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## Prescription pattern of oral anti-diabetic drugs in Indian clinical practice

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### Abstract

**Objective:** To assess the prescription pattern of oral anti-diabetic drugs among physicians and to ascertain their professional perspectives of the vildagliptin and its combinations in an Indian clinical context.

**Methods:** A cross sectional, multiple-response questionnaire based survey among physicians specialized in managing T2DM in the major Indian cities from June 2022 to December 2022. The study questionnaire included 25 questions about the current opinion, clinical observations, and clinical experience of specialists in managing T2DM.

**Results:** About 950 physicians participated in the survey by sharing their opinions/views on the questionnaire. Approximately, 35% experts preferred vildagliptin, metformin and dapagliflozin fixed dose combination in diabetic individuals, in presence of cardiovascular complications and also they preferred when glycated haemoglobin was more than 8% at the time of diagnosis. More than 50% of the physician's observed this combination reduces the dose of exogenous insulin. Also, more than 65% of the physicians also observed 1-2% HbA1c reduction with the vildagliptin and metformin combination after 3 months of the therapy. Over 38% of the physicians came across 6-10 diabetic individuals with neuropathy in their day to day clinical practice. Nearly 43% of the physicians suggested that among all the exercises, yoga was one of the best exercise for diabetic individuals.

**Conclusion:** This study concluded that majority of the physicians recommend vildagliptin and metformin as the preferred oral anti-diabetic drug for the early treatment initiation. The most preferred sodium glucose cotransporter 2 inhibitor for the management of type 2 diabetes mellitus was dapagliflozin. Experts agreed that telemedicine/teleconsultation can play an integral part in managing diabetes mellitus. Patient compliance to regular consumption of oral anti diabetic drug is the most challenging aspect in managing type 2 diabetes mellitus and it was mainly due to lack of patient awareness and education.

**Keywords:** Type 2 diabetes mellitus, diabetes, vildagliptin, metformin, dapagliflozin, complications

### Introduction

Diabetes, which ranks among the top 10 causes of death along with cancer, respiratory disorders, and cardiovascular disease (CVD) and is one of the biggest worldwide health catastrophes of this century. The World Health Organization (WHO) reported that non-communicable diseases (NCDs) accounted for 74% of fatalities worldwide in 2019. Diabetes was the tenth most common cause of death worldwide in 2019 with 1.6 million deaths. Diabetes is a progressive condition that raises healthcare expenditures for the family, community, and healthcare system when it causes major complications. Uncontrolled diabetes raises the risk of vascular disease, and consequences from type 2 diabetes, including microvascular (Diabetic retinopathy, nephropathy, and neuropathy) and macrovascular (Cardiovascular, cerebrovascular, and peripheral artery disease), account for a large portion of the disease's burden [1]. Therefore, there was a need for awareness at physician and at the public level to prevent the micro and macrovascular complications.

Healthcare professionals must encourage patients to combine lifestyle modifications with oral pharmacologic agents for optimal glycaemic control, particularly as type 2 diabetes mellitus progresses with continued loss of pancreatic beta-cell function and insulin production. The most effective management of diabetes mellitus requires an inter-professional approach involving both lifestyle modifications with diet and exercise and pharmacologic therapies as needed to meet individualized glycaemic goals [2].

To manage type 2 diabetes mellitus, the armamentarium of OAD includes- sulfonylureas, dipeptidyl peptidase 4 inhibitors (DPP4i), sodium glucose cotransporter 2 inhibitors, biguanides, alpha glucosidase inhibitors and PPAR agonists and various combinations of the above mentioned oral anti diabetic drugs.

However, it can be difficult to select the best oral anti-diabetic medication and its combinations in the real-world clinical settings. Hence, to ascertain the merits and demerits of the available oral anti diabetic drugs and its combination is of paramount importance. Various clinical trials have proved the effectiveness of DPP4i and its combination including vildagliptin and its combinations. However, there was a need to translate the clinical trial findings in day to day real world clinical practice. Vildagliptin differs from other gliptins in that it functions as a surrogate substrate, changing its own structure in response to the enzyme dipeptidyl peptidase- 4 inhibitors<sup>[3]</sup>.

To comprehensively assess the effectiveness of vildagliptin and its combinations in diabetic individuals, it is crucial to consider expert opinions on its clinical utility in day to day clinical practice. To understand the real world scenario, expert opinions will offer valuable insights into the utilization of vildagliptin and its combinations including its efficacy, safety profile, and its utility in for specific subgroup of diabetic individuals. In order to understand the prescription pattern, the current study examined the expert opinions on the preferred therapy options for an Indian clinical setting with a special focus on vildagliptin and its combinations.

**Methods**

A cross sectional, multiple-response questionnaire based survey among physicians specialized in managing T2DM in the major Indian cities from June 2022 to December 2022.

**Questionnaire**

The questionnaire booklet titled POAD (Pragmatism of Oral Anti-Diabetic Drugs in Indian Clinical Practice) study was sent to the doctors who were interested to participate. The POAD study questionnaire included 25 questions about the current opinion, clinical observations, and clinical experience of specialists in managing T2DM. 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**

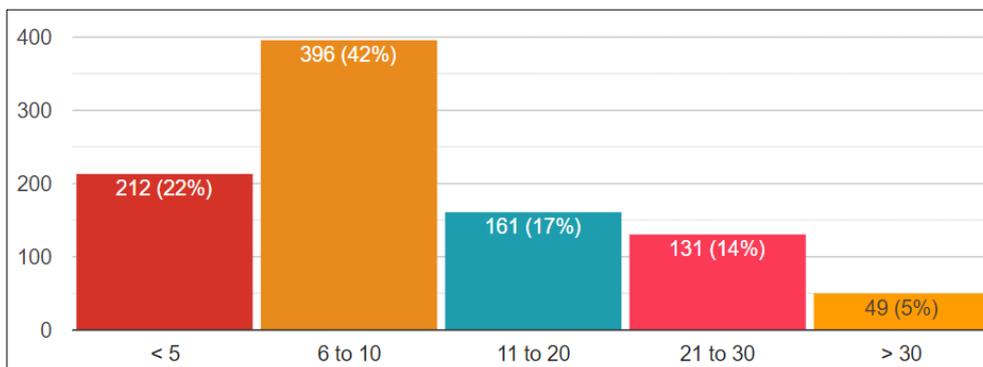
An invitation was sent to professionals across India based on their expertise and experience in treating T2DM in the month of March 2022 for participation in this Indian survey. About 950 clinicians from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. They were explicitly instructed to provide individual responses without consulting their colleagues. Before commencing the study, written informed consent was obtained from all survey participants.

**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 percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, graphs were created using Microsoft Excel 2013 (version 16.0.13901.20400).

**Results**

Out of 950 physicians, 42% of the participants responded that 6 to 10 individuals were diagnosed with T2DM among young age group of 20-35 years of age in a month, 22% of them see less than 5 individuals, 17% of them see 11 to 20 individuals, 14% of them ranges between 21 and 30 and only 5% of clinicians see more than 30 individuals with T2DM in a month (Figure 1). About 38% of the clinicians observed an incidence of diabetic neuropathy of 6 to 10 diabetes individuals in a month in their practice, 25% of them observe 11 to 20 cases, 20% observe less than 5 cases, 12% noted 21 to 30 cases and only 4% observed more than 30 cases. Nearly half of the clinicians observed an incidence of diabetic retinopathy of less than 5 cases in a month in their daily clinical practice, 33% seen 6 to 10 cases, 11% observed 11 to 20 cases, 7% noted 21 to 30 cases and only 2% noted more than 30 cases in their practice. The incidence of T2DM comorbid with obesity was 6 to 10 cases as observed by 40% of respondents in a month in their clinical practice, 27% of them see 11 to 20 cases, 15% of them noted 21 to 30 cases and 13% of them observe less than 5 cases.



**Fig 1:** Distribution of individuals newly diagnosed with T2DM among young age group

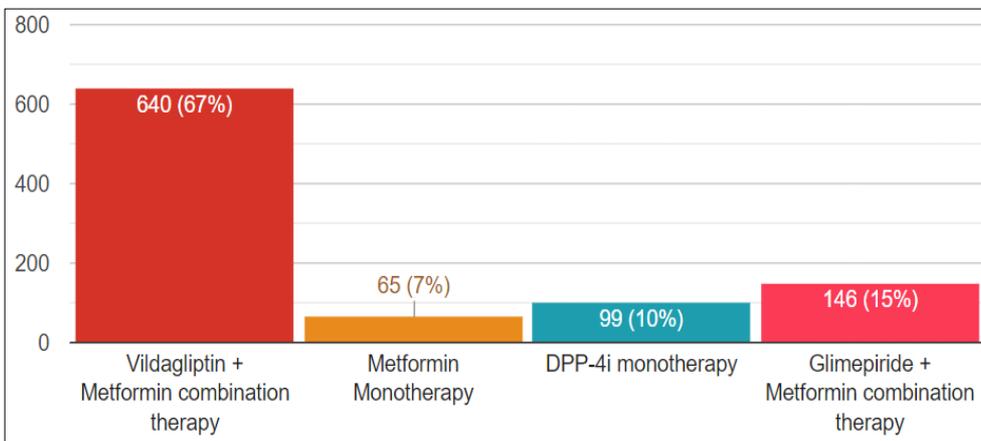
Among diabetes individuals, 38% of the clinicians diagnose 6 to 10 individuals with CV complications in a month in

their clinical practice, 24% each of them noted 11 to 20 cases and less than 5 cases, 11% of them see 21 to 30 cases

and only 4% of them observe more than 30 cases in a month. Over 35% of the physicians observe less than 5% of CKD cases in a month in their clinical practice, 33% of them see 6 to 10 cases, 19% noted 11 to 20 cases, 9% observed 21 to 30 cases and 3% of clinicians see more than 30 cases.

Over 67% of the clinicians prefer vildagliptin + metformin combination therapy for early treatment initiation with HbA1c of 7-8%. About 15% of them prefer glimepiride + metformin combination therapy, 10% of them prefer DPP4

inhibitors monotherapy and only 7% prefer metformin monotherapy (Figure 2). For HbA1c more than 8%, nearly half of the participants preferred vildagliptin + dapagliflozin combination therapy, 33% of them preferred glimepiride + metformin combination therapy, 10% of them opted glimepiride + metformin + voglibose combination therapy and only 9% of them preferred glimepiride + metformin + pioglitazone combination therapy for early treatment intensification.

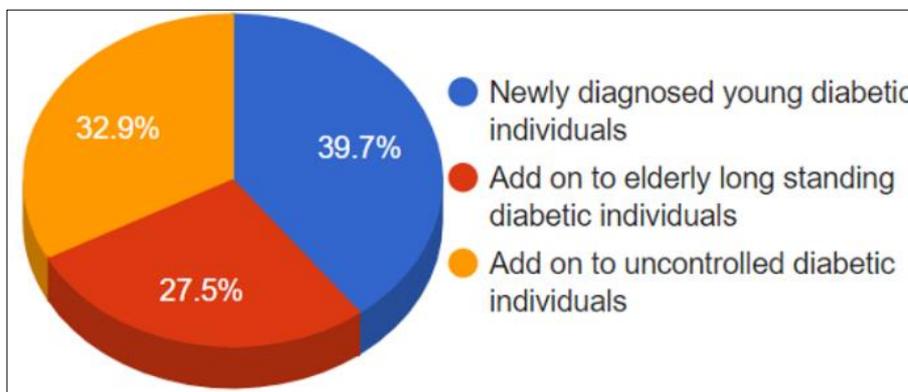


**Fig 2:** Distribution of preference of OAD for early treatment initiation

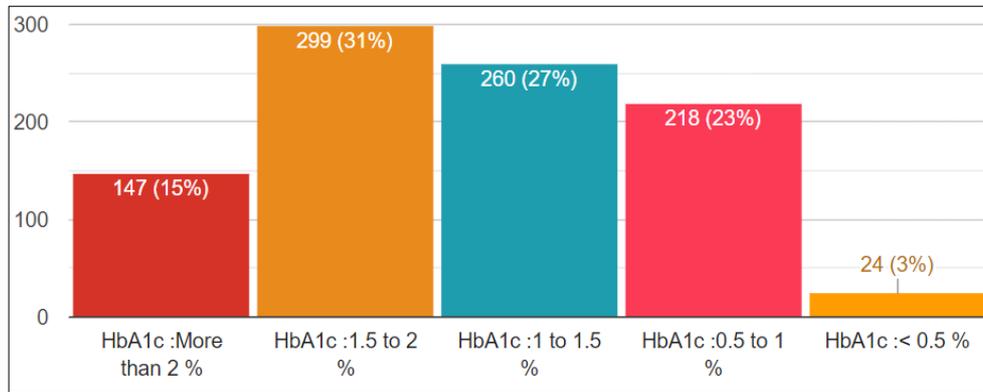
More than half of the clinicians preferred vildagliptin + dapagliflozin + metformin combination therapy to reduce the dose of exogenous insulin. About 21% of the clinicians preferred glimepiride + metformin combination therapy, 16% of them preferred glimepiride + metformin + pioglitazone combination therapy and 12% of them preferred glimepiride + metformin + sitagliptin combination therapy. Notably 84% of the clinicians preferred dapagliflozin among the SGLT2 inhibitors for the management of T2DM. Further, it was observed that 59% of the respondents noted 5 to 10 mm Hg reduction in systolic blood pressure (SBP) with dapagliflozin 10 mm Hg. About 35% of them observed less than 5 mm Hg reduction in SBP and only 6% of them seen more than 10 mm Hg reduction in SBP.

Over 81% of the clinicians prefer vildagliptin 100 mg sustained release once daily dosage instead of vildagliptin

50 mg twice daily formulation. Nearly 40% of the clinicians preferred vildagliptin 100 mg once daily formulation for newly diagnosed young diabetic individuals, 27.5% of them opted it as an add on to elderly long standing diabetic individuals and almost 33% preferred it as an add on to uncontrolled diabetic individuals (Figure 3). After 3 months of vildagliptin 100 mg SR therapy, 31% of clinicians observed 1.5 to 2% reduction in HbA1c, 27% of them seen 1 to 1.5%, 23% of them noted 0.5 to 1% HbA1c reduction, 15% of them noted more than 2% and only 3% observed less than 0.5% reduction in HbA1c (Figure 4). In addition, 38% of the clinicians opined vildagliptin + dapagliflozin therapy showed 1.5 to 2% reduction in HbA1c after 3 months of treatment. About 29% of them noted 0.5 to 1% HbA1c reduction, 16% observed more than 2%, 15% observed 0.5 to 1% and only 3% noted less than 0.5% reduction in HbA1c.



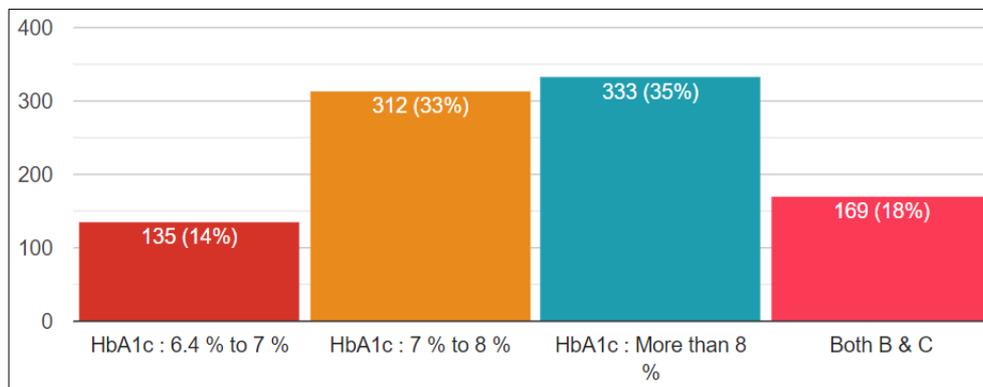
**Fig 3:** Distribution of usage of vildagliptin 100 mg once daily formulation for diabetic individuals



**Fig 4:** Distribution of HbA1c reduction with vildagliptin 100 mg SR after 3 months

About 35% of the clinicians recommend vildagliptin + metformin + dapagliflozin fixed dose combination (FDC) in cases with HbA1c more than 8%, 33% prefer among cases with HbA1c 7 to 8%, 18% of them prefer in both and only 14% of them prefer in individuals with HbA1c between 6.4 to 7% (Figure 5). More than one-third of the clinicians preferred this FDC among diabetes individuals with CV complications, 26.2% of them opted for diabetes individuals

with obesity, 19.5% of them opined for diabetes individuals with hypertension and only 17.6% of them preferred for diabetes individuals with CKD. Interestingly, 43% of the respondents prefer glimepiride + metformin + sitagliptin fixed dose combination (FDC) among individuals with HbA1c of 7% to 8%, 39% of them prefer among individuals with HbA1c more than 8% and only 17% of them prefer among individuals with HbA1c ranges 6.4 to 7%.



**Fig 5:** Distribution of preference of vildagliptin + metformin + dapagliflozin fixed dose combination (FDC) based on HbA1c levels

It was observed that more than half of the clinicians opined patient compliance to regular consumption of OADs was the most challenging aspect in managing T2DM, one-fourth of them observed patient compliance to regular diet and one fifth of them noted physical activity. In that, 36% of the clinicians observed lack of patient education was the major factor behind non-compliance to OADs, 30% reported multiple dose regimens, 22% highlighted cost of medication and 11% observed adverse events associated with medications.

Moreover, 43% of the clinicians suggested yoga for diabetic individuals, 31% of them opted aerobic exercise and 25% of them recommended stretch and resistance training. In diet restriction, more than half of the clinicians suggested intermittent fasting, ketone diet and low fat diet. About 23% of them suggested low fat diet only and 11% opined intermittent fasting alone.

Notably, 42% of the physicians agreed that they feel telemedicine plays as an integral part of diabetes management and 31% of them strongly agreed the same. Along with that, 37% of them preferred small group interactive sessions for educating the diabetes individuals, 36% of them opted individual one to one sessions, 15% preferred mass education through social media, radio and television.

## Discussion

Both wellness and sickness can benefit from yoga therapy. Recent research indicates that yoga-based lifestyle changes may have a place in the treatment of type 2 diabetes and the risk factors that go along with it. Yoga poses, mudras, bandhas, pranayama, cleansing techniques, meditation, mindfulness, and relaxation are among the techniques that have been shown to significantly improve clinical outcomes by lowering blood glucose levels and managing comorbid conditions linked to type 2 diabetes mellitus [4]. The Physicians in this study also recommend yoga as the best exercise for a diabetic individual which is in accordance with Raveendran AV *et al.*

In comparison to continuing metformin monotherapy, the combination of vildagliptin and metformin, two oral anti-diabetic medications with complementary mechanisms of action, offers superior efficacy and enables more patients to reach their glycaemic targets without raising the risk of hypoglycaemia, exposing them to weight gain, or changing common cardiovascular risk factors (hypertension and lipid profile). Furthermore, this combination has shown positive effects on  $\alpha$ - and  $\beta$ -cells in the pancreas [5]. Similarly, majority of the physicians also preferred vildagliptin and metformin as a preferred oral anti diabetic drug for early treatment when HbA1c was between 7%-8%.

A microvascular condition called diabetic retinopathy is brought on by the long-term consequences of diabetes mellitus. Diabetic retinopathy can cause retinal damage that could potentially result in blindness and pose a hazard to eyesight. In the western world, it is the most frequent cause of significant vision loss in adults in the working age range [6]. In this study, 80% of the physicians see 10 Cases of diabetic retinopathy in a month.

Patients with diabetes mellitus require a greater number of tests, treatments, and clinical visits because the condition causes problems. Telemedicine helps patients with diabetes mellitus achieve better clinical results and self-management techniques. It is a useful, reasonably priced, and dependable tool for checking diabetes patients for a range of problems, and it is easily accessible to those living in remote places. By using these technology, medical professionals can provide patients with doorstep care in underserved and remote places [7]. This is in accordance Dhediya R *et al.*, as in this study also majority of the physicians felt telemedicine/teleconsultation, can be an integral part in managing type 2 diabetes mellitus.

Regardless of the patient's history of CVD, oral dapagliflozin once daily improves glycaemic control, body weight, and blood pressure while lowering the risk of CV death/HFF and perhaps the advancement of renal disease. This makes it a valuable alternative for the care of a wide range of patients [8]. Further, the majority of the physician's preferred dapagliflozin as the most preferred sodium glucose cotransporter 2 inhibitor and also 59% physician's experienced 5-10 mm Hg of BP reduction with 10 mg of dapagliflozin.

In addition, it was noted that 81% of the clinicians prefer vildagliptin 100 mg sustained release once daily dosage instead of vildagliptin 50 mg twice daily formulation. It was in accordance with Kalra S *et al.* as once-daily dose of Vildagliptin 100 mg SR was as effective and tolerable as the twice-daily dose of 50 mg in reducing HbA1C, FPG, and PPPG when taken in conjunction with metformin 1000 mg [9].

Moreover, 67% of the clinicians prefer vildagliptin + metformin combination therapy for early treatment initiation with HbA1c of 7-8%. The VERIFY study also showed that early combination therapy of antidiabetic medications significantly reduced the relative risk for time to initial treatment failure (HbA1c  $\geq$  7.0%) by 49% compared to initial metformin monotherapy [10]. In line with this, the American Diabetes Association (ADA) recommends early combination therapy with metformin and vildagliptin (DPP-4 inhibitor) increases glycemic durability compared to a stepwise approach to treatment [11]. Chawla M *et al.* also demonstrated that vildagliptin/metformin combination therapy was associated with a significant and clinically relevant reduction in HbA1c from baseline [12].

Although this study was conducted in wider population, it relies on expert opinions which introduces the possibility of bias influencing the results. So, further research is necessary to evaluate the safety, effectiveness, and tolerability of various combinations and dosage regimens of various therapy in individuals with diabetes.

## Conclusion

The present study confirmed that vildagliptin and metformin are the recommended oral anti-diabetic drugs for the commencement of early therapy and dapagliflozin was the

most recommended inhibitor of sodium glucose cotransporter 2 for the treatment of type 2 diabetes mellitus. Experts concur that managing diabetes mellitus can benefit greatly from telemedicine and teleconsultation. The most difficult part of managing type 2 diabetes mellitus is getting patients to comply with regular oral anti-diabetic medication, which is mostly caused by a lack of patient knowledge and education. Among all the exercises, yoga was one of the best exercise for diabetic individuals.

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## Conflict of Interest

Not available

## Financial Support

Not available

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