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Original Research Article

Evaluation of Safety and Efficacy of Glimepiride and Sitagliptin in Combination with Metformin in Patients with Type 2 Diabetes Mellitus: A Prospective, Open-Label, Comparative Study

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Abstract

Background: Type 2 diabetes mellitus (T2DM) often requires combination therapy when metformin alone fails to achieve adequate glycemic control. This study compared the efficacy and safety of glimepiride and sitagliptin as add-on therapy to metformin in patients with inadequately controlled T2DM.

Material and Methods: In this prospective, open-label, randomized comparative study, 310 adults with inadequately controlled T2DM were allocated equally to receive either glimepiride plus metformin (n=155) or sitagliptin plus metformin (n=155) for six months. Glycemic parameters, body weight, renal and hepatic function, medication adherence, adverse effects, hypoglycemic episodes, dose modifications, and study completion were assessed and compared between groups.

Results: Both treatment groups demonstrated significant improvement in glycemic control, with comparable reductions in fasting plasma glucose (190.59±25.95 to 151.87±27.46 mg/dL vs. 191.44±26.96 to 152.29±29.92 mg/dL) and HbA1c (8.88±0.66% to 6.85±0.72% vs. 8.91±0.62% to 6.85±0.69%) after six months (all between-group $p>0.05$). Body weight, renal function, hepatic parameters, medication adherence (93.49±3.87% vs. 93.76±3.64%; $p=0.493$), dose adjustments, and study completion rates were similar between groups. Overall adverse effects were comparable; however, hypoglycemic episodes occurred significantly more frequently with glimepiride than with sitagliptin ($p<0.001$), and the incidence of at least one hypoglycemic event was also higher in the glimepiride group (7.1% vs. 1.9%; $p=0.029$).

Conclusion: Glimepiride and sitagliptin, when combined with metformin, provide equivalent glycemic control and comparable overall safety. However, the significantly lower risk of hypoglycemia with sitagliptin suggests a more favorable safety profile, particularly for patients at increased risk of hypoglycemic events.

Keywords: Type 2 diabetes mellitus; Metformin; Glimepiride; Sitagliptin; Glycemic control; Hypoglycemia.

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Introduction

Type 2 diabetes mellitus (T2DM) is a progressive metabolic disorder characterized by insulin resistance and progressive β-cell dysfunction, resulting in chronic hyperglycemia and an increased risk of microvascular and macrovascular complications. Despite advances in pharmacotherapy, maintaining durable glycemic control remains challenging, and many patients require combination therapy to achieve individualized glycemic targets [1]. Metformin continues to be recommended as the preferred first-line pharmacological therapy for most adults with T2DM because of its proven efficacy, favorable safety profile, low cost, and extensive long-term clinical experience. However, progressive deterioration of β-cell function frequently

necessitates the addition of a second glucose-lowering agent when glycemic targets are no longer achieved with metformin alone [2]. Selection of an appropriate add-on therapy should consider not only glucose-lowering efficacy but also the risk of hypoglycemia, effects on body weight, patient adherence, comorbidities, and treatment cost. Sulfonylureas such as glimepiride remain widely prescribed, particularly in low- and middle-income countries, because they are effective, inexpensive, and readily available. Nevertheless, their insulin secretagogue action is associated with an increased risk of hypoglycemia and weight gain [3].

Dipeptidyl peptidase-4 (DPP-4) inhibitors, including sitagliptin, enhance endogenous incretin activity and improve glucose-dependent insulin secretion while suppressing glucagon release. Owing to their glucose-dependent mechanism of action, these agents generally provide effective glycemic control with a substantially lower risk of hypoglycemia and neutral effects on body weight [4]. Comparative clinical studies have demonstrated that both glimepiride- and sitagliptin-based combinations with metformin improve glycemic control, although differences have been reported in safety outcomes, particularly the incidence of hypoglycemia. Furthermore, long-term comparative effectiveness data indicate that therapeutic selection should be individualized according to patient characteristics and risk profiles rather than glycemic efficacy alone [5,6].

Considering the continued use of both therapeutic strategies in routine clinical practice, particularly in resource-constrained settings, the present study was undertaken to compare the efficacy and safety of glimepiride and sitagliptin when administered in combination with metformin in patients with inadequately controlled type 2 diabetes mellitus.

Materials and Methods

Study design and setting: This was a prospective, open-label, randomized, parallel-group comparative study conducted in the Department of Pharmacology in collaboration with the Department of Medicine at B.R.D. Medical College, Gorakhpur, Uttar Pradesh, India.

The study protocol was approved by the Institutional Ethics Committee prior to enrollment, and written informed consent was obtained from all participants before initiation of any study procedure. The study was conducted over a period of one year, encompassing patient recruitment, treatment intervention, and a six-month follow-up for each enrolled participant.

Study Population: Patients with a confirmed diagnosis of type 2 diabetes mellitus (T2DM) attending the outpatient department of B.R.D. Medical College were screened for eligibility. Adults aged 18 to 65 years with inadequately controlled diabetes—defined as fasting plasma glucose greater than 100 mg/dL, postprandial plasma glucose greater than 140 mg/dL, and HbA1c greater than 7%—were considered for inclusion.

Patients were excluded if they had type 1 or secondary diabetes mellitus, a history of severe hypoglycemia or known hypersensitivity to the study drugs, significant renal impairment (eGFR <30 mL/min/1.73 m²), hepatic dysfunction, or clinically significant cardiovascular disease. Pregnant and lactating women were also excluded, as were patients unwilling to provide written informed consent.

Sample size: The sample size was calculated using a standard formula for comparison of two independent means, based on the anticipated difference in HbA1c reduction between the two treatment groups, a two-sided significance level (α) of 0.05, and 80% statistical power. This yielded a minimum requirement of 141 patients per group; after adjusting for an anticipated attrition rate of 10%, the target sample size was set at 155 patients per group, for a total of 310 patients.

Randomization and intervention: Eligible patients were allocated to one of two treatment arms using a random number table, in a 1:1 ratio:

- **Group A (n = 155):** Sitagliptin 100 mg once daily, added to metformin (dose individualized between 500 mg and 2000–2500 mg/day according to glycemic response and tolerability).
- **Group B (n = 155):** Glimepiride 1–4 mg once daily, titrated according to glycemic control up to a maximum of 8 mg/day, added to metformin at the same dosing range as Group A.

Metformin dosing in both arms was adjusted by the treating physician based on individual glycemic status and tolerance. Randomization was performed after baseline assessment to minimize selection bias, and the open-label design reflected routine clinical prescribing practice for both drug classes.

Baseline and follow-up assessment: At enrollment, all patients underwent a baseline clinical evaluation comprising demographic and clinical history, body weight, fasting and postprandial plasma glucose, HbA1c, serum creatinine, estimated glomerular filtration rate (eGFR), and liver enzymes (ALT, AST). Patients were followed prospectively for six months, with scheduled visits at baseline, 1, 3, 5, and 6 months. At each follow-up visit, glycemic parameters, body weight, medication adherence, and adverse events—including hypoglycemic episodes—were recorded. Renal and hepatic parameters were

reassessed at the end of the 6-month follow-up period.

Outcome Measures: The primary outcomes were the change in HbA1c from baseline to 6 months and the incidence of hypoglycemia over the study period. Secondary outcomes included change in fasting plasma glucose, change in body weight, and patient-reported treatment adherence and tolerability.

Statistical Analysis: Data were analyzed using SPSS software (version 26; IBM Corp.). Continuous variables were expressed as mean ± standard deviation and compared between groups using the independent-samples t-test. Categorical variables were expressed as frequencies and percentages and compared using the chi-square test or Fisher's exact test, as appropriate. A p-value of less than 0.05 was considered statistically significant.

Results

Baseline body weight was comparable between the two groups (75.16 ± 11.94 kg in the glimepiride group versus 76.33 ± 12.37 kg in the sitagliptin group; p = 0.398). Weight remained stable in both groups over the study period, with no statistically significant difference at 3 months (75.19 ± 11.96 kg versus 76.34 ± 12.47 kg; p = 0.409) or at 6 months (75.30 ± 11.90 kg versus 76.26 ± 12.57 kg; p = 0.487) (Table 1). Although a numerically greater proportion of weight-gain events was reported as a side effect in the glimepiride group (discussed further under Adverse Effects, Table 4), this was not reflected as a significant between-group difference in mean body weight over the study duration.

Both treatment combinations produced a substantial and statistically significant reduction in fasting plasma glucose (FPG) and HbA1c over the 6-month period, with no significant difference between groups at any time point (Table 2). Baseline FPG was 190.59 ± 25.95 mg/dL in the glimepiride group and 191.44 ± 26.96 mg/dL in the sitagliptin group (p = 0.775), and declined comparably in both groups to 175.96 ± 25.23 mg/dL and 177.15 ± 27.96 mg/dL respectively at 3 months (p = 0.695), and further to 151.87 ± 27.46 mg/dL and 152.29 ± 29.92 mg/dL at 6 months (p = 0.899). A parallel pattern was observed for HbA1c: baseline values of 8.88 ± 0.66% and 8.91 ± 0.62% in the glimepiride and sitagliptin groups respectively (p = 0.655) fell to 7.86 ± 0.75% and 7.86 ± 0.73% at 3 months (p = 0.919), and further to 6.85 ± 0.72% and 6.85 ± 0.69% at 6 months (p = 0.994) (Table 2). These findings indicate that both drug combinations achieved equivalent and clinically meaningful glycemic control over the study period. Renal function, assessed by serum creatinine and estimated glomerular filtration rate (eGFR), and hepatic function, assessed by ALT and AST, remained within normal limits and did not differ significantly between groups at baseline or at 6 months (Table 3). Serum creatinine changed minimally from 0.87 ± 0.23 mg/dL to 0.90 ± 0.22 mg/dL in the glimepiride group and from 0.86 ± 0.21 mg/dL to 0.87 ± 0.20 mg/dL in the sitagliptin group. eGFR, ALT, and AST likewise showed no clinically relevant deviation over the study period in either group (Table 3), suggesting that neither combination regimen adversely affected renal or hepatic function over 6 months.

The overall side-effect profile was comparable between the two groups, with the majority of patients in both arms reporting no adverse effects (73.5% in the glimepiride group versus 74.2% in the sitagliptin group; p = 0.895). Gastric discomfort, dizziness, headache, and nausea occurred at similar frequencies in both groups (Table 4). The most notable safety difference between the two regimens was in hypoglycemia. Patients receiving glimepiride experienced a significantly higher number of hypoglycemic episodes during the study compared to those receiving sitagliptin (p < 0.001), with 18.7% of the glimepiride group remaining free of any hypoglycemic episode compared with 40.0% of the sitagliptin group, and a correspondingly higher proportion of glimepiride patients experiencing 3 or more episodes over the study period (Table 4). Consistent with this, a significantly higher proportion of patients in the glimepiride group experienced at least one hypoglycemic event compared with the sitagliptin group (7.1% versus 1.9%; p = 0.029) (Table 4).

Mean medication adherence at the end of the study was high and comparable between the two groups, at 93.49 ± 3.87% in the glimepiride group and 93.76 ± 3.64% in the sitagliptin group (p = 0.493) (Table 5), indicating that neither regimen was associated with a meaningfully greater burden of non-adherence.

Dose adjustment was required in a similar proportion of patients in both groups (47.1% in the glimepiride group versus 46.5% in the sitagliptin group; p = 0.909), most commonly because of inadequate glycemic control rather than intolerance or hypoglycemia (Table 6).

Study completion rates were high and did not differ significantly between groups, with 91.6% of the glimepiride group and 89.7% of the sitagliptin group completing the full 6-month follow-up (p = 0.558). Reasons for withdrawal, including adverse effects, loss to follow-up, personal reasons, and poor adherence, were distributed similarly between the two arms (Table 6).

Table 1: Comparison of mean body weight between treatment groups

Time point	Group	N	Mean weight (kg)	SD	t-value	df	p-value
Baseline	Metformin + Glimepiride	155	75.16	11.94	−0.846	308	0.398
	Metformin + Sitagliptin	155	76.33	12.37			
3 months	Metformin + Glimepiride	155	75.19	11.96	−0.827	308	0.409
	Metformin + Sitagliptin	155	76.34	12.47			
6 months	Metformin + Glimepiride	155	75.30	11.90	−0.696	308	0.487
	Metformin + Sitagliptin	155	76.26	12.57			

Table 2: Comparison of glycemic parameters (FPG and HbA1c) between treatment groups

Parameter	Time point	Group	Mean	SD	t-value	df	p-value
FPG (mg/dL)	Baseline	Glimepiride	190.59	25.95	−0.447	308	0.775
		Sitagliptin	191.44	26.96			
	3 months	Glimepiride	175.96	25.23	−0.392	308	0.695
		Sitagliptin	177.15	27.96			
	6 months	Glimepiride	151.87	27.46	−0.126	308	0.899
		Sitagliptin	152.29	29.92			
HbA1c (%)	Baseline	Glimepiride	8.88	0.66	−0.447	308	0.655
		Sitagliptin	8.91	0.62			
	3 months	Glimepiride	7.86	0.75	0.102	308	0.919
		Sitagliptin	7.86	0.73			
	6 months	Glimepiride	6.85	0.72	−0.007	308	0.994
		Sitagliptin	6.85	0.69			

Table 3: Renal and hepatic safety parameters at baseline and 6 months

Parameter	Group	Baseline (Mean ± SD)	6 Months (Mean ± SD)	p-value (baseline)	p-value (6 mo)
Creatinine (mg/dL)	Glimepiride	0.87 ± 0.23	0.90 ± 0.22	0.986	0.670
	Sitagliptin	0.86 ± 0.21	0.87 ± 0.20		
eGFR (mL/min/1.73m²)	Glimepiride	92.78 ± 18.30	89.30 ± 18.34	0.207	0.573
	Sitagliptin	95.43 ± 17.72	90.42 ± 18.42		
ALT (U/L)	Glimepiride	35.30 ± 9.15	35.05 ± 10.90	0.390	0.493
	Sitagliptin	36.16 ± 9.91	35.78 ± 11.19		
AST (U/L)	Glimepiride	32.79 ± 9.17	32.24 ± 10.47	0.938	0.965
	Sitagliptin	32.76 ± 8.68	32.05 ± 9.63		

Table 4: Adverse effects and hypoglycemia at study end

Outcome	Category	Glimepiride, n (%)	Sitagliptin, n (%)	p-value
Reported side effects	Dizziness	9 (5.8%)	8 (5.2%)	0.895
	Gastric discomfort	9 (5.8%)	13 (8.4%)	
	Headache	7 (4.5%)	4 (2.6%)	
	Nausea	12 (7.7%)	11 (7.1%)	
	None	114 (73.5%)	115 (74.2%)	
	Weight gain	4 (2.6%)	4 (2.6%)	
Hypoglycemia episodes (total during study)	0	29 (18.7%)	62 (40.0%)	<0.001
	1	44 (28.4%)	36 (23.2%)	
	2	40 (25.8%)	38 (24.5%)	
	3	25 (16.1%)	11 (7.1%)	
	4	12 (7.7%)	6 (3.9%)	
	5	5 (3.2%)	2 (1.3%)	
Hypoglycemia occurrence (any vs none)	No	144 (92.9%)	152 (98.1%)	0.029
	Yes	11 (7.1%)	3 (1.9%)	

Table 5: Medication adherence at study end

Parameter	Group	Mean adherence (%)	SD	p-value
Adherence	Metformin + Glimepiride	93.49	3.87	0.493
	Metformin + Sitagliptin	93.76	3.64	

Table 6: Dose adjustments and study completion status

Outcome	Category	Glimepiride, n (%)	Sitagliptin, n (%)	p-value
Dose change required	No	82 (52.9%)	83 (53.5%)	0.909
	Yes	73 (47.1%)	72 (46.5%)	
Reason for dose change	High blood glucose	62 (40.0%)	63 (40.6%)	0.951
	Hypoglycemia	4 (2.6%)	4 (2.6%)	
	Intolerance	7 (4.5%)	5 (3.2%)	
	NA	82 (52.9%)	83 (53.5%)	
Study completion	Completed	142 (91.6%)	139 (89.7%)	0.558
	Did not complete	13 (8.4%)	16 (10.3%)	
Reason for withdrawal	Adverse effects	3 (1.9%)	3 (1.9%)	0.882
	Lost to follow-up	1 (0.6%)	3 (1.9%)	
	Personal reasons	6 (3.9%)	6 (3.9%)	
	Poor adherence	3 (1.9%)	4 (2.6%)	

Discussion

The present prospective comparative study demonstrated that the addition of either glimepiride or sitagliptin to metformin resulted in significant improvement in glycemic control over six months. Both treatment regimens produced comparable reductions in fasting plasma glucose and HbA1c, while no significant differences were observed in body weight, renal function, hepatic function, medication adherence, dose adjustments, or study completion. However, patients receiving glimepiride experienced significantly more hypoglycemic episodes than those receiving sitagliptin, indicating an important difference in safety despite equivalent glucose-lowering efficacy.

The comparable glycemic efficacy observed in the present study is consistent with previous comparative investigations evaluating sulfonylureas and DPP-4 inhibitors as add-on therapy to metformin. Although their mechanisms of action differ, both classes effectively improve β-cell function and reduce hyperglycemia when introduced after inadequate response to metformin. The START study reported meaningful reductions in HbA1c and fasting plasma glucose with both glimepiride and sitagliptin combinations, demonstrating that either regimen is capable of achieving clinically important glycemic improvement in patients with T2DM [7]. Likewise, recent evidence from a randomized Phase 3 study evaluating a fixed-dose combination of sitagliptin, metformin and glimepiride confirmed sustained improvement in glycemic parameters with acceptable tolerability, further supporting the effectiveness of these agents in combination therapy [8].

An important finding of the present study was the absence of a significant difference in body weight between the two treatment groups throughout follow-up. Although sulfonylureas have traditionally been associated with weight gain, the magnitude of change with modern sulfonylureas such as glimepiride appears relatively modest, particularly when combined with metformin. Recent reviews have similarly reported that differences in body weight between sulfonylurea- and DPP-4 inhibitor-based dual therapy are generally small over short- to medium-term follow-up, especially when background metformin therapy is maintained [9].

Renal and hepatic biochemical parameters remained stable in both groups during the study period, suggesting that neither treatment adversely affected organ function over six months. These findings are consistent with the established safety profile of both glimepiride and sitagliptin in patients without advanced renal or hepatic impairment. Contemporary reviews have similarly concluded that both drug classes are generally well tolerated when prescribed appropriately and monitored according to current recommendations [9].

The major difference between the treatment groups was the incidence of hypoglycemia. Patients treated with glimepiride experienced significantly more hypoglycemic episodes than those receiving sitagliptin. This observation is biologically plausible because sulfonylureas stimulate insulin secretion irrespective of ambient glucose concentration, whereas DPP-4 inhibitors enhance glucose-dependent insulin release, thereby reducing the likelihood of hypoglycemia. Large comparative analyses have consistently demonstrated a lower risk of hypoglycemia with DPP-4 inhibitors than with sulfonylureas [10]. Furthermore, population-based evidence has confirmed that severe hypoglycemia remains an important concern with sulfonylurea therapy, reinforcing the need for careful patient selection and monitoring [11].

Medication adherence exceeded 93% in both treatment groups, indicating that both regimens were well accepted by patients. Similar adherence rates and treatment persistence have been reported in clinical practice, where once-daily oral therapies are generally associated with satisfactory

compliance provided adverse effects remain limited [9]. Likewise, the comparable frequency of dose adjustments and high study completion rates observed in the present study suggest that both regimens were practical for routine clinical use.

The clinical implications of the present findings are particularly relevant in resource-limited settings. Glimepiride remains an inexpensive and effective second-line agent and therefore continues to play an important role in countries where treatment cost strongly influences prescribing decisions. However, in individuals at increased risk of hypoglycemia—including elderly patients, those with irregular meal patterns, or patients in occupations where hypoglycemia may have serious consequences—sitagliptin may represent the safer therapeutic option despite its higher acquisition cost. Recent comprehensive reviews of combination therapy have similarly concluded that DPP-4 inhibitor-based combinations provide glycemic efficacy comparable to sulfonylureas while offering a more favorable hypoglycemia profile [9,12].

The strengths of the present study include its prospective design, adequate sample size, randomized allocation, and comprehensive assessment of efficacy, safety, medication adherence, and treatment persistence. Nevertheless, certain limitations should be acknowledged. The open-label design may have introduced observer bias, while the single-center setting may limit generalizability. The follow-up duration of six months was sufficient to evaluate short-term efficacy and safety but inadequate to assess long-term durability of glycemic control, cardiovascular outcomes, or diabetic complications. Future multicenter studies with longer follow-up incorporating patient-reported outcomes and cost-effectiveness analyses would further clarify the optimal positioning of these treatment strategies in routine clinical practice.

Conclusion

This study demonstrates that both glimepiride and sitagliptin, when combined with metformin, produce comparable and clinically meaningful improvements in glycemic control, as reflected by similar reductions in fasting plasma glucose and HbA1c over six months, with no significant differences in body weight, renal function, hepatic function, or medication adherence between the two regimens. However, glimepiride was associated with a significantly higher incidence of hypoglycemic episodes compared with sitagliptin, indicating a less favorable safety profile despite equivalent glycemic efficacy. These findings suggest that sitagliptin in combination with metformin may be a preferable option in patients at higher risk of hypoglycemia, while glimepiride remains a valid and cost-effective alternative in appropriately selected patients where hypoglycemia risk is closely monitored.

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