International Journal of Scientific Reports
Manjula S et al. Int J Sci Rep. 2025 Aug;11(8):275-281
http://www.sci-rep.com
pISSN 2454-2156 | eISSN 2454-2164
DOI: https://dx.doi.org/10.18203/issn.2454-2156.IntJSciRep20252189

Original Research Article

Clinicians' perspectives on the use of fixed-dose combination of voglibose, glimepiride and metformin in managing type 2 diabetes mellitus in Indian settings

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Received: 09 June 2025
Revised: 14 July 2025
Accepted: 15 July 2025

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ABSTRACT

Background: To gather expert opinion on the use of fixed dose combination (FDC) of voglibose, glimepiride and metformin in managing type 2 diabetes mellitus (T2DM) in Indian settings.
Methods: This cross-sectional study was conducted among clinicians using a structured questionnaire on current feedback, clinical observations and specialists' experiences in managing T2DM, with a special emphasis on the use of FDC voglibose, glimepiride and metformin in routine practice. Descriptive statistics were used for data analysis, with graphs and pie charts for visualization.
Results: The study included 472 clinicians, with 64% preferring to manage elevated postprandial glycemic average hemoglobin A1c (PGA1c) levels using an FDC of alpha-glucosidase inhibitors (AGIs), sulfonylureas (SUs) and metformin. Voglibose therapy was reported by 73% of respondents as effective for PGA1c control, reducing glycemic variability, lowering hypoglycemic risk and being compatible with other oral antidiabetic drugs (OADs). Approximately 66% of experts preferred voglibose + SU + metformin FDC for elderly patients with elevated PGA1c levels. Around 80% found the combination of voglibose, glimepiride and metformin effective in managing all aspects of the glycemic hexad, including fasting and postprandial glucose, HbA1c, nocturnal hypoglycemia, glycemic variability and overall hypoglycemia. Additionally, 66% highlighted its role in reducing visceral and subcutaneous adipose tissue.
Conclusions: This study highlighted a strong clinician preference for voglibose, glimepiride and metformin FDC in T2DM management due to its effectiveness in controlling post-prandial blood glucose, reducing glycemic variability, minimizing hypoglycemia and improving the glycemic hexad, especially in elderly and high-risk patients.

Keywords: Glimepiride, Glycemic control, Metformin, Postprandial glucose, Type 2 diabetes mellitus, Voglibose

INTRODUCTION

The management of type 2 diabetes mellitus (T2DM) is a major health concern, with an estimated 537 million adults living with diabetes globally in 2021, expected to rise to 643 million by 2030 and 783 million by 2045.[1] Notably, three out of four individuals with diabetes live in low- and middle-income nations, where increasing urbanization, lifestyle changes and poor healthcare infrastructure have led to an increase in incidence.[2] In India alone, there were 90 million individuals with diabetes in 2021, a number expected to rise by 68%, reaching 113 million by 2030 and 152 million by 2045.[2]

Managing T2DM effectively requires addressing multiple interconnected factors, including glycemic control, post-prandial glucose (PPG) levels and glycemic variability. Achieving optimal glycemic control is crucial for delaying disease progression, preventing complications and improving overall patient outcomes.[3] The landmark

UK prospective diabetes study (UKPDS) demonstrated that a 1% reduction in HbA1c reduces the risk of microvascular and macrovascular complications, underscoring the importance of comprehensive glycemic management.[4]

Fixed-dose combinations (FDCs) have transformed T2DM management by reducing pill burden, simplifying treatment regimens and enhancing patient adherence. The addition of a third agent in triple FDCs can further improve glycemic control and treatment efficacy while reducing costs.[5] FDCs, including voglibose, glimepiride and metformin, are increasingly preferred for their role in optimizing treatment outcomes. The Research Society for the Study of Diabetes in India (RSSDI) guidelines also advocate for a patient-centric approach by recommending triple therapy in patients not achieving their glycemic targets with two drugs.[6]

Alpha-glucosidase inhibitors (AGIs), such as voglibose, play a crucial role in managing postprandial glucose (PPG) by delaying carbohydrate absorption in the gastrointestinal tract. Voglibose inhibits α-glucosidase enzymes in a reversible, competitive manner, effectively reducing hyperglycemia and hyperinsulinemia after meals. Additionally, it enhances glucagon-like peptide-1 (GLP-1) secretion, which promotes insulin release and improves overall glycemic control. Voglibose, whether used alone or in combination with other antidiabetic agents, has demonstrated both efficacy and tolerability in clinical practice.[7-9] When combined with glimepiride and metformin, voglibose offers the potential for better glycemic control without significantly increasing the risk of hypoglycemia or weight gain.[10-12] Sulfonylureas like glimepiride stimulate insulin release from pancreatic β-cells and also exert extra-pancreatic effects, while metformin enhances insulin sensitivity in muscle and liver. Metformin alters cellular energy metabolism and primarily lowers glucose levels by inhibiting hepatic gluconeogenesis and counteracting glucagon's action.[13,14]

Although there were several studies regarding its efficacy in T2DM patients, there is a dearth of study among clinicians in actual clinical practice. So, this study is intended to gather expert opinion on the efficacy of triple drug FDC of voglibose, glimepiride and metformin for individuals with T2DM presenting to routine clinical practice in Indian settings.

METHODS

We carried out a cross-sectional, multiple-response questionnaire-based study among experts managing T2DM in the major Indian cities from June 2024 to December 2024.

In March 2024, an invitation was made to renowned clinicians in the management of T2DM to participate in this Indian survey. About 472 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provided necessary data. Every participant provided written informed consent before participating in the study. Those who did not share a willingness or provide consent were excluded from the study. Participants had the option to skip any questions they chose not to answer and were instructed to complete the survey independently without consulting colleagues.

The questionnaire booklet titled HARMONY (HbA1c and post prandial glucose reduction in the management of T2DM patients with small add-on of 0.2 mg of Voglibose with Glimepiride and metformin Combination Therapy) was sent to the clinicians who were interested to participate. The HARMONY study questionnaire consisted of 23 questions focused on current feedback, clinical observations and specialists' experiences in managing T2DM, with particular emphasis on the use of the FDC of voglibose, glimepiride and metformin in routine practice. The study was carried out after obtaining approval from Bangalore Ethics, an independent ethics committee that was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

Statistical analysis

The data collected were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear insight into their distribution. Each variable's distribution was represented by its frequency of occurrence and the accompanying percentage. To visualize the distribution of the categorical variables, graphs and pie charts were created using Microsoft Excel 2013 (version 16.0.13901.20400).

RESULTS

The study included 472 clinicians. About 54% reported that the 41 to 50-year-old age group more frequently had HbA1c >9%. More than half of the clinicians (54.24%) identified overweight T2DM individuals with cardiovascular risk factors as the subgroup most frequently experiencing diabetic complications due to uncontrolled glycemic levels.

Approximately 40% of clinicians reported that 20 to 30% of diabetic individuals are aware of the high-carbohydrate (HCO) diet. As reported by 34% of clinicians, among individuals with high postprandial glycemic average HbA1c (PGA1c) levels, 21 to 30% experienced glycemic variability and nocturnal hypoglycemia. The majority of clinicians (63.56%) preferred managing elevated PGA1c levels using a combination of alpha-glucosidase enzyme inhibitors with sulfonylureas (SU) + metformin as FDC therapy (Table 1).

More than half (59.75%) of the participants opined that increased cardiovascular disease (CVD) risk and all-cause mortality are linked to the role of PGA1c in the development of CVD and overall mortality. According to

81% of clinicians, PGA1c contributes to an increase in lipid levels. Voglibose therapy has proven effective in managing PGA1c control by significantly reducing PPG levels. As reported by 73% of respondents, it is also associated with reduced glycemic variability, a lower risk of hypoglycemic episodes and compatibility with other OADs (Table 2).

Majority of the study participants (66.31%) reported voglibose + SU + metformin as the preferred therapy for elderly patients with elevated PGA1c levels (Table 3). The important role of postprandial self-monitoring of blood glucose is highlighted in glycemic and lipid control, with 50% of participants stating it improves glycemic control and lipid levels. As observed by 53% of clinicians, the role of PGA1c in insulin resistance and CVD risk is linked to the reduction in insulin and CVD risk.

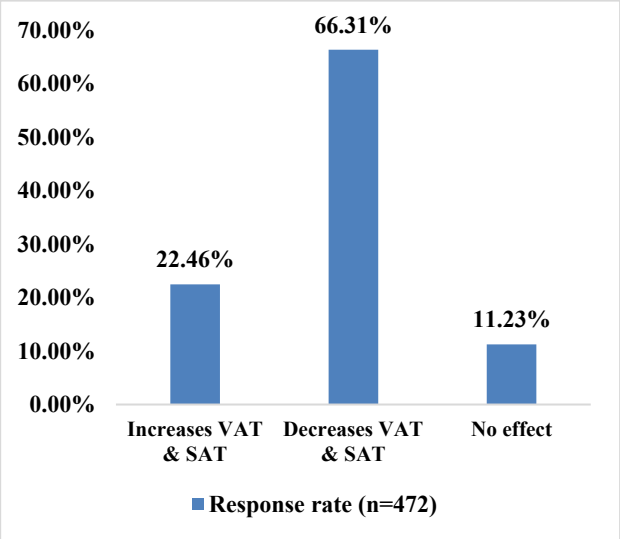

Figure 1: Distribution of responses on the role of voglibose in visceral adipose tissue area and subcutaneous adipose tissue ratio.

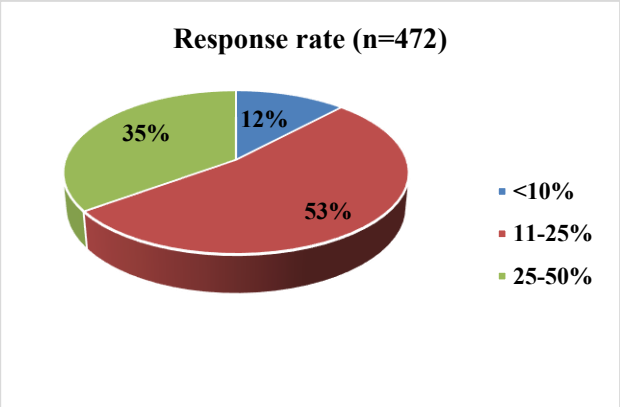

Figure 2: Distribution of responses on the proportion of diabetic individuals on voglibose + glimepiride + metformin triple drug FDC therapy in PGA1c management.

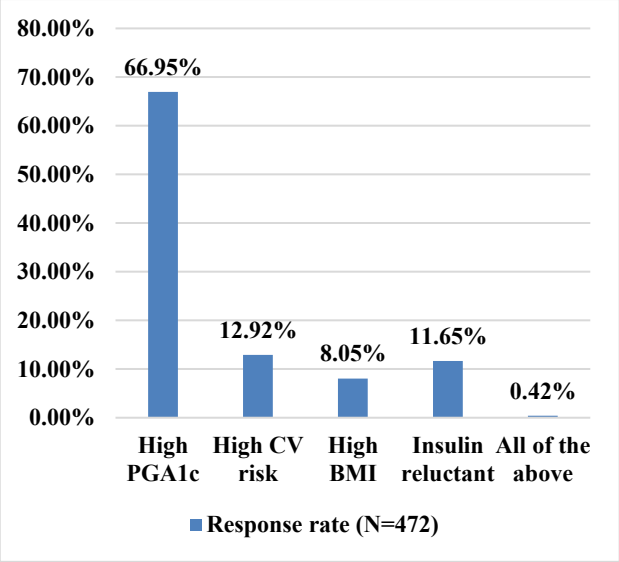

Figure 3: Distribution of responses to the clinician-recommended use of voglibose + glimepiride + metformin triple-drug FDC therapy in different diabetic patient subsets.

Most of the respondents (80.08%) indicated that the FDC of voglibose, glimepiride and metformin is effective in managing all aspects of the glycemic hexad, including fasting blood glucose (FBG), PPG, HbA1c, nocturnal hypoglycemia, glycemic variability and overall hypoglycemia (Table 4). According to 54% of clinicians, the recommended walking duration to help reduce PPBG levels after each meal is 16 to 30 minutes.

As reported by 69% of the clinicians, the preferred approach for reducing high carbohydrate intake to manage PGA1c is through individual counseling methods. Nearly half (51.48%) of the respondents reported that a combination of continuous glucose monitoring systems and self-monitoring of blood glucose levels is preferred for assessing glycemic variability in individuals with T2DM.

About 79% of clinicians indicated that the major reasons for post-meal hyperglycemia are reduced insulin sensitivity, impaired insulin secretion and an inability to effectively suppress hepatic glucose production. According to 66% of the participants, the effect of voglibose in visceral adipose tissue area (VAT) and subcutaneous adipose tissue ratio (SAT) is to reduce visceral adipose tissue area and subcutaneous adipose tissue ratio (Figure 1). About 36% of the participants stated that 15-20% of uncontrolled PGA1c individuals adhere to the recommended therapy. Approximately 10 to 15% of individuals with T2DM struggle to maintain a consistent carbohydrate (CHO) diet in their daily lives, as reported by 29% of clinicians. Over half (52.97%) of the respondents opined that 11 to 25% of diabetic patients are treated with voglibose + glimepiride + metformin triple drug FDC therapy for PGA1c management (Figure 2). As reported by 83% of the participants, the key factors in

achieving PGA1c goals are age, duration of diabetes, therapy cost, comorbidities and non-compliance with treatment. Nearly 46% of the participants stated that the benefit of achieving early PGA1c goals leads to better clinical outcomes and end-organ protection. About 67% of the clinicians reported that in diabetic individuals with a high HbA1c patient, the recommended therapy is a triple-drug FDC of voglibose + glimepiride + metformin (Figure 3).

Table 1: Distribution of responses on the preferred choice of combination in managing high PGA1c levels.

Drug combination	Response rate (n=472)
AGIs+ SU + metformin	63.56%
DPP4i + SGLT2i + metformin	30.93%
Insulin therapy	4.87%
SU+metformin+DPP4i	0.21%
Not attempted	0.42%

Table 2: Distribution of responses on the benefits of voglibose therapy in managing PGA1c control.

Benefits	Response rate (n=472)
Voglibose offers less glycemic variability	6.36%
Effective in reducing post-prandial glucose levels	16.95%
Less risk of hypoglycemic episodes	3.18%
Compatible with other OADs	0.85%
All of the above	72.67%

Table 3: Distribution of responses on the recommended FDC therapy in elderly patients with high PGA1c.

Therapy	Response rate (n=472)
Voglibose +SU+ metformin	66.31%
Gliptin+ metformin	12.71%
Gliptin+ SU+metformin+SGLT2i	20.97%

Table 4: Distribution of responses on the perspectives on the efficacy of voglibose + glimepiride + metformin FDC in managing glycemic hexad.

Opinion	Response rate (n=472)
Effectively controls all parameters of glycemic hexad	80.08%
Limited effect on all parameters	8.69%
Effective with additional drugs	11.23%

DISCUSSION

The present study highlights the clinical preference for an FDC of voglibose, glimepiride and metformin in the management of persistent hyperglycemia among patients with T2DM. The current study findings showed that the majority of clinicians favored the use of AGIs in combination with SUs and metformin for managing high PGA1c levels.

In line with this finding, Das et al recommended early use of a triple combination of AGIs (voglibose) with SU (glimepiride) and metformin, as it improves glycemic control in T2DM patients.[15] Similarly, Parmar et al demonstrated that this combination is both effective and well-tolerated in reducing HbA1c, PPG, FBG and body weight, making it a viable treatment option.[16] A double-blinded study by Derosa et al, observed a significant reduction in FBG, PPG and HbA1c with a combination of sulfonylurea, metformin and AGIs.[17] In the present study, voglibose therapy has demonstrated significant effectiveness in managing glycemic control by reducing PPG levels, lowering glycemic variability and minimizing the risk of hypoglycemic episodes. Its compatibility with other OADs makes it a valuable therapeutic option for patients with T2DM. The VICTORY study by Kalra et al highlighted that voglibose is most commonly prescribed as an add-on to metformin and sulfonylureas, accounting for 28.8% of its usage.[18] Several clinical trials have reported the efficacy of voglibose as an add-on therapy in T2DM patients.[19,20] Jindal et al found that after six months of voglibose treatment, fasting blood glucose (FBG), PPG and glycated hemoglobin (HbA1c) levels were significantly reduced ($p<0.001$) when used as part of a triple-drug regimen.[21] Similarly, Saito et al demonstrated that combining voglibose with sulfonylureas resulted in better

control of fasting and postprandial glucose levels compared to monotherapy.[22]

The majority of the current study respondents reported voglibose + SU + metformin as the preferred therapy for elderly patients with elevated PGA1c levels. Das et al concluded that a triple-drug combination can potentially improve glycemic control and can also delay or postpone the microvascular and CV complications in Indian T2DM patients.[15] Parmar et al also observed that this triple drug FDC is well-tolerated and effective in controlling HbA1c, PPG, FBG and body weight, offering an efficient approach to managing T2DM.[16]

In the present study, PGA1c was found to play a role in insulin resistance and CVD risk, primarily through its association with a reduction in insulin levels and CVD risk. Studies have indicated that insulin resistance is a significant factor contributing to the development of CVD. Henry N Ginsberg highlighted that insulin resistance is a major underlying abnormality driving CVD, the major cause of morbidity and mortality in much of the world.[23] Ormazabal et al reported that metabolic alterations during insulin resistance, such as increased free fatty acids and inflammatory cytokines, contribute to the development of CVD.[24]

The study results showed that the FDC of voglibose, glimepiride and metformin is effective in managing all aspects of the glycemic hexad. Kalra et al demonstrated that the triple FDC of metformin, SU and voglibose targets fasting blood sugar and postprandial blood sugar and thereby improves all five elements of the glycemic pentad.[18] Rao and Faruqui further concluded that this combination significantly reduced HbA1c, FBG and PPG levels by the end of treatment.[25] Similarly, Murti et al observed that the addition of voglibose to glimepiride and metformin showed a significant benefit in controlling the glucose triad (HbA1c, FBG and PPG) compared to dual therapy.[26]

The study results highlighted the role of voglibose in decreasing visceral adipose tissue area and subcutaneous adipose tissue ratio. Takami et al evaluated the effects of dietary management alone and in addition to voglibose on abdominal obesity and metabolic syndrome in Japanese individuals with newly diagnosed T2DM. The study found that while all treatment groups experienced reductions in both VAT and SAT with a mean weight loss of 2-3 kg, only the group receiving diet plus voglibose revealed a significant reduction in the VAT-to-SAT ratio. This suggests that voglibose may have a specific effect in reducing visceral fat more than subcutaneous fat.[27] Fujitaka et al in their study highlighted that in T2DM patients with excess VAT and SAT, diet combined with voglibose therapy led to a significant reduction in VAT, which was closely linked to better glycemic control.[28]

The current study highlighted the widespread use of voglibose, glimepiride and metformin triple-drug FDC for PGA1c management, particularly in diabetic patients with high HbA1c levels. Arif A. Faruqui reported significant reductions in HbA1c (10.6±1.3 to 6.6±0.4; P<0.0001), FPG (208.33 mg/dL to 118.06 mg/dL; P<0.0001) and PPG (360.14 mg/dL to 168.36 mg/dL; P<0.0001) after three months. The combination effectively controlled both FBG and PPG levels and was well-tolerated. With proper medication counseling, the triple FDC (voglibose 0.2 mg, glimepiride 0.5 mg and metformin 500 mg SR) offers safe and effective glycemic control.[29] Shamanna et al found in a retrospective study that the most commonly prescribed FDC was a combination of 1 mg glimepiride, 500 mg metformin and 0.2 mg voglibose (40.14%). The preferred dosing frequency was once daily (52.92%), with the most common treatment duration being one to three months (48.78%).[30] Nigam et al also evaluated the efficacy and safety of FDC of voglibose (0.2 mg), glimepiride (1 mg or 2 mg) and metformin (500 mg) in patients with T2DM poorly controlled on dual therapy. The results indicated a significant decrease in HbA1c levels over a three-month treatment period.[31]

This study offers valuable insights into clinical preferences for managing T2DM using the FDC of voglibose, glimepiride and metformin. A significant strength of the survey is its use of a well-structured and validated questionnaire to gather data from clinicians. However, several limitations should be noted. The reliance on expert opinion introduces potential bias, as individual clinician perspectives and preferences may have influenced the results. Furthermore, the study may not completely capture new patterns or recent findings in diabetes care. To validate the study findings and inform optimal treatment strategies, prospective trials or real-world observational studies are needed.

CONCLUSION

This study indicated a strong preference among clinicians for the FDC of voglibose, glimepiride and metformin in managing persistent hyperglycemia in T2DM. This combination is favored for its efficacy in controlling PPG, reducing glycemic variability and minimizing hypoglycemia. It is particularly recommended for elderly patients and those with high cardiovascular risk. It also helps in improving all aspects of the glycemic hexad in T2DM patients.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Manjula S, Krishna KM. Clinicians' perspectives on the use of fixed-dose combination of voglibose, glimepiride and metformin in managing type 2 diabetes mellitus in Indian settings. Int J Sci Rep 2025;11(8):275-81.