Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

Effectiveness and safety of add-on antidiabetic therapies to metformin in type 2 diabetes mellitus patients of south odisha population: A prospective observational cohort study.

Dr. Suvendu Kumar Panda[1,*], Dr. Bikash Chandra Das[2], Dr. Pratyush Mishra[1], Dr. Srikanta Panigrahy[3]
[1]Assistant Professor, Department of Pharmacology, MKCG, Medical College and Hospital, Berhampur, Odisha
[2]Assistant Professor, Department of Pharmacology, SCB Medical College and Hospital,
[3]Senior Resident, Department of Pharmacology, MKCG Medical College and Hospital, Berhampur

Abstract

Background

Type 2 Diabetes Mellitus (T2DM) is a growing public health concern in India, particularly in resource-limited regions like South Odisha. While metformin remains the first-line therapy, combination regimens are often required for sustained glycemic control. However, real-world comparative data on the effectiveness and safety of such add-on therapies remain limited.

Objective

To assess the effectiveness and safety of various oral antidiabetic add-on regimens to metformin in T2DM patients attending a tertiary care center in South Odisha.

Methods

This prospective observational cohort study followed 289 patients (of 323 enrolled) over 9 months at MKCG Medical College, Berhampur. Patients were assessed at baseline, 3, 6, and 9 months for glycemic parameters, renal and lipid profiles, adverse drug reactions (ADRs), and health-related quality of life (HRQoL) using the WHO-5 Wellbeing Index.Statistical analysis was performed using SPSS v22.0 with significance set at $p<0.05$.

Results

The mean age of participants was 48.8 ± 15.5 years; 51% were male. Most were overweight or obese (66.7%) and 61.6% lived in rural areas. All add-on regimens showed significant reductions in FPG, PPPG, and HbA1c compared to metformin monotherapy ($p < 0.05$). DPP-4 inhibitor–based regimens (teneligliptin/vildagliptin) produced the greatest improvements in glycemic and lipid parameters (↓ triglycerides, LDL, VLDL; ↑ HDL). Renal and electrolyte values remained stable across groups. ADRs were reported in 157 patients, with hypoglycemia (19.7%) being most frequent, mainly linked to glimepiride. HRQoL scores improved significantly across all add-on groups compared to metformin alone.

Conclusion

Combination therapies, especially those including DPP-4 inhibitors, offer superior glycemic and lipid control with acceptable safety and improved quality of life in South Odisha T2DM patients.

Recommendations

Clinicians should consider DPP-4 inhibitor-based combinations for optimal outcomes in T2DM management. Further multicentre, randomized controlled trials with longer follow-up and inclusion of newer agents are recommended to strengthen the evidence base.

Keywords: *Diabetes Mellitus, Type 2; Metformin; Hypoglycemic Agents/therapeutic use; Dipeptidyl-Peptidase IV Inhibitors; Drug Combinations; Treatment Outcome; Quality of Life; Adverse Drug Reaction Reporting Systems.*
Submitted: *2025-07-10* ***Accepted:*** *2025-08-12* ***Published:*** *2025-09-01*

Corresponding author: *Dr. Suvendu Kumar Panda*
Email id: ***suvendukumarpanda041@gmail.com***
ORCID ID: - https://orcid.org/0009-0008-5830-7351
Assistant Professor, Department of Pharmacology, MKCG, Medical College and Hospital, Berhampur, Odisha

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

Introduction

Diabetes Mellitus (DM) is a chronic metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism results from defective insulin secretion, and it's action. [1-2] Diabetes mellitus arises from genetic and environmental factors, leading to hyperglycemia due to reduced insulin secretion, decreased glucose use, or increased glucose production. This dysregulation affects multiple organs and remains a major cause of global morbidity and mortality.[3] The major contributors to diabetes-related morbidity are chronic complications from prolonged hyperglycemia, including neuropathy, retinopathy, nephropathy, and cardiovascular disease. These can be reduced through sustained blood glucose control and management of comorbidities like hypertension and dyslipidemia. Diabetes is broadly classified into type 1 and type 2. [4]

In 2024, 589 million adults (11.1% of the global population) were living with diabetes, a number projected to reach 853 million by 2050 if no interventions occur. Over 40% (252 million) remain undiagnosed, and the disease caused 3.4 million deaths in 2024, with global healthcare costs rising to USD 1 trillion, a 338% increase since 2007. In India, 89.8 million adults (10.5%) had diabetes in 2024, the second-highest globally after China, with 43% undiagnosed. This figure is expected to grow by 75% to 156.7 million by 2050, while prevalence may rise from 10.5% to 12.8%. National health expenditure on diabetes reached USD 9.8 billion in 2024, or USD 109.5 per person. [5]

Rapid economic growth, aging populations, and Westernized lifestyles drive the rise of diabetes in low- and middle-income countries like India. Despite this, management remains suboptimal, with guidelines recommending lifestyle changes and metformin as first-line therapy. While metformin reduces cardiovascular risk and improves macrovascular outcomes, monotherapy often sustains glycemic control only briefly.[6] Hyperglycemia usually worsens through the years, primarily due to the progression of β-cell dysfunction. [7]

Combination therapy of metformin with other antidiabetic agents is often necessary to maintain good glycemic control. Second-line options recommended with metformin include insulin, insulin secretagogues, thiazolidinediones (TZDs), glucagon-like peptide-1 (GLP-1) analogs, and dipeptidyl peptidase-IV inhibitors.[8]

The recent American Diabetes Association/European Association for the Study of Diabetes Position Statement recommends that treatment choices be guided by effectiveness, tolerability, long-term safety, cost, and patients' preferences and values.[9] Reviews on the efficacy and safety of various add-on regimens are available from randomized controlled trials (RCTs), but these findings may not fully reflect real-world clinical scenarios.[8, 10-13] In clinical practice, research on the effectiveness of add-on regimens is crucial, as the available data can help develop more patient-centered treatment algorithms.[14] Only efficacy in terms of good glycemic control isn't enough; there are many other components to measure the effectiveness of a therapy that decides an individual's health. Apart from glycemic control, reports on the efficacy of add-on regimens toward change in HRQoL, decreasing cardiometabolic risks, cost-effectiveness, medication adherence, and possible ADRs are still inadequate. Therefore, seeking to provide more evidence, this prospective observational observation will be performed to compare the effectiveness of differing add-on regimens to standard care with metformin in T2 DM patients.

Primary objectives

To compare the effectiveness and safety of different add-on oral regimens to metformin therapy among T2 DM cases in terms of different clinical and laboratory indicators

Secondary objectives

1. To estimate FPG, PPPG and HbA1c in different treatment groups
2. To know the ADR profile of anti-diabetic drugs used
3. To study effect of different antidiabetic drug regimens on health-related QoL

Materials and methods

This prospective OPD based, observational study "Effectiveness and safety of add-on antidiabetic therapies to metformin in Type 2 diabetes mellitus patients of South Odisha population: a prospective observational study",

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

was conducted by the Department of Pharmacology, in collaboration with the Department of Endocrinology and General Medicine of MKCG Medical College and Hospital, Berhampur, Odisha, India. The study was conducted during two years period from October 2022 to September 2024. Before the initiation of the study, the study protocol was approved by the institutional ethics committee of the institution (690/ Chairman-IEC, M.K.C.G Medical College, Berhampur-4).

Selection of study population

The diagnosed cases of Type 2 diabetes mellitus patients 18 to 85 years of age group of either sex who visited the out-patient department of Endocrinology and General Medicine were included in this study during the period from October 2022 to September 2024. Patients of who were willing to give written informed consent were enrolled in this study.

Inclusion criteria

1. Both male and female patients between ≥18 to ≤ 85 years of age

2. Diagnosed case of Type 2 diabetes mellitus patients as per ADA guideline and under oral antidiabetic therapy either with metformin or add on therapy along with metformin

Exclusion criteria

1. Patients suffering from dementia and other psychiatric illnesses
2. Patients suffering from communicable, infectious diseases (TB, HIV, Filaria).
3. Critically ill patients who needed hospitalization
4. Pregnancy and lactation

Study participants

The sample size, calculated using Raosoft software, was 323. Accordingly, 323 patients with T2DM meeting the inclusion and exclusion criteria were enrolled. During follow-up, 34 patients were excluded due to loss to follow-up (n=20), migration (n=8), or incomplete data (n=6). Thus, 289 patients were included in the final analysis.

Study procedure:

All data were collected from the treatment record and asking questions to the patient/relative in a predesigned case record form (CRF). The demographic characteristics such as age, sex, education, monthly family income, occupation, lifestyle, duration of disease, duration of treatment were recorded. Other data like body weight, BMI were recorded. The detailed treatment history like the initiation of therapy, all the clinical and laboratory data were recorded during the initial visit as well as at each visit in every three months up to 1 year. The laboratory parameters such as FPG, PPPG, Hb1Ac were recorded at initial and each follow up visits. Clinical examinations for the presence of diabetes-related complications like hypertension, neuropathy, nephropathy, etc. were conducted and mentioned in case record form in every visit from 2nd visit onwards. Other investigation reports like lipid profile (serum triglyceride, total cholesterol, HDL, LDL, and VLDL), hemogram, and renal function (BUN, serum creatinine, sodium, potassium, and chloride)biomarkers were noted in CRF. Health related quality of life (HRQoL) score were assessed in all study subjects using the WHO-5 Wellbeing Index at initial visit and all follow up visits. ADRs, if any were collected in ADR reporting form of PvPI.

Study tools

1. Case Record Form
2. WHO-5 Wellbeing Index
3. PvPI ADR collection format.

Statistical analysis

Data were entered in Microsoft excel 2016 and complied and analysed by using statistical software SPSS version 22.0 .Descriptive statistics like mean, standard deviation, median, quartiles of continuous scale variables like age, BMI, waist circumference, systolic and diastolic blood pressure, FPG, PPPG, Hb1Ac, renal profile and lipid profile in the beginning of the study, 3 months, 6 months, 9 months, quality of life domains were computed using descriptive procedures. Categorical variables like gender, residence, physical activities, family history, comorbidities, were expressed as frequency and percentage. ADRs and medication adherence were expressed as frequency and percentage. FPG, PPPG and HbA1c at 3 month/6 month/9 month compared with

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

baseline data in only metformin treatment group by One Way Anova test. Non-parametric data were analysed by using Kruskal Walis test. P-value less than 0.05 was considered as significant.

Results

A total of 323 patients with Type 2 Diabetes Mellitus were enrolled based on predefined inclusion and exclusion criteria. Of these, 34 patients were excluded during follow-up: 20 due to loss to follow-up, 8 due to migration, and 6 due to incomplete data. The remaining 289 patients completed all visits and were included in the final analysis.

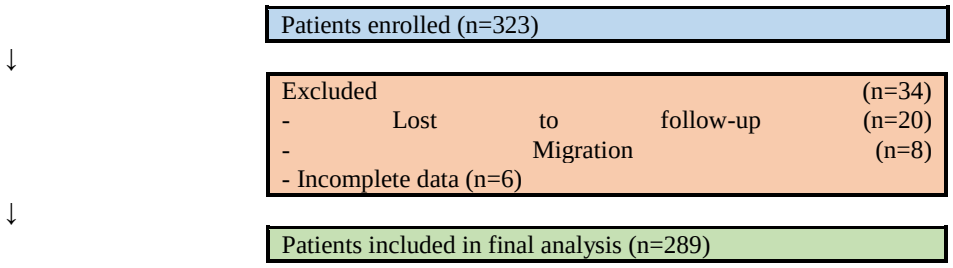

Figure 1. Flow diagram showing patient enrolment and follow-up.

Table. 1 Demography profile study population (n=289)

Characteristics			**Frequency**	**Percentage (%)**	**Mean± SD**
Age in years	18-60		226	78.2	48.77±15.51
	>60		63	21.8	
Gender	Male		146	51	
	Female		143	49	
BMI (Kg/m^2)	Underweight	<18.5	2	0.7	26.44±3.29
	Normal	18.5-24.9	90	31.6	
	Overweight	25.0-29.9	157	55.1	
	Class 1 Obesity	30.0-34.9	33	11.6	
	Class 2 Obesity	35.0-39.9	3	1.1	
Waist circumference (cm)	Males	<102	140	95.9	
		>102	6	4.1	88.07±8.70
	Females	<88	81	56.6	
		>88	62	43.4	
Residency	Rural		178	61.59	
	Urban		111	38.41	
Physical activity	Sedentary		157	54.33	
	Moderate intensity		108	37.37	
	Severe Intensity		24	8.30	
Family history	Present		215	75	
	Absent		56	19	
	Unknown		18	6	
Co-morbidity	Present		213	73.7	
	Absent		78	26.3	

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

The table no-1 displayed that the mean age of participants was 48.77 ± 15.51 years, with the majority (78.2%) falling within the 18–60-year age group, while 21.8% were older than 60 years. The gender distribution was nearly equal, with males accounting for 51% (n=146) and females 49% (n=143).The mean body mass index (BMI) was 26.44 ± 3.29 kg/m². Most participants were overweight (55.1%) or had a normal BMI (31.6%), while 11.6% had class 1 obesity and 1.1% had class 2 obesity; only 0.7% were underweight. Waist circumference assessment revealed that 95.9% of males had a measurement <102 cm, while 4.1% exceeded this threshold. Among females, 56.6% had a waist circumference <88 cm and 43.4% had values >88 cm.The majority of participants resided in rural areas (61.59%), with 38.41% living in urban settings. Regarding physical activity, 54.33% were sedentary, 37.37% reported moderate activity, and 8.30% engaged in severe-intensity activity. A positive family history was observed in 75% of the participants, while 19% had no family history and 6% were uncertain. Co-morbidities were present in 73.7% of the study population, whereas 26.3% reported no associated conditions.

Table 2: Baseline parameters of study groups assigned to receive different antidiabetic treatment

	Met N=79	Met+Glim N=26	Met+Glim +Vog N=76	Met+Glim+Tene+Vog N=30	Met+Glim+Vil+Vog N=34	Met+Tene+Vog N=28	Met+Vog N=16
FPG (mg/dl)	218.39 ±8.11	217±10.44	222.30±12 .13	223.47±3.70	223.41±7.50	222.43±10.37	219.69±7.56
PPPG (mg/dl)	289.86 ±6.65	289.27±8.55	292.99±9. 75	294.07±6.98	293.85±7.17	292.46±8.5	289.81±3.97
HbA1c (%)	11.60± 0.24	11.60±0.30	11.74±0.3 6	11.75±0.26	11.77±0.28	11.71±0.31	11.65±0.11
BUN (mg/dl)	26.08± 8.62	24.71±6.59	25.44±7.2 0	27.01±8.73	22.08±5.36	25.92±7.48	27.91±8.37
S Creatinine (mg/dl)	0.72±0. 31	0.94±0.23	0.77±0.36	0.89±0.28	0.80±0.42	0.81±0.41	0.87±0.43
S Na+ (mEq/L)	142.74 ±7.22	145.98±8.27	142.37±7. 71	138.64±6.49	144.12±6.66	144.47±5.65	142.54±7.70
S K+ (mEq/L)	3.91±0. 34	3.91±0.37	3.96±0.35	3.99±0.28	3.98±0.23	3.71±0.37	3.98±0.28
S Cl- (mEq/L)	101.07 ±3.37	100.10±3.79	99.96±3.0 7	100.43±3.69	101.35±3.63	101.35±3.34	102.03±4.35
S Albumin (g/L)	4.01±0. 554	4.22±0.64	4.05±0.48	4.04±0.51	4.24±0.63	4.22±0.47	4.38±0.48
S Triglyceride (mg/dl)	175.58 ±34.25	196.58±73.0 5	193.08±79 .19	209.93±63.18	205.50±46.2 9	188.61±42.94	170.94±13.68
S Total Choleste	167.79 ±19.48	176.81±57.3 2	175.74±40 .42	191.40±38.10	189.85±26.4 7	192.25±66.15	164.56±11.30

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

rol (mg/dl)							
HDL (mg/dl)	46.33± 5.64	46.69±7.27	47.75±6.9 0	42.80±3.88	43.03±4.16	46.93±6.84	45.56+4.33
LDL (mg/dl)	125.80 ±14.97	124.50±18.6 7	120.34±18 .68	133.70±16.56	135.29±10.2 7	129.89±20.43	126.19±10.34
VLDL (mg/dl)	33.35± 4.06	35.35±3.74	33.75±5.0 3	35.17±3.61	35.68±2.07	35.93±3.84	33.19±2.61

Table No.2 clearly showed no significant difference among baseline values of glycemic parameters like FPG, PPPG, HbA1c between the group assign to receive metformin therapy and other groups for metformin with add on therapy. There was no significant difference among the baseline renal parameters (Serum BUN, Serum Creatinine, Serum Sodium, Potassium, Chloride, and Albumin) as well as lipid profile (Serum triglyceride, total cholesterol, HDL, LDL, and VLDL).

Table No.3: Distribution of antidiabetic drugs prescribed by physician (n=289)

Drugs	Frequency	Percentage (%)
Metformin	79	27.33
Metformin+Glimepiride	26	8.99
Metformin+Glimepiride+Voglibose	76	26.29
Metformin+Glimepiride+Teneligliptin+Voglibose	30	10.38
Metformin+Glimepiride+Vildagliptin+Voglibose	34	11.76
Metformin+Teneligliptin+Voglibose	28	9.68
Metformin+Voglibose	16	5.53

Table No.3 showed that 27.33% of participants were prescribed only metformin, followed by *metformin+glimepiride+voglibose* (26.29%). Metformin, along with three drugs such as glimepiride, teneligliptin/vildagliptin, and voglibose, were given in (22.14%) cases. The patient received *metformin+teneligliptin+voglibose* in 9.68% cases. The least common antidiabetic drug regimen prescribed was *metformin+voglibose* (5.53%).

Table No.4: Comparative effect of metformin therapy with baseline value at different time interval(n=79)

	At the beginning	3 months	6 months	9 months
FPG **(mg/dl)**	218.39±8.11	130.95±5.454*	130.52±5.454*	130.13±5.250*
PPPG **(mg/dl)**	289.86±6.652	171.43±9.139*	170.44±8.909*	171.14±8.551*
HbA1C **(%)**	11.608±0.2448	7.529±0.3187*	7.494±0.3151*	7.515±0.3105*
BUN **(mg/dl)**	26.08±8.62	24.632±7.93	25.36±7.34	26.50±7.09
S.Creatinine**(mg/dl)**	0.72±0.31	0.70±0.30	0.73±0.32	0.72±0.27
S. Na+ **(mEq/L)**	142.74±7.22	142.86±7.87	143.55±6.33	142.43±6.39
S. K+**(mEq/L)**	3.91±0.34	3.89±0.34	3.83±0.31	3.92±0.26

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

S. Cl^- **(mEq/L)**	101.07±3.37	99.75±2.66	100.53±2.96	100.6±2.76
S .Albumin **(g/L)**	4.01±0.554	4±0.54	4.05±0.54	4.06±0.532
S.Triglyceride**(mg/dl)**	175.58±34.25	166.47±20.09	165.52±18.25	165.25±17.18
S. Total Cholesterol **(mg/dl)**	167.79±19.48	163.94±14.22	163.05±14.76	163.59±15.06
HDL **(mg/dl)**	46.33±5.64	46.46±5.42	46.71±5.36	47.87±5.39
LDL **(mg/dl)**	125.80±14.97	126.29±14.65	124.44±14.35	122.61±15.15
VLDL **(mg/dl)**	33.35±4.06	33.30±3.76	33.05±3.53	31.77±3.22

Table No.4 showed that there is a significant reduction of FBS, PPPG, and Hb1Ac in 3 month/6 month/9 month as compared to the baseline value after initiating metformin therapy. There is no significant change in renal parameters (Serum BUN, creatinine, sodium, potassium, chloride, and albumin) and lipid profile (Serum triglyceride, total cholesterol, HDL, LDL, VLDL) in 3 month/6month/9 month as compared to the baseline value.

Table No.5: Comparison of effect of metformin with metformin along with add on antidiabetic drugs at 3 months

	Met N=79	Met+Glim N=26	Met+Glim+Vog N=76	Met+Glim +Tene+Vog N=30	Met+Glim +Vil+Vog N=34	Met+Tene+ Vog N=28	Met+Vog N=16
FPG (mg/dl)	130.95 ±5.45	119.15±9. 01*	100.92±10.42*	92.73±7.9 2*	92.15±7.4 3*	103.64±5.3 4*	118.63±3. 99*
PPPG (mg/dl)	171.43 ±9.13	162.58±13 .94*	147.04±7.82*	132.40±16 .14*	135.15±15 .22*	147.00±5.5 1*	161.63±9. 90*
HbA1c (%)	7.52±0. 31	7.21±0.49 *	6.67±0. .27*	6.18±0.54 *	6.25±0.53 *	6.67±0.20*	7.15±0.42 *
BUN (mg/dl)	24.632 ±7.93	24.754±5. 92	25.384±7.28	27.393±7. 83	23.547±4. 95	25.157±7.1 5	29.256±7. 78
S Creatinine (mg/dl)	0.70±0. 30	0.89±0.18	0.78±0.33	0.91±0.35	0.81±0.40	0.83±0.40	0.79±0.46
S Na+ (mEq/L)	142.86 ±7.87	146.92±8. 71	141.48±7.47	139.68±5. 79	145.28±6. 55	145.65±4.4 1	144.11±6. 67
S K+ (mEq/L)	3.89±0. 34	4.02±0.29	3.92±0.31	4.03±0.37	4.04±0.28	3.83±0.40	4.11±0.35
S Cl-(mEq/L)	99.75± 2.66	99.97±2.3 9	100.05±3.61	100.56±3. 54	101.94±3. 08	101.48±3.6 4	100.90±1. 48
S Albumin (g/L)	4±0.54	4.20±0.66	4.07±0.50	3.97±0.50	4.25±0.62	4.23±0.45	4.33±0.50 9
Triglyceride (mg/dl)	166.47 ±20.09	173.69±13 .21	149.22±13.60*	*131.11±11 .44†**	*134.55±12 .21†**	*136.72±12. 99†**	168.31±11 .88
Total Cholesterol (mg/dl)	163.94 ±14.22	163.15±10 .69	151.18±11.24*	*140.36±10 .19†**	*142.01±9. 72†**	*141.67±10. 45†**	160.45±10 .60

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

HDL (mg/dl)	46.46±5.42	46.19±7.20	50.31±6.22*	*56.45±4.85†**	*55.91±5.10†**	*54.80±5.63†**	47.10±4.67
LDL (mg/dl)	126.29±14.65	123.65±16.31	108.39±10.75*	*96.25±9.71†**	*95.50±9.83†**	*98.73±10.02†**	122.80±11.15
VLDL (mg/dl)	33.30±3.76	35.85±3.77	29.84±3.00*	*26.22±2.66†**	*26.91±2.49†**	*27.34±2.81†**	33.66±2.37

* indicates a statistically significant difference ($p < 0.05$) compared to the Metformin monotherapy group.

† indicates a statistically significant difference ($p < 0.05$) compared to all other non–DPP-4 inhibitor groups (i.e., Met, Met+Glim, Met+Glim+Vog, Met+Vog), highlighting the superior lipid profile improvement in DPP-4 inhibitor combinations (Met+Glim+Tene+Vog, Met+Glim+Vil+Vog, Met+Tene+Vog).

The Table no-5 demonstrated that all combination therapies produced significantly greater reductions in FPG, PPPG, and HbA1c levels compared to metformin monotherapy ($p < 0.05$). Among these, the combinations containing DPP-4 inhibitors (metformin with glimepiride, teneligliptin, and voglibose; metformin with glimepiride, vildagliptin, and voglibose; and metformin with teneligliptin and voglibose) exhibited the most pronounced improvements in glycemic parameters. Renal function indices, including blood urea nitrogen and serum creatinine, showed no significant alterations across the groups. Electrolyte levels (sodium, potassium, chloride)

and serum albumin remained largely stable, indicating no major impact on fluid and protein balance.

In terms of lipid profile, combinations incorporating DPP-4 inhibitors produced significantly superior outcomes. These regimens were associated with marked reductions in triglycerides, total cholesterol, low-density lipoprotein (LDL), and very low-density lipoprotein (VLDL) levels, alongside significant elevations in high-density lipoprotein (HDL) compared to metformin monotherapy ($p < 0.05$). Notably, the DPP-4 inhibitor-containing groups also showed significantly greater improvements in lipid parameters relative to all other non–DPP-4 inhibitor combinations.

Table No.6: Comparison of effect of metformin with metformin along with add on antidiabetic drugs at 6 months

	Met N=79	Met+Glim N=26	Met+Glim+Vog N=76	Met+Glim+Tene+Vog N=30	Met+Glim+Vil+Vog N=34	Met+Tene+Vog N=28	Met+Vog N=16
FPG (mg/dl)	130.52±5.25	117.27±8.96*	101.47±10.61*	91.33±7.46*	92.68±7.94*	103.11±7.59*	117.06±4.35*
PPPG (mg/dl)	170.44±8.90	162.69±12.44*	146.84±8.31*	132.60±13.08*	132.76±14.56*	144.54±6.16*	161.50±12.72*
HbA1c (%)	7.49±0.31	7.19±0.45*	6.66±0.30*	6.18±0.45*	6.18±0.50*	6.58±0.23*	7.18±0.42*
BUN (mg/dl)	25.36±7.34	23.94±4.40	24.95±6.51	25.67±7.58	23.39±5.81	28.02±7.11	27.30±7.07
S.Creatinine (mg/dl)	0.73±0.32	0.79±0.34	0.73±0.32	0.93±0.32	0.79±0.36	0.83±0.42	0.89±0.42
S Na+ (mEq/L)	143.55±6.33	143.86±7.34	141.27±6.25	140.09±4.92	144.49±6.47	144.77±6.19	142.18±8.44

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

S K+ (mEq/L)	3.83±0.31	4.02±0.24	3.88±0.34	3.97±0.33	4 ±0.27	3.81±0.33	3.93±0.44
S Cl- (mEq/L)	100.53±2.96	100.13±3.48	100.37±2.82	102.2±2.93	100.44±3.23	101.19±2.53	102.67±2.44
S Albumin (g/L)	4.05±0.54	4.20±0.6	4.10±0.46	4±0.47	4.27±0.61	4.26±0.43	4.28±0.58
S.Triglyceride	164.06±5.91	171.07±4.22	147.11±2.73*	*129.05±3.66†**	*132.70±3.04†**	*134.81±2.50†**	166.29±4.29
S.Total Cholesterol	161.80±4.70	161.16±3.77	149.14±2.88*	*138.42±2.98†**	*140.17±3.25†**	*139.86±2.57†**	158.63±3.90
HDL	46.15±5.32	45.80±4.03	49.95±3.10*	*55.80±3.21†**	*55.35±2.40†**	*54.20±2.97†**	46.78±4.42
LDL	124.40±5.13	121.87±4.31	107.14±3.61*	*95.30±3.54†**	*94.76±2.61†**	*97.84±3.65†**	121.55±4.87
VLDL	32.89±4.47	35.49±3.69	29.53±3.88*	*25.94±2.86†**	*26.65±2.90†**	*27.09±3.05†**	33.25±3.99

* indicates a statistically significant difference ($p < 0.05$) compared to the Metformin monotherapy group.
† indicates a statistically significant difference ($p < 0.05$) compared to all other non–DPP-4 inhibitor groups (i.e., Met, Met+Glim, Met+Glim+Vog, Met+Vog), highlighting the superior lipid profile improvement in DPP-4 inhibitor combinations (Met+Glim+Tene+Vog, Met+Glim+Vil+Vog, Met+Tene+Vog).

The Table No-6 indicated that all combination therapies were associated with significantly greater reductions in FPG, PPPG, and HbA1c levels compared to metformin monotherapy ($p < 0.05$). Among these, the combinations containing DPP-4 inhibitors (metformin with glimepiride, teneligliptin, and voglibose; metformin with glimepiride, vildagliptin, and voglibose; and metformin with teneligliptin and voglibose) achieved the most substantial improvements in glycemic parameters at six months. Renal function indices, including blood urea nitrogen and serum creatinine, remained stable across the groups, with no clinically significant differences observed. Similarly, electrolyte levels (sodium, potassium, chloride) and serum albumin showed minimal variation, indicating the safety of all regimens on these parameters.The lipid profile demonstrated the most pronounced improvements with DPP-4 inhibitor-containing combinations. These groups achieved significantly lower levels of triglycerides, total cholesterol, low-density lipoprotein (LDL), and very low-density lipoprotein (VLDL), along with higher high-density lipoprotein (HDL) levels compared to metformin monotherapy ($p < 0.05$). Furthermore, the differences in lipid parameters were significantly superior in the DPP-4 inhibitor groups when compared with all other non–DPP-4 inhibitor combinations.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

Table No.7: Comparison of effect of metformin with metformin along with add on antidiabetic drugs at 9 months.

	Met N=79	Met+Glim N=26	Met+Glim +Vog N=76	Met+Glim+Tene+Vog N=30	Met+Glim+Vil +Vog N=34	Met+Tene +Vog N=28	Met+Vog N=16
FPG (mg/dl)	130.13±4.88	117.65±7.95*	100.58±10.62*	91.30±7.11*	91.29±7.79*	103.04±8.49*	117.19±5.63*
PPPG (mg/dl)	170.44±8.90	162.69±12.44*	146.84±8.31*	132.60±13.08*	132.76±14.56*	144.54±6.16*	161.50±12.72*
HbA1c (%)	7.51±0.31	7.18±0.37*	6.61±0.29*	6.17±0.52*	6.28±0.53*	6.65±0.18*	7.16±0.42*
BUN (mg/dl)	26.50±7.09	22.85±5.71	24.62±6.02	27.98±7.22	22.38±4.93*	26.65±6.23	27.76±5.78
S.Creatinine (mg/dl)	0.72±0.27	0.85±0.19	0.78±0.32	0.90±0.29	0.78±0.33	0.85±0.36	0.92±0.37
S.Na+(mEq/L)	142.43±6.39	147.11±7.11	143.10±5.71	140.69±4.45	143.09±5.46	144.68±5.98	141.0±4.84
S. K+(mEq/L)	3.92±0.26	3.88±0.24	4.0±0.28	3.99±0.3	3.95±0.26	3.76±0.24	4.0±0.25
S.Cl-(mEq/L)	100.6±2.76	99.72±3.12	100.31±2.63	100.72±2.62	100.42±2.96	102.0±2.78	99.46±2.53
S.Albumin(g/L)	4.06±0.532	4.25±0.690	4.09±0.47	4.0±0.44	4.28±0.63	4.33±0. 49	4.3±0.50
S.Triglyceride	162.75±5.58	170.01±4.11	146.13±2.64*	*128.10±3.55†**	*131.91±2.77†**	*133.92±2.43†**	165.44±4.14
S.Total Cholesterol	160.78±4.32	160.15±3.64	148.02±2.74*	*137.45±2.76†**	*139.44±2.90†**	*139.02±2.38†**	157.79±3.72
HDL	45.87±5.17	45.60±3.85	49.65±2.97*	*55.45±3.11†**	*54.90±2.26†**	*53.88±2.86†**	46.50±4.19
LDL	123.50±4.96	121.05±4.15	106.34±3.45*	*94.75±3.39†**	*94.01±2.49†**	*97.25±3.50†**	120.78±4.63
VLDL	32.58±4.19	35.11±3.47	29.32±3.73*	*25.75±2.76†**	*26.39±2.70†**	*26.93±2.84†**	32.94±3.86

* indicates a statistically significant difference ($p < 0.05$) compared to the Metformin monotherapy group.

† indicates a statistically significant difference ($p < 0.05$) compared to all other non–DPP-4 inhibitor groups (i.e., Met, Met+Glim, Met+Glim+Vog, Met+Vog), highlighting the superior lipid profile improvement in DPP-4 inhibitor combinations (Met+Glim+Tene+Vog, Met+Glim+Vil+Vog, Met+Tene+Vog).

The table no-7 depicted that all combination therapies significantly improved FPG, PPPG, and HbA1c levels compared to metformin monotherapy ($p < 0.05$). The most pronounced glycemic control was observed with combinations containing DPP-4 inhibitors (metformin with glimepiride, teneligliptin, and voglibose; metformin with glimepiride, vildagliptin, and voglibose; and

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

metformin with teneligliptin and voglibose). Renal function markers such as blood urea nitrogen and serum creatinine did not show clinically significant adverse changes, although minor variations were noted across groups. Electrolytes, including sodium, potassium, and chloride, as well as serum albumin levels, remained largely stable throughout the treatment period, indicating the safety of all regimens in maintaining electrolyte and protein balance.Significant improvements in lipid profile parameters were recorded with DPP-4 inhibitor-containing combinations. These regimens demonstrated lower triglycerides, total cholesterol, low-density lipoprotein (LDL), and very low-density lipoprotein (VLDL) levels, along with higher high-density lipoprotein (HDL) levels compared to both metformin monotherapy and non–DPP-4 inhibitor combinations ($p < 0.05$). The differences in lipid profile were consistently superior in the DPP-4 inhibitor groups when compared with all other treatment arms.

Table 8: Effect of drugs on hqol score between only metformin vs metformin with add on antidiabetic agents

	Met N=79	Met+Glim N=26	Met+Glim+Vog N=76	Met+Tene+Glim+Vog N=30	Met+Glim+Vil+Vog N=34	Met+Tene+Vog N=28	Met+Vog N=16
HQOL at beginning of treatment	13.94±1.20	14.12±1.30	13.37±1.71	13.03±1.42	13.06±1.55	13.36±1.66	13.69±0.60
HQOL at 3 months	17.25±1.21	19.50±1.10*	19.86±1.05*	22.50±1.07*	22.44±0.78*	19.43±1.47*	19.19±0.75*
HQOL at 6 months	17.37±1.43	19.77±1.07*	20.08±1.23*	22.43±1.04*	22.38±0.95*	19.68±1.12*	19.38±1.08*
HQOL at 9 months	17.42±1.12	19.96±1.03*	20.49±1.21*	22.27±0.98*	22.35±0.88*	19.89±1.03*	20.19±1.04*

Table No.9 showed that there was a significant increase in health-related quality of life in 3 month/6 month/ 9 month as compared to baseline HQOL after initiation of the metformin therapy.It was also showed no significant difference between the health-related quality of life between the metformin therapy group and other groups for metformin and add-on therapy at the beginning of the study. But after initiation of therapy, there was a significant improvement in health-related quality of life score at 3month,6 month and 9 months in metformin with add-on treatment groups compared with only metformin group.

Table 9: Adverse drug reactions profile of antidiabetic therapy (n=157)

ADR	Frequency	Percentage (%)	Suspected Drug(s)	WHO-UMC Causality	Naranjo Scale
Abdominal discomfort	27	17.19%	Metformin, Voglibose	Probable	6 (Probable)
Bloating	10	6.36%	Voglibose	Possible	4 (Possible)
Constipation	22	14.01%	Glimepiride, Voglibose	Possible	3 (Possible)
Diarrhoea	18	11.46%	Metformin, Voglibose	Probable	5 (Probable)
Flatulence	16	10.19%	Voglibose	Probable	5 (Probable)
Nausea	8	5.09%	Metformin	Possible	4 (Possible)
Peripheral neuritis	17	10.82%	Metformin (via Vit B12 deficiency)	Possible	4 (Possible)
Vomiting	8	5.09%	Metformin	Probable	6 (Probable)

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

Hypoglycaemia	31	19.74%	Glimepiride	Probable	7 (Probable)

The table No. 9 represented the most frequently observed ADR was hypoglycaemia, reported in 31 cases (19.74%), predominantly associated with glimepiride and categorized as "probable" according to the WHO-UMC causality assessment, with a Naranjo score of 7 indicating probable causality. Abdominal discomfort was the second most common ADR, occurring in 27 patients (17.19%) and linked primarily to metformin and voglibose. This reaction was also deemed probable by both the WHO-UMC and Naranjo criteria, with a score of 6. Constipation was reported in 22 patients (14.01%) and attributed to glimepiride and voglibose. The causality was classified as possible, with a lower Naranjo score of 3. Diarrhoea, associated with metformin and voglibose, was observed in 18 patients (11.46%) and assessed as a probable ADR, supported by a Naranjo score of 5. Flatulence, also linked to voglibose, occurred in 16 cases (10.19%), and was categorized as probable with a similar score. Peripheral neuritis, reported in 17 patients (10.82%), was associated with metformin, potentially via vitamin B12 deficiency. It was deemed a possible ADR with a Naranjo score of 4. Bloating and nausea were less common, affecting 10 (6.36%) and 8 (5.09%) patients respectively. Bloating was attributed to voglibose and assessed as a possible ADR with a Naranjo score of 4. Nausea was linked to metformin and similarly categorized. Vomiting, also associated with metformin, was seen in 8 patients (5.09%) and considered a probable ADR, supported by a Naranjo score of 6.

Discussion

This study was conducted in MKCG Medical College and Hospital, Berhampur, and a tertiary care teaching hospital aimed to observe effectiveness, and safety of add on antidiabetic drug to metformin alone among T2DM patients. The effectiveness in terms of FPG, PPPG, HbA1c and HRQoL were studied. The ADR profile also studied.

In this study, 78.2% of patients were aged 18–60 years, while 21.8% were over 60 years. These findings align with previous study, who reported a higher diabetes risk among middle-aged and older adults, likely due to increased insulin resistance and declining pancreatic function with age, obesity, and physical inactivity. Males (51%) were slightly more affected than females (49%), indicating a higher prevalence of diabetes among men [15]. This may be attributed to greater obesity and fat accumulation in males, consistent with the observations the previous study [15]. Obesity and fat deposition, assessed by BMI and waist circumference, were strongly associated with insulin resistance. In present study, 55.1% of participants were overweight, 36.1% had normal weight, 11.6% were class I obese, 1.1% class II obese, and 0.7% underweight. These findings differ from those reported by study conducted at Gujurat [16]. The different result in our study in because Asian Indians as they have a characteristic obesity phenotype, with relatively lower BMI but with central obesity [17]. This study showed that 54.33% of participants had sedentary occupations, while 37.37% and 8.30% were engaged in moderate and high-intensity work, respectively. These findings are consistent with the study conducted at Kalyanpur,India [18]. People in rural areas often have lower education levels, leading to limited T2DM knowledge, poor self-management, low self-efficacy, and reduced continuity of care [19].

Family history is a key risk factor for type 2 diabetes. In this study, 75% of participants had a positive family history, indicating a strong familial link. This finding is consistent with the study by Shaikh et al [20].T2DM is commonly linked with comorbidities, as seen in the current study where 73.7% of participants had coexisting conditions. Among them, 55.39% were cardiovascular-related, including hypertension, dyslipidemia, and coronary artery disease, supporting findings from other studies. [21,22] .

Glycaemic control is contemplated as the cornerstone of management of T2DM plus prevention of severe consequences [23.] This study found no significant baseline differences in glycemic parameters (FPG, PPPG, HbA1c) between the metformin monotherapy group and those receiving add-on therapies. Similarly, baseline renal parameters and lipid profiles were comparable across all groups.

Significant diminution in FBS, PPPG, and HbA1c were detected at 3, 6, and 9 months after beginning metformin therapy. However, renal parameters and lipid profiles showed no significant changes over the same period compared to baseline.

In this study, all combination therapies with metformin showed significantly greater reductions in FPG, PPPG, and HbA$_1$c at 3, 6, and 9 months compared to metformin

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

alone ($p < 0.05$). Regimens including DPP-4 inhibitors (teneligliptin or vildagliptin) with glimepiride and/or voglibose yielded the most marked glycemic improvements. These results align with previous Indian and global studies showing that teneligliptin combinations significantly reduce HbA_1c, FPG, and PPG without affecting renal function, and are more effective than combinations with voglibose or pioglitazone [24-26]. Recent reviews confirm that DPP-4 inhibitors combined with metformin offer superior glycemic efficacy and safety compared to sulfonylurea-based combinations [27].Voglibose added to metformin improves glycemic control, particularly postprandial glucose, though it does not consistently outperform glimepiride or teneligliptin.

[28]. In this study, metformin + glimepiride + voglibose significantly reduced glycemic parameters, though the effect was less pronounced than with DPP-4 inhibitor-based triple regimens.

DPP-4 inhibitor combinations (Met+Glim+Tene+Vog, Met+Glim+Vil+Vog, Met+Tene+Vog) led to significant reductions in triglycerides, total cholesterol, LDL, and VLDL, along with increased HDL. These findings align with earlier studies showing teneligliptin improves lipid profiles, possibly via enhanced adiponectin and insulin sensitivity. Although reviews report variable effects, many trials noted significant lipid improvements with DPP-4 inhibitors.

[27]. Comparatively, voglibose has modest or inconsistent lipid benefits, and sulfonylureas like glimepiride generally do not alter lipid profiles substantially [29].Renal markers (BUN, creatinine), electrolytes (Na^+, K^+, Cl^-), and serum albumin remained stable across all groups, indicating no renal or electrolyte disturbances. This supports previous findings that teneligliptin is safe even in renal impairment [30].

In this study, HRQoL drastically enhanced at 3, 6, and 9 months after initiating metformin therapy. While baseline HRQoL differed between groups, all showed improvement over time. Add-on therapy groups had greater HRQoL gains than metformin alone, likely due to better glycemic control. The highest improvements were seen with metformin+glimepiride+teneligliptin+voglibose and metformin+glimepiride+vildagliptin+voglibose regimens.

In this study, 54.32% of ADRs were linked to antidiabetic drugs, with none being fatal, life-threatening, or requiring hospitalization. Hypoglycemia (19.74%) was most common, followed by abdominal discomfort (17.19%) and constipation (14.01%). Nausea and vomiting each occurred in 5.09%. Overall, 72% of ADRs affected the gastrointestinal system, 10% the nervous system, and 18% other systems. Metformin was most frequently associated with ADRs (77 cases), followed by glimepiride (47) and voglibose (33). These findings align with the study conducted at Eastern India.[31]

Generalisability

The findings of this study are primarily applicable to the South Odisha population, reflecting real-world prescribing patterns and patient outcomes in a tertiary care setting. The study included a diverse group of T2DM patients with varying ages, BMI categories, co-morbidities, and socio-demographic profiles, thereby providing insights relevant to similar semi-urban and rural populations across South Odisha. The use of commonly prescribed antidiabetic drug combinations and adherence to standard clinical practice guidelines enhances the external validity and relevance of the results to routine clinical care in comparable resource-limited settings.

Strength of the Study

It was conducted in a real-world outpatient setting of a tertiary care hospital, reflecting actual clinical prescribing practices and outcomes among the South Odisha population. It offered a comprehensive evaluation by assessing not only glycemic control (FPG, PPPG, HbA1c) but also renal and lipid profiles, adverse drug reactions, health-related quality of life (HRQoL), and medication adherence. By comparing multiple commonly used add-on antidiabetic regimens with metformin monotherapy, the study provided practical, comparative insights for clinicians. The use of validated tools like the WHO-5 Wellbeing Index and the PvPI ADR reporting format enhanced the reliability of safety and quality of life assessments. Additionally, the study maintained ethical standards through prior approval and adherence to a predefined protocol with appropriate statistical analysis.

Conclusion

This prospective observational study in South Odisha assessed the effectiveness and safety of various oral antidiabetic combinations added to metformin in T2DM

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

patients. While metformin alone improved glycemic parameters, combinations—especially those with DPP-4 inhibitors like teneligliptin or vildagliptin—achieved significantly greater reductions in FPG, PPPG, and HbA1c at 3, 6, and 9 months. These regimens also showed notable lipid profile improvements and significantly better HRQoL, particularly with DPP-4 inhibitor combinations. Renal function and electrolytes remained stable, confirming safety. ADRs were reported in 157 patients, mostly mild to moderate, with hypoglycemia and gastrointestinal symptoms being the most common. Overall, DPP-4 inhibitor-based add-on therapies provided superior glycemic and lipid control, improved quality of life, and acceptable safety, supporting their tailored use in T2DM management per ADA/EASD guidelines.

Limitations

Being a non-randomized observational design, it cannot establish definitive causality between treatment regimens and outcomes, and potential confounding factors may have influenced the results. As it was conducted in a single tertiary care hospital, the findings may not be fully generalisable to broader populations or different healthcare settings. Although 289 patients completed follow-up, some subgroup analyses involved smaller sample sizes, such as the metformin plus voglibose group, which could reduce statistical power. The 9-month follow-up duration may be insufficient to assess long-term glycemic control, cardiovascular benefits, or late-onset adverse effects. Additionally, HRQoL were assessed through self-reported tools, which are subject to recall and reporting bias. Lastly, the study did not include insulin, GLP-1 receptor agonists, or SGLT-2 inhibitors, limiting its applicability to all current second-line treatment options.

Recommendations

Based on the findings of this study, it is recommended that clinicians consider combination therapy, particularly those including DPP-4 inhibitors along with metformin, for improved glycemic and lipid control in patients with Type 2 Diabetes Mellitus. Routine monitoring of renal function, lipid profile, and quality of life should be integrated into diabetes management to ensure both safety and holistic outcomes. Future studies with larger multicenter cohorts and longer follow-up durations are needed to validate these findings and assess long-term efficacy and safety. Additionally, inclusion of newer antidiabetic agents such as SGLT-2 inhibitors and GLP-1 receptor agonists would offer a broader comparative perspective. Randomized controlled trials may also be warranted to establish causal relationships between treatment regimens and clinical outcomes in diverse populations.

Acknowledgment

We sincerely thank all the patients who participated in this study for their cooperation and follow-up. We are grateful to the Departments of Endocrinology and General Medicine, MKCG Medical College and Hospital, Berhampur, for their clinical support and collaboration. Our thanks to the Institutional Ethics Committee (Ref: 690/Chairman-IEC) for approving the study. We also acknowledge the PvPI unit for ADR reporting support, and the laboratory, nursing, and medical records staff for their assistance.

Conflict of Interest

The authors declare no conflict of interest related to this study.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data Availability

De-identified participant data (n = 289) from this study will be available on reasonable request to the corresponding author, subject to Institutional Ethics Committee approval (MKCG Medical College & Hospital, Berhampur; Ref: 690/Chairman-IEC) and a signed data-use agreement. Shared materials will include de-identified IPD (demographics, anthropometrics, clinical history, treatment regimens, laboratory results at baseline/3/6/9 months, and WHO-5 scores), derived variables, a data dictionary, the blank CRF, protocol synopsis, and SPSS v22 syntax with output logs to reproduce the analyses. Direct identifiers, quasi-identifiers, and source PvPI ADR forms will not be released; only aggregate ADR summaries will be provided. Data may be requested via the corresponding author's institutional email before publication, and will be deposited in an open repository (e.g., Zenodo or OSF) under a CC BY-NC 4.0 license with DOI after acceptance. Access is restricted to non-commercial, ethically

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

approved research proposals, with acknowledgment of this study and citation of the repository DOI required. Data will be available within three months of acceptance and maintained for at least five years. Requests will be reviewed by investigators and the IEC, and transfer will occur only after IEC clearance and agreement execution. Controlled access is necessary as the original consent did not allow unrestricted public release. SPSS syntax used in analyses will be shared; no custom software was applied. The WHO-5 tool is freely available for non-commercial use, and scoring guidance will be provided.

Table 10: List of abbreviation

Abbreviation	Full Form
T2DM	Type 2 Diabetes Mellitus
FPG	Fasting Plasma Glucose
PPPG	Postprandial Plasma Glucose
HbA1c	Glycated Hemoglobin
ADR	Adverse Drug Reaction
HRQoL	Health-Related Quality of Life
WHO-5	World Health Organization-5 Wellbeing Index
SPSS	Statistical Package for the Social Sciences
MKCG	Maharaja Krushna Chandra Gajapati (Medical College and Hospital)
ADA	American Diabetes Association
DPP-4	Dipeptidyl Peptidase-4
GLP-1	Glucagon-Like Peptide-1
TZDs	Thiazolidinediones
PvPI	Pharmacovigilance Programme of India
IEC	Institutional Ethics Committee
CRF	Case Record Form
BUN	Blood Urea Nitrogen
S.	Serum (used as prefix, e.g., S.Creatinine = Serum Creatinine)
Na^+	Sodium Ion
K^+	Potassium Ion
Cl^-	Chloride Ion
HDL	High-Density Lipoprotein
LDL	Low-Density Lipoprotein
VLDL	Very Low-Density Lipoprotein
OPD	Outpatient Department
RCT	Randomized Controlled Trial

Authors' Contribution

- **Dr. Suvendu Kumar Panda** – Conceived and designed the study; coordinated with the Departments of Endocrinology and General Medicine for patient recruitment; supervised data collection; performed statistical analysis and interpretation; drafted and critically revised the manuscript; approved the final version for submission.
- **Dr. Bikas Chandra Das** – Contributed to study design and methodology; participated in interpretation of results; reviewed the manuscript for intellectual content.
- **Dr. Pratyush Mishra** – Assisted in developing the case record forms and data collection tools; contributed to patient follow-up and clinical monitoring; participated in statistical analysis and drafting of the results section; reviewed and approved the final manuscript.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

- **Dr. Srikanta Panigrahy** – Collected patient data and laboratory reports; performed HRQoL assessment and ADR documentation; assisted in data entry and preliminary analysis; contributed to manuscript preparation and proof-reading.

Authors' Biography

1. Dr. Suvendu Kumar Panda, First Author, Corresponding author
Assistant Professor, Department of Pharmacology, MKCG, Medical College and Hospital, Berhampur, Odisha
Email id: suvendukumarpanda041@gmail.com
Phone no. 9437748309.
ORCID ID:- https://orcid.org/0009-0008-5830-7351
Address: Academic block, MKCG Medical College and Hospital, Berhampur, Odisha, 760004
2. Dr. Bikash Chandra Das, Second Author
Assistant Professor, Department of Pharmacology, SCB Medical College and Hospital, Cuttack, Odisha
Email id:- drbikashchandradas1234@gmail.com
Phone No:-9078722929
3.Dr. Pratyush Mishra, Third author
Assistant Professor, Department of Pharmacology, MKCG, Medical College and Hospital, Berhampur, Odisha
Email id: prometheus190890@gmail.com
Phone no. 9692179970
Address: Academic block, MKCG Medical College and Hospital, Berhampur, Odisha, 760004
4. Dr. Srikanta Panigrahy, Fourth author
Senior Resident, Department of Pharmacology , MKCG Medical College and Hospital, Berhampur
Email id: srikantapanigrahy.panigrahy@gmail.com
Phone no. 83389 67503
Address: Academic block, MKCG Medical College and Hospital, Berhampur, Odisha, 760004

Reference

1. Kannan, Arshad, Senthil K. A study on drug utilization of oral hypoglycemic agents in Type-2 diabetic patients. Asian J Pharm Clin Res. 2011;5:60-4.
2. https://apps.who.int/iris/bitstream/handle/10665/325182/9789241515702-eng.pdf?/ Classification of diabetes mellitus: © World Health Organization 2019: Access on 04-12-2019
3. Jameson J.L, Kasper DL, Longo DL. Harrison's Principles of Internal Medicine. New York: McGraw Hill, Medical Pub. Division,20th edition; 2018.
4. Goodman L, Gilman A, Brunton L, Lazo J, Parker K. Goodman & Gilman's the pharmacological basis of therapeutics. New York: McGraw-Hill; 2018
5. International Diabetes Federation. IDF Diabetes Atlas. 11th ed. Brussels, Belgium: International Diabetes Federation; 2025 [cited 2025 January 30]. Available from: https://www.idf.org.
6. R. C. Turner, C. A. Cull, V. Frighi, and R. R. Holman,"Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus. Progressive requirement for multiple therapies (UKPDS 49)," Journal of the American Medical Association, vol. 281, no. 21, pp. 2005- 2012, 1999. https://doi.org/10.1001/jama.281.21.2005 PMid:10359389
7. Weir GC, Bonner-Weir S. Five stages of evolving beta-cell dys¬function during progression to diabetes. Diabetes 2004;53 Suppl 3:S16-21. https://doi.org/10.2337/diabetes.53.suppl_3.S16 PMid:15561905
8. Ru¨diger Go¨ke Giovanni Bader Markus Dworak. Real-Life Effectiveness and Tolerability of Vildagliptin and Other Oral Glucose-Lowering Therapies in Patients with Type 2 Diabetes in GermanyDiabetes Ther 2014; 5:183-191 https://doi.org/10.1007/s13300-014-0060-4 PMid:24643724 PMCid:PMC4065295
9. Inzucchi SE, Bergenstal RM, Buse JB et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2012; 35: 1364-79. https://doi.org/10.2337/dc12-0413 PMid:22517736 PMCid:PMC3357214
10. Arijit Ghosh1, Pranab Kumar Sahana2, Chanchal Das3, AnanyaMandal4, Nilanjan Sengupta. Comparison of Effectiveness and Safety of Add-on Therapy of Saroglitazar and Fenofibrate with Metformin in Indian Patients with Diabetic Dyslipidaemia. Journal of Clinical

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

and Diagnostic Research. 2016 Mar, Vol-10(3): FC01-FC04

11. Kazuhiro Eto1, Yusuke Naito and Yutaka Seino. Evaluation of the efficacy and safety of lixisenatide add-on treatment to basal insulin therapy among T2DM patients with different body mass indices from GetGoal trials. Diabetol Metab Syndr (2015) 7:106 https://doi.org/10.1186/s13098-015-0104-6 PMid:26594250 PMCid:PMC4654794
12. Osamu Tomonagaa, l, Hiroshi Sakurab, Naotake Hashimotoc, Kazuo Sasamotod, Hiroshi Ohashie, Sumiko Hasumif, Noriko Ujiharag, Tadasu Kasaharah et al. Renal Function During an Open-Label Prospective Observational Trial of Sitagliptin in Patients With Diabetes: A Sub-Analysis of the JAMP Study. J Clin Med Res 2018; (1): 32-40. https://doi.org/10.14740/jocmr3225w PMid:29238432 PMCid:PMC5722043
13. M Gutch, A Joshi, Sukriti k, a Agrawal, R K Pahan,S M Razi. Gemigliptin: Newer promosing gliptin for Type 2 Diabetes Mellitus. I J End Met. 2017;21:898-902 https://doi.org/10.4103/ijem.IJEM_20_17 PMid:29285456 PMCid:PMC5729681
14. C. Mathieu,1 A. H. Barnett,2 H. Brath,3 I. Conget,4 J. J. de Castro,5 R. G€oke,6 E. M_arquez, etal. Effectiveness and tolerability of second-line therapy with vildagliptin vs. other oral agents in type 2 diabetes: A real-life worldwide observational study (EDGE) Int J Clin Pract, October 2013, 67, 10, 947-956 https://doi.org/10.1111/ijcp.12252 PMid:23961850 PMCid:PMC4231206
15. Binu Mathew1 , Elizabeth A. M.1 , M. Rajkumar Reddy1 , Adeena Balkees1 , H. Doddayya1 and S. S. Antin. Pharmacoepidemiological assessment of insulin therapy in T2DM patienta. EJPMR. 2019,6(3), 298-302.
16. Himansu M Rana,Parag Chavada,Chirag C Rathod,Meera Mavani.Sociodemographicand anthropometric profile of diabetes patients attending diabetes clinic in tertiary care hospital of central Gujurat.
17. Mohan V, Deepa R. Obesity and abdominal obesity in Asian Indians. Indian J Med Res 2006; 123: 593-596.
18. Gahlot A,Singh S P,Alam Md Irshad. Study of determinants of type 2 diabetes related to lifestyle behaviouramoung urban population of Kalyanpur:Indain Journal of Foresnic and Community medicine,April-June 2017,4(2):85-89
19. Nicholas C. Arpey1 , Anne H. Gaglioti2 , and Marcy E. Rosenbaum1. How Socioeconomic Status Affects Patient Perceptions of Health Care: A Qualitative Study. Journal of Primary Care & Community Health 2017, Vol. 8(3) 169-175 https://doi.org/10.1177/2150131917697439 PMid:28606031 PMCid:PMC5932696
20. Shaikh ZA, Akhund S, Ali M, Khan MH. Type 2 diabetes, Effects of socio-demographic factors among patients. Professional Med J 2013;20(2): 244-249. https://doi.org/10.29309/TPMJ/2013.20.02.628
21. Mathur M,Mathur N,Singh O, Solanki J. Demograhpic characters and factors favouring emergence of diabetes mellitus type two:International journal of Research in Medical Sciences Mathur M et al. Int J Res Med Sci.2018 Mar.6(3):950-954 https://doi.org/10.18203/2320-6012.ijrms20180621
22. Kevin M Pantalone,Todd M Hobbs, Brain J Wells. Clinical charactertstics,complications,comorbidities and treatment pattern among patient with type 2 diabetes mellitusin a large integrated health system.BMJ Open Diabetes Research and Care 2015:e000093.doi:10.1136/bmjdrc-2015-000093. https://doi.org/10.1136/bmjdrc-2015-000093 PMid:26217493 PMCid:PMC4513350
23. Fincke, B. G. et al. Assessment of Long-term Complications due to Type 2 Diabetes Using Patient Self-report: The Diabetes Complications Index. The Journal of ambulatory care management 28, 262-273 (2005). https://doi.org/10.1097/00004479-200507000-00010 PMid:15968219
24. Raghavan V, Lahiri A, Akul SK, Utpal U, Gupta CN, Sen S. Effect of teneligliptin vs metformin on glycemic control in Indian patients with newly-diagnosed, drug-naïve type 2 diabetes mellitus: A 12-week randomized comparative clinical study. Int J Adv Med 2019;6:481-8. https://doi.org/10.18203/2349-3933.ijam20191163
25. Gupta CN, Raghavan V, Sen S, Kothari S. Role of teneligliptin in rural India as add-on third

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

drug in patients with type 2 diabetes mellitus. Int J Adv Med [Internet]. 2017 Mar. 23 [cited 2025 Aug. 2];4(2):401-5. Available from: https://www.ijmedicine.com/index.php/ijam/article/view/522 https://doi.org/10.18203/2349-3933.ijam20170966

26. Maladkar, M. , Sankar, S. and Kamat, K. (2016) Teneligliptin: Heralding Change in Type 2 Diabetes. Journal of Diabetes Mellitus, 6, 113-131. doi: 10.4236/jdm.2016.62012. https://doi.org/10.4236/jdm.2016.62012
27. Santwana Padhi, Amit Kumar Nayak, Anindita Behera, Type II diabetes mellitus: a review on recent drug based therapeutics, Biomedicine & Pharmacotherapy, Volume 131,2020,110708,ISSN 0753-3322,https://doi.org/10.1016/j.biopha.2020.110708. https://doi.org/10.1016/j.biopha.2020.110708 PMid:32927252
28. Hasan A, Pratik. Comparison of efficacy and safety of combination of metformin with tenegliptin, metformin with voglibose and metformin with glimepiride in treatment of patients with type 2 diabetes mellitus. Saudi J Med Pharm Sci. 2020 Apr;6(4):368-71. doi:10.36348/sjmps.2020.v06i04.006. https://doi.org/10.36348/sjmps.2020.v06i04.006
29. Oh TJ, Yu JM, Min KW, Son HS, Lee MK, Yoon KH, Song YD, Park JY, Jeong IK, Cha BS, Kim YS, Baik SH, Kim IJ, Kim DM, Kim SR, Lee KW, Park JH, Lee IK, Park TS, Choi SH, Park SW. Efficacy and Safety of Voglibose Plus Metformin in Patients with Type 2 Diabetes Mellitus: A Randomized Controlled Trial. Diabetes Metab J. 2019 Jun;43(3):276-286. doi: 10.4093/dmj.2018.0051. Epub 2018 Dec 7. PMID: 30604594; PMCID: PMC6581551. https://doi.org/10.4093/dmj.2018.0051 PMid:30604594 PMCid:PMC6581551
30. Sharma SK, Panneerselvam A, Singh KP, Parmar G, Gadge P, Swami OC. Teneligliptin in management of type 2 diabetes mellitus. Diabetes Metab Syndr Obes. 2016 Aug 16;9:251-60. doi: 10.2147/DMSO.S106133. PMID: 27574456; PMCID: PMC4993264. https://doi.org/10.2147/DMSO.S106133 PMid:27574456 PMCid:PMC4993264
31. Deb T,Chakrabarti A,Ghosa A.Adverse drugreactions in type 2 diabetes mellitus patient on oral antidiabetic drugs in a diabetes outpatient department of a tertiary care teaching hospital in Eastern India.Int J Med Sci Public health 2017;6(3):554-557 https://doi.org/10.5455/ijmsph.20173203102016

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
https://doi.org/10.51168/sjhrafrica.v6i9.2021
Original Article

PUBLISHER DETAILS

Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
(ISSN 3006-1059) Print
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256 775 434 261
Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa