Section: Endocrinology

Original Research Article

ASSESSMENT OF USAGE PATTERN, EFFECTIVENESS AND SAFETY OF FIXED-DOSE COMBINATION OF SITAGLIPTIN, METFORMIN AND PIOGLITAZONE IN INDIAN TYPE 2 DIABETES PATIENTS

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) remains a major public health challenge in India, with rising prevalence and associated cardiovascular, microvascular, and macrovascular complications. Fixed-dose combinations (FDC) simplifying multi-drug regimens offer potential advantages of improved adherence, pill burden reduction, and synergistic pharmacological action. The FDC of Sitagliptin (DPP-4 inhibitor), Metformin (biguanide), and Pioglitazone (thiazolidinedione) combines complementary mechanisms of action targeting insulin secretion, hepatic glucose production, and peripheral insulin resistance. **Objective:** To assess the real-world usage pattern, glycaemic effectiveness, and safety profile of the FDC of Sitagliptin + Metformin + Pioglitazone over a 3-month treatment period in Indian T2DM patients.

Materials and Methods: This observational, multi-centre, retrospective real-world study enrolled T2DM patients prescribed with the FDC of Sitagliptin + Metformin + Pioglitazone across India. Demographic data, risk factors, prior medications, HbA1c, fasting plasma glucose (FPG), post-prandial glucose (PPG), body weight, and HOMA-IR were recorded at baseline and 3 months of treatment. Clinician's global assessment of safety and effectiveness, pedal oedema incidence, and other adverse drug reactions (ADRs) were also evaluated.

Results: A total of 25,040 patients were enrolled. Mean age was 58.7 ± 11.0 years; 64.8% were male. The majority (71.9%) received Sitagliptin 100 mg + Metformin 500 mg + Pioglitazone 15 mg. After 3 months, mean HbA1c fell from 8.35 ± 1.25% to 7.14 ± 1.05% (Δ −1.21%), FPG from 169.8 ± 44.5 to 129.7 ± 35.4 mg/dL (Δ −40.1 mg/dL), and PPG from 246.0 ± 75.6 to 178.3 ± 52.9 mg/dL (Δ −67.7 mg/dL) (all $p<0.001$). Clinicians rated safety as Excellent/Good in 94.2% and effectiveness as Excellent/Good in 94.2% of patients. The mean HOMA-IR value at baseline was 1.26 ± 1.09 (median: 1.00), which significantly decreased to 1.10 ± 0.93 (median: 0.90) after 3 months of treatment, representing a mean reduction of 0.16 units (12.7%; 95% CI: 0.15–0.17). This reduction was statistically significant, indicating a

meaningful improvement in insulin resistance following the intervention. Treatment was well tolerated without any significant safety concerns.
Conclusion: The Sitagliptin + Metformin + Pioglitazone FDC demonstrated significant glycaemic effectiveness with acceptable tolerability in a large real-world Indian T2DM cohort. These findings support its use as an effective combination therapy, especially in patients with high baseline HbA1c, insulin resistance, and cardiovascular risk.
Keywords: Type 2 diabetes mellitus, Sitagliptin, Metformin, Pioglitazone, Fixed-dose combination, Real-world evidence, HbA1c, India.

INTRODUCTION

India bears one of the world's largest burdens of type 2 diabetes mellitus (T2DM). The nationally representative ICMR-INDIAB survey estimated a weighted diabetes prevalence of 11.4% among adults aged 20 years and older, corresponding to approximately 101 million individuals, alongside a further 136 million with prediabetes.[1] Global projections indicate continued rise in the coming decades,[2] and Indian cohorts have consistently described an earlier age at onset and a more adverse cardiometabolic phenotype than Western populations.[3] The management of T2DM is complex, often requiring multiple antidiabetic agents to achieve and maintain adequate glycaemic control.[4,5] Pathophysiologically, T2DM is characterized by progressive beta-cell dysfunction, insulin resistance in peripheral tissues (muscle, adipose, liver), and impaired incretin secretion — mandating combination pharmacotherapy that targets multiple defects simultaneously.[6]

Fixed-dose combinations (FDCs) represent a rational strategy to enhance adherence while providing complementary mechanisms of action in a single tablet. A meta-analysis of antihyperglycaemic regimens reported both a greater HbA1c reduction (mean difference −0.53%) and higher medication possession ratios with FDCs than with the same agents co-administered as separate tablets.[7] The triple FDC of Sitagliptin (a dipeptidyl peptidase-4 [DPP-4] inhibitor), Metformin (a biguanide), and Pioglitazone (a thiazolidinedione) combines three synergistic agents: Sitagliptin augments incretin-mediated insulin secretion and suppresses glucagon,[8]; Metformin primarily reduces hepatic glucose output and improves peripheral insulin sensitivity; and Pioglitazone activates PPAR-γ receptors to reduce insulin resistance and improve lipid profiles.[9]

Indian clinical practice recommendations endorse early combination therapy and permit triple oral regimens in patients whose glycaemic targets are not met on dual therapy.[10] Despite growing clinical interest, large-scale real-world Indian data on the effectiveness and safety of this triple FDC remain limited. The study was therefore designed as a multi-centre, observational study enrolling a large cohort of Indian T2DM patients to characterize usage patterns, glycaemic effectiveness, and tolerability of Sitagliptin + Metformin + Pioglitazone FDC in routine clinical practice.

MATERIALS AND METHODS

2.1 Study Design

The study was an observational, retrospective, multi-centre study conducted at multiple sites across India. Patients with confirmed T2DM who were initiated on or switched to the Sitagliptin + Metformin + Pioglitazone FDC at the investigator's clinical discretion were enrolled. The study followed standard clinical practice without protocol-mandated interventions, and is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.[11]

2.2 Patient Population

Inclusion criteria: Adults (age ≥18 years) with confirmed T2DM diagnosis, prescribed Sitagliptin + Metformin + Pioglitazone FDC, and capable of providing follow-up data. Patients with type 1 diabetes, severe renal or hepatic impairment, pregnancy, or documented contraindications to any study drug component were excluded.

2.3 Data Collection

At baseline, the following parameters were recorded: patient demographics (age, gender, height, weight), BMI category (classified using the Asia-Pacific cut-offs recommended by the WHO expert consultation for Asian populations,[12]) cardiovascular and metabolic risk factors (smoking, alcohol use, tobacco use, family history of diabetes, physical inactivity), existing diabetic complications, blood pressure, prior antidiabetic drug history, FDC dose prescribed, and reasons for choosing this FDC. Laboratory investigations included HbA1c (%), fasting plasma glucose (FPG, mg/dL), post-prandial plasma glucose (PPG, mg/dL), body weight (kg), and HOMA-IR, the latter derived from paired fasting glucose and fasting insulin values using the homeostasis model assessment described by Matthews et al.[13] The same parameters were reassessed at 3 months post-initiation.

2.4 Outcomes

Primary effectiveness outcome was change in HbA1c from baseline to 3 months while secondary outcomes were changes in FPG, PPG, body weight, and HOMA-IR. Safety outcomes: Clinician's Global Assessment of Safety and Effectiveness (Excellent /

Good / Fair / Poor), incidence of pedal oedema, and other reported adverse drug reactions (ADRs).

2.5 Statistical Analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables are presented as mean ± standard deviation (SD). Categorical variables are expressed as frequencies and percentages. Within-group changes from baseline to 3 months were analysed using paired t-tests. Statistical significance was set at $p<0.001$ given the large sample size.

RESULTS

3.1 Patient Demographics and Baseline Characteristics

A total of 25,040 patients were enrolled across multiple centres in India. After excluding records with implausible age values, 24,833 patients with valid demographic data formed the analysis population. The demographic profile is summarized in Table 1.

Table 1: Baseline Demographic and BMI Characteristics of Study Patients (n=24,833)

Parameter	N (%)
Total Enrolled	25,040 (100%)
Valid Age Records	24,833
Mean Age ± SD (years)	58.7 ± 11.0; Range: 19–100
Gender: Male	16,082 (64.8%)
Gender: Female	8,751 (35.2%)
BMI: Normal (18.5–22.9 kg/m²)	9,297 (37.4%)
BMI: Overweight (23.0–24.9 kg/m²)	8,701 (35.0%)
BMI: Obese (≥25 kg/m²)	3,472 (14.0%)
BMI: Underweight (<18.5 kg/m²)	3,363 (13.5%)

SD = standard deviation.

The mean age of the study population was 58.7 ± 11.0 years (median 57 years, range 19–100 years). The predominant age group was 51–60 years, comprising 41.3% of patients, followed by 61–70 years (25.3%). Male patients constituted 64.8% of the cohort. Regarding BMI, 37.4% had normal BMI, 35.0% were overweight, 14.0% were obese, and 13.5% were underweight.

3.2 Cardiovascular and Metabolic Risk Factors

Risk factor distribution is presented in Figure 1. Family history of diabetes was the most prevalent risk factor, reported in 35.8% (n=8,972) of patients. Physical inactivity was present in 25.1% (n=6,231), active smoking in 17.1% (n=4,239), alcohol consumption in 16.6% (n=4,135), and tobacco use in 13.4% (n=3,327) of enrolled patients.

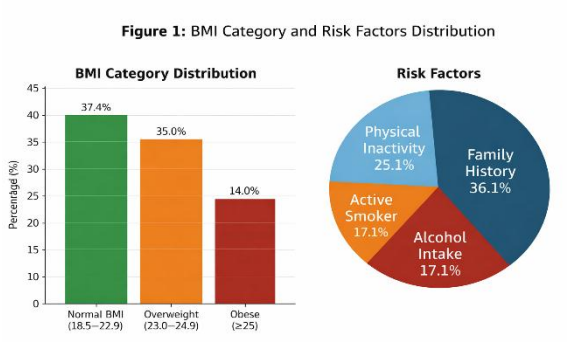

Figure 1: BMI category distribution and prevalence of cardiovascular/metabolic risk factors

3.3 Diabetic Complications at Time of Diagnosis

Diabetic complications were present in a significant proportion of enrolled patients at the time of diagnosis. The most common complication was neuropathy alone (22.4%; n=5,599), followed by combined neuropathy and nephropathy (8.9%; n=2,233), nephropathy alone (8.5%; n=2,121), coronary artery disease (CAD) (7.8%; n=1,965), stroke (5.7%; n=1,422), retinopathy (4.3%; n=1,073), and combined neuropathy with nephropathy and stroke (3.8%; n=954). The distribution is shown in Figure 2.

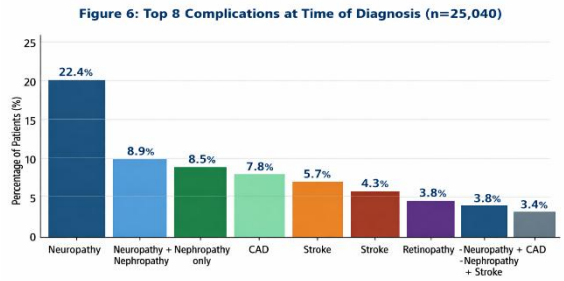

Figure 2: Distribution of diabetic complications present at time of diagnosis.

3.4 Prior Antidiabetic Drug History

Prior drug history was available for the majority of enrolled patients. The most common prior regimen was Metformin + Sulfonylurea (SU) (21.3%; n=5,321), followed by Metformin alone (18.0%; n=4,499), Metformin + Pioglitazone + DPP-4 inhibitor (4.9%; n=1,219), Metformin + DPP-4 inhibitor (4.9%; n=1,215), SU alone (4.6%; n=1,157), and Metformin + SU + AGI (3.3%; n=826). This pattern underscores the treatment inadequacy experienced before FDC initiation (Figure 3).

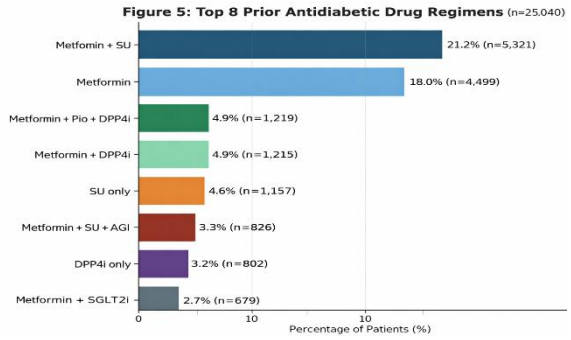

Figure 3: Top 8 prior antidiabetic drug regimens before initiating SitaMetPio FDC.

3.5 FDC Dose Prescribed and Reasons for Choice

The majority of patients (71.9%; n=18,006) were prescribed Sitagliptin 100 mg + Metformin 500 mg + Pioglitazone 15 mg, while 28.1% (n=7,034) received Sitagliptin 100 mg + Metformin 1000 mg + Pioglitazone 15 mg. Key reasons cited for prescribing the SitaMetPio FDC are shown in Figure 4. High baseline HbA1c was the most frequent reason (n=16,223), followed by insulin resistance improvement (n=11,971), excellent efficacy (n=10,743), cardiovascular benefit (n=9,863), good safety profile (n=7,715), and less weight gain (n=4,533). Multiple reasons could be selected per patient.

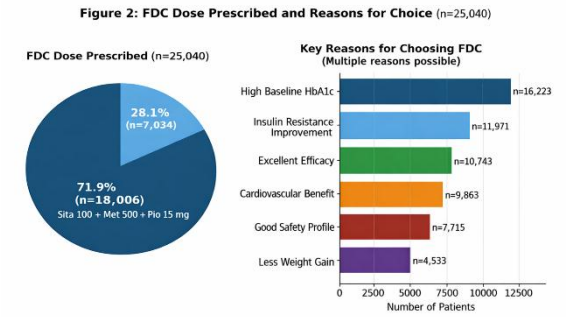

Figure 4: FDC dose distribution and key reasons for prescribing the SitaMetPio FDC.

3.6 Glycaemic Efficacy and Clinical Outcomes

All five efficacy parameters demonstrated statistically significant improvement over the 3-month treatment period. Results are summarized in Table 2 and Figure 5.

Table 2: Efficacy Outcomes at Baseline vs. 3-Month Post-Treatment. *p<0.001 (paired t-test). FPG=Fasting Plasma Glucose; PPG=Post-Prandial Glucose; HOMA-IR=Homeostatic Model Assessment of Insulin Resistance

Parameter	Baseline (Mean ± SD)	Post 3 Months (Mean ± SD)	Mean Change (Δ ± SD)	N
HbA1c (%)	8.35 ± 1.25	7.14 ± 1.05	−1.21 ± 1.19*	23,019
FPG (mg/dL)	169.8 ± 44.5	129.7 ± 35.4	−40.1 ± 40.9*	23,405
PPG (mg/dL)	246.0 ± 75.6	178.3 ± 52.9	−67.7 ± 70.0*	23,318
Body Weight (kg)	75.3 ± 14.9	72.5 ± 13.1	−2.75 ± 8.07*	23,677
HOMA-IR	1.26 ± 1.09	1.10 ± 0.93	−0.16 (95% CI 0.15–0.17)*	23,739

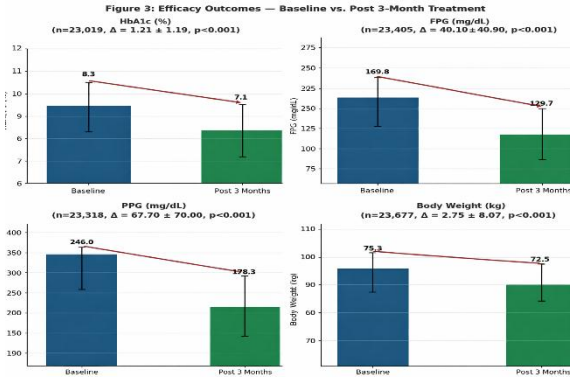

Figure 5: Comparison of efficacy parameters at baseline and 3 months post-treatment: HbA1c, FPG, PPG, and body weight (mean ± SD; *p<0.001).

The most clinically meaningful reduction was observed in HbA1c, with a mean decline of 1.21 ± 1.19 percentage points (from 8.35% to 7.14%; p<0.001). Fasting plasma glucose fell by 40.1 ± 40.9 mg/dL (from 169.8 to 129.7 mg/dL; p<0.001) and post-prandial glucose by 67.7 ± 70.0 mg/dL (from 246.0 to 178.3 mg/dL; p<0.001). Mean body weight decreased by 2.75 ± 8.07 kg (from 75.3 to 72.5 kg; p<0.001), highlighting the metabolically neutral-to-beneficial weight profile of this combination. HOMA-IR declined from 1.26 ± 1.09 (median 1.00) to 1.10 ± 0.93 (median 0.90), a mean reduction of 0.16 units (12.7%; 95% CI 0.15–0.17; p<0.001), reflecting improvement in insulin resistance consistent with the pioglitazone-mediated mechanism.

3.7 Safety and Tolerability Profile

The safety assessment is summarized in Figure 6. Clinicians rated the global safety of the SitaMetPio FDC as Excellent in 57.3% (n=14,355) and Good in 36.9% (n=9,251), giving a combined Excellent/Good rating of 94.2%. Fair and Poor ratings were reported in 4.1% and 1.6% of cases respectively.

Global effectiveness was rated Excellent in 56.4% (n=14,122) and Good in 37.8% (n=9,465), giving a combined Excellent/Good effectiveness rating of 94.2%. The high concordance between the safety and effectiveness assessments supports the favourable therapeutic index of this FDC in routine clinical practice.

Pedal oedema, a known class effect of thiazolidinediones, was observed in 12.4% (n=3,115) of patients. Other adverse drug reactions were reported by 0.54% (n=135) of patients across

various centres. Detailed adverse events and clinician assessments are shown in Figure 6.

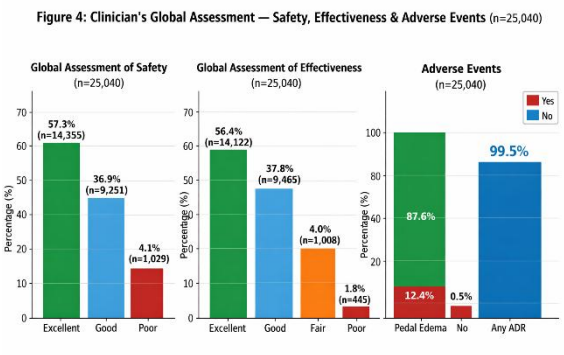

Figure 6: Clinician's global assessment of safety, effectiveness, and adverse event profile

DISCUSSION

The SitaMetPio study represents one of the largest real-world observational datasets evaluating a triple fixed-dose combination of Sitagliptin, Metformin, and Pioglitazone in Indian T2DM patients, with 25,040 enrolled patients and 3-month follow-up data. The findings provide compelling evidence of the clinical utility of this FDC across a broad, heterogeneous Indian diabetic population.

The mean patient age of 58.7 years and male predominance (64.8%) are consistent with published Indian T2DM registries.[3] The high proportion of patients in the 51–60-year age group (41.3%) reflects the mid-life peak of T2DM onset in India. Approximately half the cohort (49.0%) had a BMI ≥23 kg/m², the threshold above which cardiometabolic risk rises appreciably in Asian populations and which lies below the conventional Western overweight cut-off of 25 kg/m².[12] This distribution is consistent with Indian consensus statements describing greater visceral adiposity and insulin resistance at any given BMI in Asian Indians.[14]

The most significant finding is the robust HbA1c reduction of −1.21 percentage points over 3 months — from a mean baseline of 8.35% to 7.14%. This result is particularly meaningful given that the ADA and IDF recommend a target HbA1c of <7.0% for most T2DM patients.[4] The reduction in FPG by 40.1 mg/dL and PPG by 67.7 mg/dL further corroborates comprehensive glycaemic control achieved through the dual targeting of both fasting and post-meal glucose excursions. In the UKPDS observational analysis, each 1% fall in updated mean HbA1c was associated with a 21% lower risk of any diabetes-related endpoint,[15] a mean reduction of this magnitude is therefore of potential prognostic as well as biochemical relevance, although the 3-month follow-up reported here cannot demonstrate such outcomes directly.

The complementary pharmacological mechanisms of the three components likely account for the glycaemic control observed. Sitagliptin enhances glucose-dependent insulin release and glucagon suppression via GLP-1 and GIP pathways,[8] Metformin addresses hepatic insulin resistance and suppresses gluconeogenesis; and Pioglitazone, through PPAR-γ agonism, improves muscle and adipose tissue insulin sensitivity while offering additional lipid-lowering and potential cardiovascular benefits.[9] Together, these agents address several of the classical "ominous octet" mechanisms of hyperglycaemia in T2DM.[6]

The reduction in body weight (−2.75 kg) and HOMA-IR (−0.16) are additional positive findings. The weight reduction is particularly noteworthy given the known weight gain associated with pioglitazone monotherapy; the combination with the weight-neutral DPP-4 inhibitor and mildly weight-reducing Metformin appears to attenuate this effect, producing a net modest reduction in weight, which is clinically desirable in the predominantly overweight Indian T2DM population.[5]

The improvement in HOMA-IR, although modest, is consistent with the insulin-sensitizing action of pioglitazone,[13] and is clinically relevant given that insulin resistance improvement was among the top reasons cited for choosing this FDC. Cardiovascular benefit was cited by 9,863 prescribers — reflecting awareness of pioglitazone's secondary-prevention findings in the PROactive trial,[16] and the neutral cardiovascular profile of Sitagliptin established in TECOS.[17]

The safety profile was favourable. The Excellent/Good combined rating for safety (94.2%) and effectiveness (94.2%) from clinicians indicates high clinical satisfaction with this regimen in real-world practice. Pedal oedema occurred in 12.4% of patients — a rate broadly consistent with pooled estimates of oedema risk from randomised trials of thiazolidinedione-containing regimens.[18] Other ADRs were rare, reported in only 0.54% of patients, suggesting good overall tolerability, although passive collection is likely to underestimate true incidence.

The study also highlights important patterns in prior medication use. The predominance of Metformin + SU as the most common prior regimen (21.3%) before transitioning to SitaMetPio FDC reflects the inadequacy of dual oral antidiabetic therapy to achieve optimal glycaemic control and the clinical need for a more potent, mechanism-diverse triple combination, an escalation pathway anticipated by current Indian recommendations.[10] Additionally, a substantial proportion had received prior DPP-4 inhibitor therapy, suggesting that physicians chose the triple FDC for its convenient delivery and complementary mechanisms even in previously treated patients.

4.1 Limitations

Several limitations should be considered when interpreting these findings. The study was observational and retrospective, with no randomised comparator or control arm, so the changes observed

cannot be attributed to the FDC alone; regression to the mean, concurrent lifestyle modification, and improved adherence following a change of prescription may each have contributed. Enrolment at investigator discretion introduces the possibility of selection bias, and the absence of a pre-specified sampling frame limits generalisability beyond the participating centres. Follow-up was restricted to 3 months, which is adequate for assessing HbA1c but too short to evaluate durability of glycaemic control, weight trajectory, or the longer-term safety considerations associated with thiazolidinedione exposure. Safety and effectiveness were captured through a clinician's global assessment rather than a validated instrument, and adverse events were recorded passively, so the incidence of pedal oedema and other reactions is likely to be underestimated. Laboratory measurements were performed locally without central standardisation, and HOMA-IR was derived from single fasting samples, which carry substantial within-individual variability. Finally, paired data were unavailable for a proportion of patients at each parameter, and analyses were confined to those with complete observations, which may bias effect estimates if missingness was related to response. These constraints are common to large pragmatic real-world datasets and are acknowledged in line with STROBE guidance,[11] they temper causal interpretation while preserving the descriptive value of the findings regarding routine prescribing practice.

CONCLUSION

The SitaMetPio study, with 25,040 patients from multiple Indian centres, demonstrates that the FDC of Sitagliptin + Metformin + Pioglitazone significantly improves HbA1c, fasting and post-prandial glucose, body weight, and insulin resistance markers over 3 months of treatment. The combination achieved an HbA1c reduction of 1.21 percentage points on average, approaching guideline-recommended glycaemic targets. Safety and effectiveness were rated Excellent or Good by clinicians in over 94% of cases, with a low overall ADR rate. Pedal oedema, attributable to pioglitazone, occurred in 12.4% of patients and requires monitoring.

These real-world findings support the SitaMetPio FDC as a clinically effective, well-tolerated, and guideline-consistent therapeutic option for Indian T2DM patients, particularly those with high baseline HbA1c, insulin resistance, or cardiovascular comorbidities. Given the observational design and short follow-up, prospective comparative studies with longer follow-up are warranted to confirm durability and long-term safety.

Declarations

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional ethics committee approval was obtained prior to study initiation. Patient data were anonymized and de-identified prior to analysis. The requirement for written informed consent was waived given the retrospective nature of the study.

Conflict of Interest

The authors declare no conflicts of interest.

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Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

REFERENCES

1. Anjana RM, Unnikrishnan R, Deepa M, Pradeepa R, Tandon N, Das AK, et al. Metabolic non-communicable disease health report of India: the ICMR-INDIAB national cross-sectional study (ICMR-INDIAB-17). Lancet Diabetes Endocrinol. 2023;11(7):474-489.
2. International Diabetes Federation. IDF Diabetes Atlas, 10th ed. Brussels: International Diabetes Federation; 2021.
3. Mohan V, et al. Epidemiology of type 2 diabetes: Indian scenario. Indian J Med Res. 2007;125(3):217-230.
4. American Diabetes Association. Standards of Medical Care in Diabetes—2023. Diabetes Care. 2023;46(Suppl 1).
5. Inzucchi SE, et al. Management of hyperglycemia in type 2 diabetes, 2015. Diabetes Care. 2015;38(1):140-149.
6. DeFronzo RA. Banting Lecture. From the triumvirate to the ominous octet: a new paradigm for the treatment of type 2 diabetes mellitus. Diabetes. 2009;58(4):773-795.
   Han S, Iglay K, Davies MJ, Zhang Q, Radican L. Glycemic effectiveness and medication adherence with fixed-dose combination or coadministered dual therapy of antihyperglycemic regimens: a meta-analysis. Curr Med Res Opin. 2012;28(6):969-977.
7. Hermansen K, et al. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor, sitagliptin, in patients with type 2 diabetes mellitus inadequately controlled on glimepiride alone or on glimepiride and metformin. Diabetes Obes Metab. 2007;9(5):733-745.
8. Defronzo RA, et al. Pioglitazone for diabetes prevention in impaired glucose tolerance. N Engl J Med. 2011;364(12):1104-1115.
9. Research Society for the Study of Diabetes in India. RSSDI clinical practice recommendations for the management of type 2 diabetes mellitus 2022. Int J Diabetes Dev Ctries. 2022;42(Suppl 1):1-143.
10. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007;370(9596):1453-1457.
11. WHO Expert Consultation. Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies. Lancet. 2004;363(9403):157-163.
12. Matthews DR, Hosker JP, Rudenski AS, Naylor BA, Treacher DF, Turner RC. Homeostasis model assessment: insulin resistance and beta-cell function from fasting plasma glucose and insulin concentrations in man. Diabetologia. 1985;28(7):412-419.
13. Misra A, et al. Consensus dietary guidelines for healthy living and prevention of obesity, the metabolic syndrome, diabetes, and related disorders in Asian Indians. Diabetes Technol Ther. 2011;13(6):683-694.

14. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000;321(7258):405-412.
15. PROactive Investigators. Secondary prevention of macrovascular events in patients with type 2 diabetes in the PROactive Study. Lancet. 2005;366(9493):1279-1289.
16. Green JB, et al. Effect of Sitagliptin on Cardiovascular Outcomes in Type 2 Diabetes (TECOS). N Engl J Med. 2015;373(3):232-242.
17. Berlie HD, Kalus JS, Jaber LA. Thiazolidinediones and the risk of edema: a meta-analysis. Diabetes Res Clin Pract. 2007;76(2):279-289.