National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 4, Pages 448–458, April 2026
DOI 10.61770/NBEJMS.2026.v04.i04.002

**ORIGINAL ARTICLE**

# Clinical Profile, Treatment Combinations, and Glycemic Outcomes in Indian Patients with Type 2 Diabetes: An Observational Study

Jnanaprakash B. Karanth,[1,*] Kiran Maribashetti[2] and Gangapooja J. Karanth[1]

[1]*Shripad Hegde Kadave Institute of Medical Sciences, Sirsi, Karnataka – 581402*
[2]*Armed Forces Medical College (AFMC), Pune*

Accepted: 26-January-2026 / Published Online: 3-April-2026

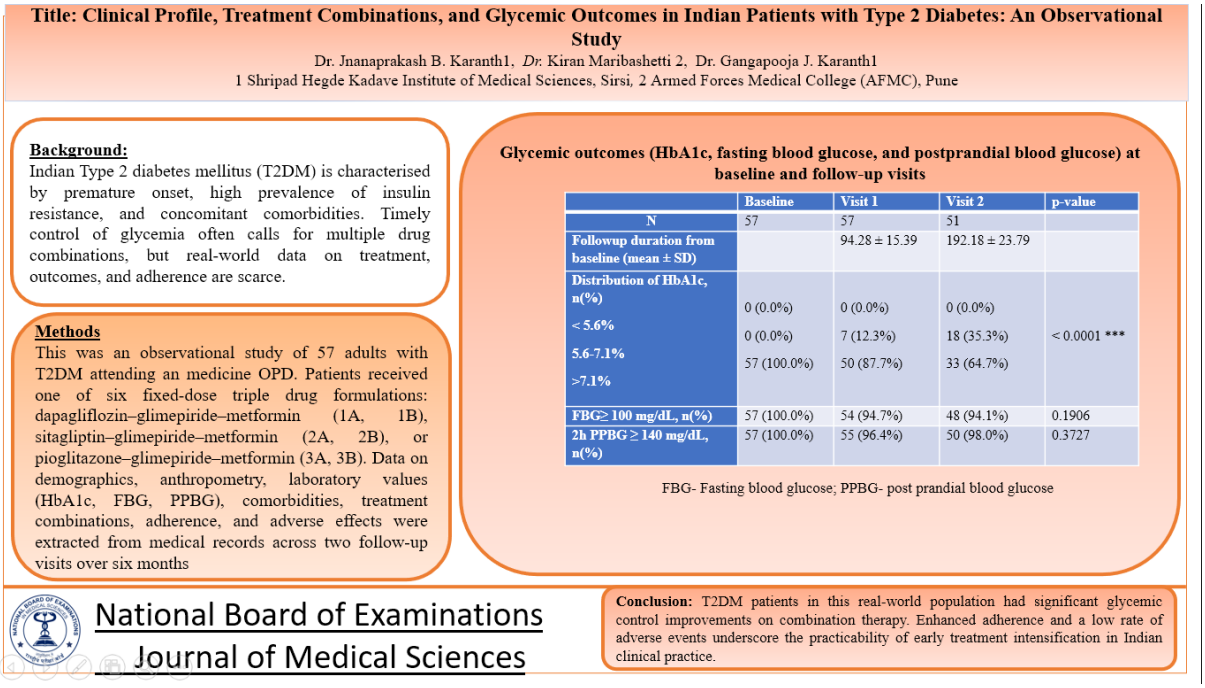
## Abstract

**Background:** Indian Type 2 diabetes mellitus (T2DM) is characterised by premature onset, high prevalence of insulin resistance, and concomitant comorbidities. Timely control of glycemia often calls for multiple drug combinations, but real-world data on treatment, outcomes, and adherence are scarce. **Objective:** To compare clinical profiles, treatment strategies, glycemic control, drug adherence, and safety outcomes in T2DM patients during a six-month follow-up in the real-world Indian clinical practice. **Methods:** This was an observational study of 57 adults with T2DM attending an medicine OPD. Patients received one of six fixed-dose triple drug formulations: dapagliflozin–glimepiride–metformin (1A, 1B), sitagliptin–glimepiride–metformin (2A, 2B), or pioglitazone–glimepiride–metformin (3A, 3B). Data on demographics, anthropometry, laboratory values (HbA1c, FBG, PPBG), comorbidities, treatment combinations, adherence, and adverse effects were extracted from medical records across two follow-up visits. **Results:** The patients' mean age was 58.95 ± 8.24 years, and 57.9% were female. All patients had baseline HbA1c >7.1%, which were highly improved over time; 35.3% had HbA1c ≤7.1% by visit 2 ($P < 0.0001$). The most frequent regimen was 1A + 2A combination with 2 mg Glimepiride. Mean BMI was 23.5 kg/m². The most frequent comorbidity was hypertension (56.1%). Adherence was modestly improved, and adverse events were rare, with hypoglycaemia reduced from 8.8% to 5.3%. **Conclusion** T2DM patients in this real-world population had significant glycemic control improvements on combination therapy. Enhanced adherence and a low rate of adverse events underscore the practicability of early treatment intensification in Indian clinical practice.

**Keywords:** Type 2 diabetes mellitus, combination therapy, glycemic control, India, real-world study, adherence

*Corresponding Author: Jnanaprakash B. Karanth
Email: jbkaranth@gmail.com

## Graphical Abstract




## Introduction

Type 2 diabetes mellitus (T2DM) is an evolving public health issue in India, and it bears one of the largest diabetes burdens worldwide [1]. The pathophysiology of T2DM among Indians is often dominated by the onset of disease at a young age, a modest body mass index (BMI), and extensive central obesity, insulin resistance, and cardiometabolic comorbidities [2]. These specific characteristics account for a faster disease course and increased risk of complications, requiring early and tailored interventions [3].

Even with improvement in pharmacologic choices, glycemic control is suboptimal in a large percentage of patients [4]. Contributing to poor control are clinical inertia, variable medication adherence, and patient-level barriers like cost, lack of understanding, and lack of formal diabetes education [5]. Early combination therapy is frequently required in the management of T2DM to attain and maintain glycemic goals, particularly in low-resource settings where postponement of treatment intensification is prevalent. Yet, evidence for treatment patterns, efficacy, and tolerability of combination regimens in actual Indian clinical practice is limited [6].

This research was conducted to assess the clinical and demographic features, treatment regimens, glycemic response, patterns of adherence, and safety events in patients with T2DM at one center. The aim was to provide real-world evidence regarding the efficacy and tolerability of different treatment strategies in early- to mid-stage T2DM in the Indian setting.

## Materials and Methods

This was an observational study in an Indian specialised Medicine OPD. The aim was to assess the clinical and biochemical profiles, patterns of antidiabetic treatment, glycemic control, and safety outcomes in type 2 diabetes mellitus (T2DM) patients within a six-month follow-up. The data were gathered from the medical records of the patients

who had a minimum of two follow-up appointments following the first consultation. The research period ranged from June 2024 to April 2025.

Adult patients aged 18 years or older with a confirmed T2DM diagnosis with baseline HBA1C > 7.1. They were included and followed up for two visits. Patients were excluded if they had missing records, known chronic kidney disease (stage ≥2), type 1 diabetes mellitus, secondary diabetes, or were pregnant or lactating during data collection. Complete clinical and biochemical data on at least two visits were available for fifty-seven patients and were included in the final analysis.

Demographic information such as age and gender, and anthropometric measures such as height, weight, BMI, waist circumference, and waist–hip ratio were obtained from patient records. Clinical information consisted of the duration of diabetes and presence or documentation of comorbidities like hypertension, dyslipidemia, cardiovascular disease, thyroid disease, or chronic kidney disease. Laboratory investigations recorded at baseline and subsequent visits included glycated haemoglobin (HbA1c), fasting blood glucose (FBG), and two-hour postprandial blood glucose (PPBG). Antidiabetic treatment regimens were documented for each visit, including changes in combination therapies. Medication adherence was assessed based on patient-reported frequency of missed doses during each follow-up. Adverse events, including episodes of hypoglycaemia and urinary tract infections, were also documented.

Patients were treated with numerous oral antidiabetic drug combinations. These were generally divided into three classes on the basis of pharmacologic class and action mechanism: insulin sensitisers, insulin secretagogues or incretin-based agents, and SGLT2 inhibitors or other newer drugs. Combinations of these classes were denoted as 1A, 2A, 3A, etc., for the analysis (Table 1). Discontinuation of any medication was not observed during the follow-up.

Table 1. Fixed-dose triple combination formulations of oral antidiabetic agents

| Class Combination | Formulation Code | Composition |
|---|---|---|
| **SGLT2 inhibitor + Sulfonylurea + Biguanide** | 1A | Dapagliflozin 10 mg + Glimepiride 2 mg + Metformin 1000 mg |
| | 1B | Dapagliflozin 10 mg + Glimepiride 1 mg + Metformin 1000 mg |
| **DPP-4 inhibitor + Sulfonylurea + Biguanide** | 2A | Sitagliptin 50 mg + Glimepiride 2 mg + Metformin 1000 mg |
| | 2B | Sitagliptin 50 mg + Glimepiride 1 mg + Metformin 1000 mg |
| **Thiazolidinedione + Sulfonylurea + Biguanide** | 3A | Pioglitazone 15 mg + Glimepiride 2 mg + Metformin 1000 mg |
| | 3B | Pioglitazone 15 mg + Glimepiride 1 mg + Metformin 500 mg |

The major outcome was glycemic control change, measured by HbA1c levels between visits. Secondary outcomes were changes in FBG and PPBG, trends in adherence, and rates of adverse events. The average interval between the baseline and each follow-up visit was computed to measure the time-dependent change in the parameters.

Descriptive statistics were employed to present baseline demographic, clinical, and laboratory data. Continuous measures were represented as mean ± standard deviation (SD), and categorical variables were presented as absolute counts and percentages. Repeated measures analysis was used to compare the glycemic parameters between visits. A p-value of less than 0.05 was regarded as statistically significant. IBM SPSS Statistics software (version, IBM Corp., Armonk, NY, USA) was used for statistical analysis.

The research was done in accordance with ethical standards of the Declaration of Helsinki. Individual patient consent was not required as this was a retrospective analysis of anonymised clinical data. Institutional Ethics Committee approval was sought before data retrieval and analysis**.** We also deny using AI in analysing the data and interpreting results or conclusions,

## Results

### *Patient Demographics and Baseline Characteristics*

A total of 57 patients were enrolled in the study. The mean age was 58.95 ± 8.24 years, and 24 (42.1%) were men and 33 (57.9%) were women. The mean height and weight were 163.65 ± 7.32 cm and 62.92 ± 10.19 kg, respectively. Body mass index profile revealed that five patients (8.8%) were with BMI <19 kg/m², 23 (40.4%) were with BMI 19–22.9 kg/m², and 29 (50.9%) were with BMI >23 kg/m². Waist circumference greater than the risk threshold (≥90 cm in men and ≥80 cm in women) was found in six female patients (10.5%) while none of the male patients crossed the cut-off. The mean waist-to-hip ratio was 0.91 ± 0.03 in men and 0.81 ± 0.05 in women, giving a combined mean of 0.86 ± 0.07. The mean length of diabetes was 3.71 ± 2.05 years. These features are presented in Table 2.

### *Comorbid Conditions*

The most common comorbidity was hypertension, with 32 patients (56.1%), followed by cardiovascular disease (7 patients, 12.3%), dyslipidemia (6 patients, 10.5%), and thyroid disease (5 patients, 8.8%). CKD was not observed (Table 2).

### *Treatment Regimens and Adaptations*

At visit 1, most patients (n = 52, 91.2%) were taking the 1A + 2A combination regimen, and five patients (8.8%) were taking 3A + 2A. By visit 2, treatment allocation had become more varied, with 42 patients (82.2%) on 1A + 2A, 5 (9.8%) on 3A + 2A, 2 (4.0%) on 1B + 2B, and one patient each on 3A + 2B and 3B + 2B (2.0% each). There were no discontinuations of medications throughout the study (Table 2).

Table 2. Baseline demographic, anthropometric, comorbidity profile, and treatment regimens of the study population

| | N= 57 |
|---|---|
| **Age, in years (mean ± SD)** | 58.95 ± 8.24 |
| **Gender** | |
| Male | 24 (42.1%) |
| Female | 33 (57.9%) |
| **Height (mean ± SD)** | 163.65 ± 7.32 |
| **Weight (mean ± SD)** | 62.92 ± 10.19 |
| **BMI (kg.m$^2$)** | |
| <19 | 5 (8.8%) |
| 19-22.9 | 23 (40.4%) |
| >23 | 29 (50.9%) |
| **Waist circumference** | |
| Male ≥ 90 cm | 0 (0.0%) |
| Female ≥ 80 cm | 6 (10.5%) |
| **Waist:hip ratio (mean ± SD)** | 0.86 ± 0.07 |
| Male | 0.91 ± 0.03 |
| Female | 0.81 ± 0.05 |
| **Duration of diabetes (mean ± SD)** | 3.71 ± 2.05 |
| **Comorbidities** | |
| Hypertension | 32 (56.1%) |
| Dyslipidemia | 6 (10.5%) |
| CKD | 0 (0.0%) |
| CVD | 7 (12.3%) |
| Thyroid disease | 5 (8.8%) |
| **Combination therapies*** | |
| ***Visit 1*** **(N = 57)** | |
| 1A and 2A | 52 (91.2%) |
| 3A and 2A | 5 (8.8%) |
| ***Visit 2*** **(N = 51)** | |
| 1A and 2A | 42 (82.2%) |
| 1B and 2B | 2 (4.0%) |
| 3A and 2A | 5 (9.8%) |
| 3A and 2B | 1 (2.0%) |
| 3B and 2B | 1 (2.0%) |
| Medication discontinuation | Nil |

*Formulation codes:

1A: Dapagliflozin 10 mg + Glimepiride 2 mg + Metformin 1000 mg; 1B: Dapagliflozin 10 mg + Glimepiride 1 mg + Metformin 1000 mg; 2A: Sitagliptin 50 mg + Glimepiride 2 mg + Metformin 1000 mg; 2B: Sitagliptin 50 mg + Glimepiride 1 mg + Metformin 1000 mg; 3A: Pioglitazone 15 mg + Glimepiride 2 mg + Metformin 1000 mg; 3B: Pioglitazone 15 mg + Glimepiride 1 mg + Metformin 500 mg.

***Glycemic Control***

The average follow-up period was 94.28 ± 15.39 days for visit 1 and 192.18 ± 23.79 days for visit 2. At baseline, 100.0% of patients had HbA1c >7.1%. At visit 1, 7 (12.3%) patients achieved 5.6–7.1%, and 50 (87.7%) continued to be >7.1%. At visit 2, the improvement in HbA1c was more significant, with 18 (35.3%) patients achieving 5.6–7.1% and 33 (64.7%) continuing to be >7.1%. Decrease of HbA1c with time was significant ($p < 0.0001$) (Table 3, Figure 1).

By contrast, FBG ≥100 mg/dL was found in all patients at baseline (100.0%), 54 (94.7%) at visit 1, and 48 (94.1%) at visit 2 (P = 0.1906). Likewise, two-hour postprandial blood glucose (PPBG) ≥140 mg/dL was found in all patients at baseline (100.0%), 55 patients (96.4%) at visit 1, and 50 (98.0%) at visit 2 (P = 0.3727). These were not statistically significant (Table 3).

Table 3. Glycemic outcomes (HbA1c, fasting blood glucose, and postprandial blood glucose) at baseline and follow-up visits.

| | Baseline | Visit 1 | Visit 2 | p-value |
|---|---|---|---|---|
| N | 57 | 57 | 51 | |
| **Followup duration from baseline (mean ± SD)** | | 94.28 ± 15.39 | 192.18 ± 23.79 | |
| **Distribution of HbA1c, n(%)**<br>< 5.6%<br>5.6-7.1%<br>>7.1% | <br>0 (0.0%)<br>0 (0.0%)<br>57 (100.0%) | <br>0 (0.0%)<br>7 (12.3%)<br>50 (87.7%) | <br>0 (0.0%)<br>18 (35.3%)<br>33 (64.7%) | <br><br>< 0.0001<br>*** |
| **FBG≥ 100 mg/dL,** n(%) | 57 (100.0%) | 54 (94.7%) | 48 (94.1%) | 0.1906 |
| **2h PPBG ≥ 140 mg/dL, n(%)** | 57 (100.0%) | 55 (96.4%) | 50 (98.0%) | 0.3727 |

FBG- Fasting blood glucose; PPBG- post prandial blood glucose

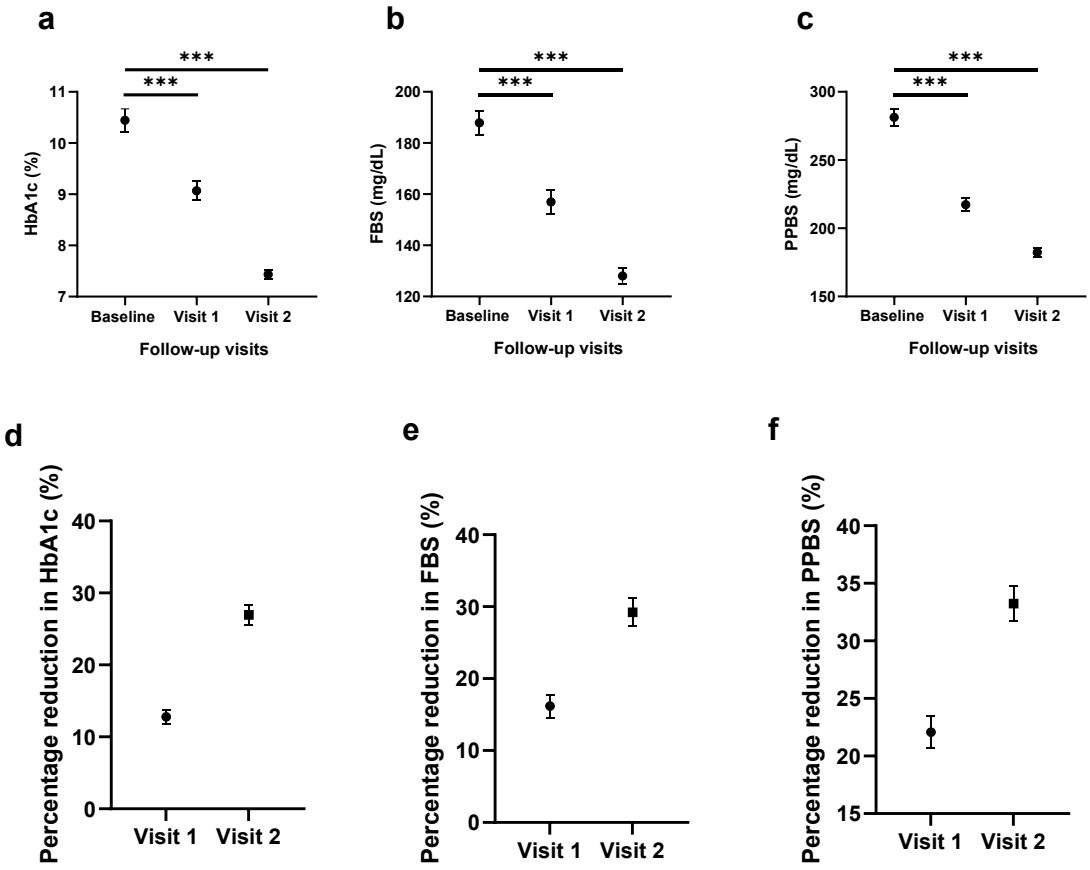



Figure 1. Changes in glycaemic indices over two follow-up visits and percentage reduction from baseline.

(a) HbA1c (%), (b) fasting blood glucose (FBG; mg/dL), and (c) postprandial blood glucose (PPBG; mg/dL) at baseline, Visit 1 (~3 months), and Visit 2 (~6 months). (d–f) Percentage reduction from baseline in HbA1c, FBG, and PPBG at Visit 1 and Visit 2. Data are mean ± SEM (baseline/Visit 1, $n$=57; Visit 2, $n$=51). Statistics by repeated-measures analysis with post-hoc paired comparisons; significance shown as * $p$<0.05, ** $p$<0.01, *** $p$<0.001. Abbreviations: FBG, fasting blood glucose; PPBG, postprandial blood glucose; SEM, standard error of the mean.

**Medication Adherence**

At visit 1, 6 patients (10.5%) had not missed any doses, but this increased to 12 (21.1%) at visit 2. The number of patients missing doses once a week decreased from 24.6% to 8.8%, and once every three weeks, from 61.4% to 47.4%. On the other hand, the number of patients missing once every two weeks rose from 0.1% to 12.3% (Table 4).

**Safety Outcomes**

There were a few adverse events. Hypoglycaemia was noted in five patients (8.8%) at visit 1 and 3 patients (5.3%) at visit 2. 5 patients (8.8%) developed urinary tract infection (UTI) at visit 1, but none at visit 2 (Table 4).

Table 4. Medication adherence patterns and adverse events reported across study visits.

| | Visit 1 | Visit 2 |
|---|---|---|
| N | 57 | 57 |
| Frequency of missing a dose | | |
| None | 6 (10.5%) | 12 (21.1%) |
| Once a week | 14 (24.6%) | 5 (8.8%) |
| Once every 2 weeks | 2 (3.5%) | 7 (12.3%) |
| Once every 3 weeks | 35 (61.4%) | 27 (47.4%) |
| Adverse events | | |
| Hypoglycaemia | 5 (8.8%) | 3 (5.3%) |
| Urinary tract infections | 5 (8.8%) | 0 (0.0%) |

**Discussion**

This observational study sought to compare clinical features, treatment regimens, and their effects on glycemic control in Indian patients with type 2 diabetes. The results indicated that in real-world settings, earlier consideration of combination therapies was effective in achieving good glycemic response in terms of HbA1c reduction, along with a reasonable tolerance.

The study population included a heterogeneous set of individuals at relatively earlier stages of diabetes and presenting with multiple comorbidities, thus reflecting the real-world clinical setting. The mean age of the cohort in the study of 58.9 years was dominated by females (57.9%). Over half of the patients (50.9%) had BMI >23 kg/m² (Table 2), consistent with Asian-specific cut-offs for overweight [7]. These findings are in line with previous Indian studies in that overweight and obesity are common among type 2 diabetic patients [8]. Interestingly, central adiposity was more prevalent in female patients (Table 2), which is a reflection of earlier South Asian observations indicating gender-differentiated fat distribution and cardiometabolic risk [9]. The relatively shorter mean duration of diabetes (3.7 years) (Table 2) suggests that the majority of patients were in the early disease phase, at earlier time points, either immediately following diagnosis or say, less than five years of disease duration, intensive glycemic interventions are considered to be most effective in maintaining β-cell function and retarding the onset of complications [10]. The highest comorbidity rate was of hypertension in 56.1% of the patients, followed by cardiovascular disease (12.3%) and dyslipidemia (10.5%) (Table 2). These results are similar to earlier Indian and South Asian literature, where hypertension has been reported between 50–70% in diabetics [11]. Lack of chronic kidney disease in our cohort may be due to the early stage of the disease. However, longitudinal studies indicate that CKD prevalence increases sharply with duration of diabetes [12].

Worldwide recommendations like the ADA/EASD consensus also support

early combination therapy treatment in patients not likely to reach targets with monotherapy [13]. The practice setting in India usually considers metformin along with sulfonylureas or incretin agents as the pillar of therapy based on cost-effectiveness and availability [14]. Accordingly, in the study cohort, most of the patients had received the 1A + 2A regimen, which was the most commonly employed combination. There was notable improvement in HbA1c with 35.3% of patients attaining levels of 5.6–7.1% by Visit 2 versus none at baseline (Table 3, Figure 1). The result follows the increasing evidence for the benefits of early combination therapy in diabetes treatment. The VERIFY trial showed similar results, in which vildagliptin and metformin early dual therapy offered more sustained glycemic control than stepwise escalation [15].

During follow-up with combinations, the postprandial glucose and fasting levels did not vary significantly. This can be attributed to the relatively short study period, inter-individual dietary variability, and non-adherence, similar to other Indian studies [16]. However, HbA1c is still the strongest marker of long-term glycemic control, and its substantial decrease supports the efficacy of the therapeutic approach used. Compliance was modestly better, with patients reporting zero missed doses increasing from 10.5% at Visit 1 to 21.1% at Visit 2. Absence of medication discontinuations supports the tolerability and acceptability of these regimens for clinical practice. The treatment regimens were tolerated well, with hypoglycaemia incidence decreased from 8.8% to 5.3% and urinary tract infection being zero at Visit 2. These are reassuring data, and according to reports, contemporary double or triple regimens, particularly those with incretin-based or SGLT2 inhibitors, have a lower risk of adverse events than previous regimens [6,18]. A decrease in hypoglycaemia could also be because of improved dose adjustment and closer follow-up. Despite this, patterns of non-adherence continued, which is consistent with well-documented issues including pill burden, expense, and absence of organised diabetes education for the population [17]. Past research indicates that fixed-dose combinations, simplified regimens [14] and electronic adherence support [17] have the potential to greatly enhance compliance, and therefore, the incorporation of such measures into day-to-day practice is imperative.

**Limitations**

Limitations to the study include its small sample size, brief follow-up (~6 months), and lack of control group or randomisation, which restrict causal inference.

**Conclusion**

This study proved early initiation of combination therapies in type 2 diabetic Indian patients with a remarkable reduction in HbA1c, modest increase in adherence, and a good safety profile. The prevalence of comorbid conditions like hypertension and obesity highlights the necessity for comprehensive cardiometabolic management. Higher cohorts, longer follow-up, and randomised trials are needed in the future to confirm the durability of glycemic effects and study intensive interventions for enhancing adherence.

**Statements and Declarations**

**Funding**

The authors did not receive support from any organization for the submitted work.

**Competing interests**

The authors have no competing interests to declare that are relevant to the content of this article.

**Ethics Statement**

This observational study used anonymized data collected in routine clinical practice. In accordance with institutional and national regulations, formal ethics committee approval was not required.

**References**

1. Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. Indian J Ophthalmol. 2021;69:2932–8.
2. Ke C, Narayan KMV, Chan JCN, Jha P, Shah BR. Pathophysiology, phenotypes and management of type 2 diabetes mellitus in Indian and Chinese populations. Nat Rev Endocrinol. 2022;18:413–32.
3. Mphasha M, Mothiba T. Personalised nutrition approaches in the prevention and management of type 2 diabetes: A narrative review of evidence and practice. Int J Environ Res Public Health. 2025;22:1047.
4. Khunti K, Zaccardi F, Amod A, Aroda VR, Aschner P, Colagiuri S, Mohan V, Chan JCN. Glycaemic control is still central in the hierarchy of priorities in type 2 diabetes management. Diabetologia. 2025;68:17–28.
5. Kvarnström K, Westerholm A, Airaksinen M, Liira H. Factors contributing to medication adherence in patients with a chronic condition: A scoping review of qualitative research. Pharmaceutics. 2021;13:1100.
6. Kim JY, Kim NH. Initial combination therapy in type 2 diabetes. Endocrinol Metab (Seoul). 2024;39:23–32.
7. Verma M, Rajput M, Sahoo SS. Revised BMI cut-offs for Asian Indians for screening cardiovascular risk factors: A cross-sectional study. J Family Med Prim Care. 2019;8:3893–7.
8. Anjana RM, Deepa M, Pradeepa R, et al. Prevalence of diabetes and prediabetes in 15 states of India: Results from the ICMR–INDIAB population-based cross-sectional study. Lancet Diabetes Endocrinol. 2017;5:585–96.
9. Misra A, Khurana L. Obesity and the metabolic syndrome in developing countries. J Clin Endocrinol Metab. 2008;93:S9–30.
10. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HAW. 10-year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med. 2008;359:1577–89.
11. Hossain FB, Shawon MSR, Al-Abid MS, et al. Association between body mass index (BMI) and hypertension in South Asian populations: Evidence from Demographic and Health Survey. Clin Obes. 2019;9:e12314.
12. Afkarian M, Zelnick LR, Hall YN, et al. Clinical manifestations of kidney disease among US adults with diabetes, 1988–2014. JAMA. 2016;316:602–10.
13. Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycemia in type 2 diabetes, 2018: A consensus

report by the ADA and the EASD. Diabetes Care. 2018;41:2669–701.
14. Kalra S, Gupta Y, Patil S, et al. Fixed-dose combinations in diabetes: Lessons from real-world evidence. Diabetes Ther. 2021;12:473–87.
15. Matthews DR, Paldánius PM, Proot P, et al. Glycemic durability of early combination therapy vs monotherapy in newly diagnosed type 2 diabetes: 5-year follow-up of the VERIFY study. Lancet. 2019;394:1519–29.
16. Mohan V, Shah S, Saboo B. Current glycemic status and diabetes related complications among type 2 diabetes patients in India: Data from the A1chieve study. J Assoc Physicians India. 2013;61:12–5.
17. Tolley A, Hassan R, Sanghera R, Grewal K, Kong R, Sodhi B, Basu S. Interventions to promote medication adherence for chronic diseases in India: A systematic review. Front Public Health. 2023;11:1194919.
18. Zinman B, Wanner C, Lachin JM, Fitchett D, Bluhmki E, Hantel S, Mattheus M, Devins T, Johansen OE, Woerle HJ, Broedl UC, Inzucchi SE; EMPA-REG OUTCOME Investigators. Empagliflozin, cardiovascular outcomes, and mortality in type 2 diabetes. N Engl J Med. 2015;373:2117–28.