-mg dose of vildagliptin is sufficient to fully suppress DPP-4 activity in patients with T2DM [22].

Clinicians favored vildagliptin over other agents primarily due to its weight-neutral properties, ability to preserve beta-cell function, lower glycemic variability, and minimal adverse effects. Foley and Jordan noted that while DPP-4i are generally weight-neutral, vildagliptin has been associated with modest weight loss in patients with relatively low baseline glycemia [23]. Foley et al. found that one-year treatment with vildagliptin significantly improved beta-cell secretory capacity, though this effect was not sustained after discontinuation [24].Panina highlighted that vildagliptin is a potent, selective DPP-4i that enhances islet alpha- and beta-cell responsiveness to glucose [25].Pan and Wang added that vildagliptin is well-tolerated with a low incidence of adverse events and does not increase the risk of cardiovascular or cerebrovascular events [26].

Many participants highlighted the benefits of vildagliptin 100 mg SR once daily over vildagliptin 50 mg twice daily, such as reduced dosing frequency and enhanced patient compliance. Sangana et al. confirmed the therapeutic equivalence of the IR and SR formulations in terms of DPP-4 enzyme inhibition, suggesting that the 100 mg SR formulation may enhance treatment compliance [27]. Warrier et al. demonstrated that once-daily vildagliptin SR 100 mg is bioequivalent to twice-daily vildagliptin IR 50 mg. The 100 mg SR formulation provides over 80% DPP-4 inhibition for 24 hours, which may lead to a meaningful glucose-lowering effect while reducing the pill burden for patients with diabetes [28].

The majority of clinicians cited the benefits of once-daily dosing, better adherence, reduced pill burden, and proven glycemic efficacy as key reasons for selecting vildagliptin 100 mg SR + metformin SR as an initiation strategy. Chatterjee and Chatterjee found that a once-daily metformin-vildagliptin combination significantly reduced plasma glucose and HbA1c, making it a viable, cost-effective alternative to a twice-daily regimen [29].A review with real-world case reports by Chawla et al. emphasized that early initiation of combination therapy helps achieve glycemic goals faster, with metformin SR–vildagliptin FDC offering better tolerability, fewer adverse events, and improved compliance compared to the metformin IR–vildagliptin FDC[30].

Thisstudy offers valuable clinical insights into current clinical practices in the management of T2DM, with responses from 242 clinicians highlighting trends in disease prevalence, treatment preferences, and adherence challenges. It effectively captures practical perspectives on the use of metformin and DPP-4 inhibitors, particularly vildagliptin, and underscores key factors influencing clinicians' therapeutic choices, such as efficacy, safety, dosing convenience, and patient compliance. These findings align with existing clinical guidelines, adding relevance and applicability to day-to-day practice. However, the study's reliance on self-reported data introduces the possibility of recall and selection bias, and the lack of information on geographic distribution, methodology, and objective patient outcomes limits the generalizability of the survey findings.

Conclusion

The study highlights clinicians' perspectives in managing T2DM, with metformin remaining the cornerstone of therapy and vildagliptin favored for its efficacy, safety, and convenience. The preference for once-daily dosing and fixed-dose combinations supports better adherence and glycemic control. Overall, early combination therapy appears to be a practical and effective strategy in routine diabetes care.

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Author contributions

Both authors have contributed equally to the development of the manuscript.

Disclosure of compliance with ethical principles

The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

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