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Global Journal of Obesity, Diabetes and Metabolic Syndrome
OPEN ACCESS JOURNAL

ISSN: 2455-8583 DOI: https://dx.doi.org/10.17352/gjodms

Research Article

The Glycemic Outcomes of Metformin with Add-on Vildagliptin or Sitagliptin in T2DM

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Received: 12 August, 2025
Accepted: 28 August, 2025
Published: 29 August, 2025

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Keywords: T2DM; Metformin; Vildagliptin; Sitagliptin; Glycemic control; HbA1C; DPP-4inhibitor

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Abstract

Introduction: T2DM is a global health concern requiring effective glycaemic management to reduce complications. While DPP-4 inhibitors like vildagliptin and sitagliptin are widely used in combination with metformin, limited studies have compared their efficacy in lowering plasma glucose levels. This study aims to address this gap by evaluating the effectiveness of these combinations in glycaemic control. This study aims to address this gap by evaluating the effectiveness of these combinations in glycemic control.

Objective: To compare the glycemic outcomes of vildagliptin with metformin versus sitagliptin with metformin in patients with T2DM, focusing on HbA1c reduction as the primary indicator.

Methods: A comparative observational study on 172 T2DM patients (≥ 30 years) was done with comorbidities like hypertension, dyslipidemia, and obesity. Inclusion required lab data (FBG, PLBS, HbA1c, Cr, TG) and consent, while exclusions included T1DM, gestational diabetes, insulin therapy, alcohol use, and emergencies. Outcomes assessed were primary (HbA1c), secondary (Cr, TG).

Hypothesis:

Null (H0): There is no difference in the efficacy of Vildagliptin + Metformin versus Sitagliptin + Metformin.

Alternative (Ha): There is a significant difference in the efficacy of Vildagliptin + Metformin versus Sitagliptin + Metformin.

Results and conclusion: The study showed that adding vildagliptin or sitagliptin to metformin significantly improved glycaemic control in T2DM over six months. Both combinations effectively reduced FBS, PLBS, HbA1c, and TG without affecting renal function.

Vildagliptin achieved slightly better glycaemic reductions compared to sitagliptin with add-on metformin.

Both treatments were well-tolerated, with no significant side effects including renal dysfunction or hyperlipidemia. These findings confirm the safety and efficacy of both therapies, with vildagliptin having a slight edge.

Introduction

DM encompasses metabolic illnesses distinguished by relentless hyperglycemia, Stemming from modulation of insulin release and its physiological effects, insulin action, or both [1].

The yield of insulin spawned by Langerhans organ is crucial for facilitating the body's assimilation of glucose. For an individual who is non-diabetic, Langerhans organ generates more insulin. Whenever BSL rises, insulin signals the bodily cells to ingest glucose. In DM, Langerhan's organ capacity to yield insulin and adaptation are altered [2].

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T1DM embodies a persistent autoimmune dysfunction primarily distinguished via the devastation of insulin-yielding β - cells which being the principal source of insulin integrated via the Langerhans organ, directing to an absolute deficiency in insulin [3].

T2DM comes about when bodily cells become inferior and responsive to insulin's efforts to drive glucose onto cells, an illness known as defiance to insulin. Consequently, glucose begins to linger in the blood.

Increment in BSL and prolonged unavailability of hormone may cause ketoacidosis, which accrues ketones within the bloodstream when uses Fat rendering as energy rather than glucose. Ketone makes blood acidic and reduce all body functions. This also eventually render to death.

The extensiveness continues to ascend globally, with projections suggesting the affect of approximately 0.07% of one-on-one by 2030.

The met accompanying DPP - IV inhibitors enhances the triad (reducing HbA1c by 0.5–1.0%) while diminishing blood sugar-dropping risk. Here's weight-neutral, suitable for overweight patients, and offers cardiovascular protection, reducing diabetes-related cardiovascular events.

DPP-IV inhibitors, and biguanides, particularly metformin, are frequently articulated in combined therapeutic approaches to manage T2DM.

In 2022 among candidates having DM, 2.65% inhabited India, 1.85% in China, 0.52% in US, and 0.45% in Pakistan. Indonesia and Brazil constituted a further 0.3%M, 22M cases, respectively.

Mechanism of actions

Metformin: Metformin primarily acts by decreasing hepatic glucose production, reducing intestinal glucose absorption, and improving insulin sensitivity to increase peripheral glucose uptake.

It decreases hepatic glucose production by inhibiting gluconeogenesis and, to a lesser extent, glycogenolysis.This is considered its main effect on blood glucose. It involves inhibition of mitochondrial respiration complex I, leading to altered cellular energy state and subsequent activation of AMP-activated protein kinase (AMPK). Metformin can also inhibit mitochondrial glycerophosphate dehydrogenase, impacting the cellular redox state [4].

It also alters the composition and function of the gut microbiome, which is increasingly recognized as a key contributor to its therapeutic effects [5].

Sitagliptin: Sitagliptin primarily works as a dipeptidyl peptidase-4 (DPP-4) inhibitor to enhance the body's natural ability to control blood glucose levels.Sitagliptin selectively inhibits the enzyme dipeptidyl peptidase-4 (DPP-4), which normally inactivates incretin hormones such as GLP-1 and GIP. By blocking DPP-4, sitagliptin increases the circulating levels and activity of these intact incretin hormones.

Elevated levels of active GLP-1 and GIP lead to enhanced glucose-dependent insulin secretion from pancreatic beta cells. This means insulin is released more effectively when blood glucose levels are high, minimizing the risk of hypoglycemia.

The increased incretin levels also suppress glucagon secretion from pancreatic alpha cells. Reduced glucagon contributes to lower hepatic glucose production, further aiding in glycemic control [5].

Sitagliptin in combination with metformin: Sitagliptin works by preventing the breakdown of incretin hormones (GLP-1 and GIP). This leads to glucose-dependent increases in insulin secretion from pancreatic beta cells and decreases in glucagon secretion from alpha cells, thereby lowering both fasting and postprandial glucose levels.

Metformin, a biguanide, primarily reduces the amount of glucose produced by the liver (hepatic gluconeogenesis) and improves the sensitivity of body tissues to insulin, allowing for better glucose uptake and utilization. It also slightly reduces intestinal glucose absorption [5].

Vildagliptin: Vildagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor that improves glucose control in type 2 diabetes by enhancing the body's own incretin system.

It specifically inhibits the DPP-4 enzyme, which is responsible for inactivating incretin hormones, namely glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). This inhibition leads to increased circulating levels of active GLP-1 and GIP [4].

The elevated incretin levels result in glucose-dependent stimulation of insulin secretion from pancreatic beta cells, thereby increasing insulin release when blood glucose is high.

Vildagliptin in combination with metformin: Vildagliptin, a DPP-4 inhibitor, increases the availability of active incretin hormones (GLP-1 and GIP) by preventing their breakdown. This leads to glucose-dependent enhancement of insulin secretion from pancreatic beta cells and suppression of glucagon secretion from alpha cells, thereby improving both fasting and postprandial glucose levels.

Metformin, a biguanide, primarily acts by reducing hepatic glucose production (gluconeogenesis) and, to a lesser extent, by improving peripheral insulin sensitivity, leading to increased glucose uptake by tissues. It also has a minor effect on intestinal glucose absorption [6].

Prevalence

Global wise: The substantial increment in 2024 is serious worldwide health concern. This increase is causing a strain on worldwide health network and provoking complications for those affected [7].

In the 2024 epidemiology study the worldwide extensiveness concerning T2DM aged twenty- seventy-nine years is approximately 10.5%. The fast-paced metropolitan growth, dietary changes, and habitual inactivity are significant

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contributors to this emerging prevalence,with India exhibiting overwhelming rates globally [8].

National wise: By 2024, approximately across India, 77M are reckoned distressed with DM, pertaining preponderance of cases [9].

This represents a rise in previous year, a national prevalence reckoned around 11-13% among adults, emphasizing the condition as being a serious worldwide health challenge [10].

The inquiry implies that nascent DM paces are coupled with socioeconomic disparities, impacting both awareness and conceptualization of treatment [11].

State wise: Recent surveys signify that 25% of grouping in RR district suffers from diabetes, as revealed by door-to-door inquiries undertaken between January and August 2024 [12].

Another nationwide health inquiry conveyed that around 18% in Telangana are living with high BSL [13].

This data emphasizes a concern about increasing rates of diabetes, predominantly in certain ages in assorted geographic areas [14].

Literature review

1. Ndayishimye Samuel, et al. (2018) to retrospectively compare the effectiveness and safety in 160 subjects of groups A and B, in group A 80 subjects received a fixed dose combination of sitagliptin 50mg with metformin 500mg and 80 subjects in group B received a fixed dose combination of vildagliptin 50mg with metformin 500mg for a period of 24 weeks. Both groups have shown a greater reduction in plasma glucose parameters: HbA1C reduced up to 0.97% for vildagliptin group versus 0.928% in sitagliptin group, FBS reduced up to 27.46 mg/dl in vildagliptin group versus 20.925 mg/dl for sitagliptin and PLBS reduced up to 42.25 mg/dl for vildagliptin versus 35.260 mg/dl for sitagliptin [15].

2. Hiroshi Nomoto, et al. (2024) in total, 32 patients were enrolled, completed the initial examination. The mean HbA1c levels were 7.3 ± 0.6%. The baseline characteristics of participants are shown. All participants had used sitagliptin or vildagliptin for more than 3 months at the time of enrolment (n =18, sitagliptin; n = 14, vildagliptin) [16].

3. Goksun Ayvaz, et al. (2015) observational, prospective cohort study with 665 samples Efficacy was evaluated by measuring HbA1c levels. Tolerability/safety parameters evaluated included hypoglycemic events, gastrointestinal events, peripheral edema, and weight gain. Decrease in HbA1c of 0.8% from a baseline value of 7.8%. The percentages of patients who achieved HbA1c targets of ≤6.5% and ≤7.0% increased, from 10.7% to 33.6% and from 22.1% to 52.6%. The decrease in HbA1c was independent of baseline HbA1c (≤8% *vs.* 8–10% *vs.* ≥10%). Vildagliptin and Metformin combination showed improvements in reaching target HbA1c levels, even in elderly and obese patients with T2DM. Moreover, vildagliptin and metformin give a good overall tolerability/safety profile [17].

4. V. Lukashevich, et al. (2014) A multicentre, double-blind, placebo-controlled study randomized patients to receive treatment with vildagliptin 50 mg bid (n = 158) or placebo (n = 160) for 24 weeks. The difference in FBS reduction between Vildagliptin and placebo was -1.13 mmol/l. Vildagliptin reduced HbA1c by 0.74% from baseline 7.82%. Vildagliptin was well tolerated with a low incidence of hypoglycemia, slightly higher than with placebo (5.1% *vs.* 1.9%), and no clinically relevant weight gain [18].

5. Masato Odawara, et al. (2014) r andomized, double-blind, placebo-controlled, parallel-arm study compared vildagliptin 50 mg bid with placebo in T2DM patients with a total of 139 patients. Vildagliptin showed a similar reduction in HbA1c of -1.1% for both the subpopulations of patients receiving metformin 500 mg bid. Vildagliptin 50 mg bid added to metformin improved glycemic control without any tolerability issues and hypoglycemia in Japanese patients with T2DM inadequately controlled on metformin monotherapy [19].

6. Yadav Praveen et al. (2021) the aim of this observational comparative study is to compare the efficacy of vildagliptin (50mg) and sitagliptin (50mg) metformin (500mg) for T2DM with course duration of 28 weeks over 150 patients were diagnosed. Group A and Group B have shown a greater reduction in plasma glucose FBS reduced up to 48.08mg/ dl in vildagliptin group versus sitagliptin group 48.11 mg/dl, PLBS reduced up to 49.16mg/dl in vildagliptin group and sitagliptin group reduced up to 47.2mg/dl and HbA1c reduced up to 0.97% in vildagliptin group versus sitagliptin group reduced up to 0.93%. The body weight was increased by 0.70kg with sitagliptin and reduced by 0.62kg with vildagliptin [20].

7. Li-Nong Ji, et al. (2013) a 24-week, phase 4, prospective, randomized, multicenter, open-label, parallel-group study, will include 3312 Chinese T2DM patients [21].

8. B Guerci, et al. (2012) Continuous glucose profiles with vildagliptin versus sitagliptin in add-on to metformin A multicentre, prospective, randomized study. Data acquired over three days – firstly on metformin alone and then 8 weeks after the addition of either vildagliptin (n = 14) or sitagliptin (n = 16) – were blinded and analyzed centrally [22].

James E Signorovitch, et al. (2011) Vildagliptin and sitagliptin are DPP-4 inhibitors approved in Japan for the treatment of T2DM when adequate glycaemic control is not achieved with diet, exercise, or sulfonylurea and randomized compare 12-week glycaemic control with vildagliptin 50 mg

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BD versus sitagliptin 50 or 100 mg OD. A total of 264 patients were treated with vildagliptin 50 mg BD, 235 were treated with sitagliptin 50 mg OD, and vildagliptin 50 mg BD was associated with significantly greater HbA1C reduction than sitagliptin 50 mg or 100 mg OD [23].

Misu Rani Saha et al. 2020 randomised study design this study was carried out to compare the effectiveness of glycemic control between combined therapy of sitagliptin-metformin and metformin monotherapy. HbA1c change from baseline was 0.82% with metformin and 1.83% with sitagliptin-metformin combination. Fbs changed from 9.41±1.34mmol/l to 8.04±1.10mmol/l with metformin and from 9.75±1.40mmol to 7.25±0.80 with sitagliptin-metformin therapy. The administration of sitagliptin-metformin combined therapy to control hyperglycemia uniquely is preferable [24].

Y Ding Y Liu, et al. 2022 Randomised controlled test with 8533 samples The aim is to assess the comparative efficacy and safety of combination therapy with vildagliptin and metformin *vs.* metformin monotherapy in the treatment of type 2 diabetes mellitus (T2DM) combination therapy with vildagliptin and metformin (dose of metformin ≥ 1500mg/d) had a significantly higher reduction in (HbA1c)fasting plasma glucose (FPG) level than combination therapy with vildagliptin and metformin (dose of metformin< 1500 mg/d). The results indicated that compared with the metformin, vildagliptin combined with metformin could significantly reduce FPG, HbA1c ad body weight. When the dose of metformin in the combination group of vildagliptin and metformin is ≥1500 mg/d, the results showed s reduction in HbA1c and FPG [25].

Methodology

Study design and settings

The Randomized, observational, and prospective inquiry was carried out at Dept of General Medicine, RVM HOSPITAL (RVM Institute of Med. Science and Research Centre) [Laxmakkapally (V), Mulugu (M), Siddipet (D), TG], from Aug 2024 to Jan 2025.

Study population and sample size

The study population will be recruited using convenient sampling method,targeting both inpatients and out patients from the RVM hospital across age grops from 30 years. The sample size was determined using the Raosoft online sample size calculator, considering T2DM patientsbased on 95% confidence level, 5% margin of error and assuming 50% response rate. The estimated sample size was found to be 180 participants. However, the final size obtained was 172. Despite this minor reduction, the remains statistically sufficient for meaningful analysis.

Study criteria

Inclusion criteria and Exclusion criteria: The study included both male and female of T2DM using metformin with add-on vildagliptin or sitagliptin. Age above 30 years.Subjects with co-morbid conditions, common comorbidities include: HTN, Dyslipidemia, MASLD, Heart disease, Sleep disorders, Cancer, Obesity, and Thyroid Disorders. FBG, PLBS, HbA1c, Cr, TGs values available. Outpatients and Inpatients. Pt is interested in participating. Conversely, patients with T1DM, GDM, Denovo DM, Candidates on insulin and or other hypoglycemia agents, Pregnant, pediatrics, mentally disabled, emergency cases, Subjects whose lab data is unavailable, Surgical condition, Patients who consume alcohol

Randomization and group allocation

Eligible participants were randomized using a simple randomization method. Each participant was assigned to one of the two treatment groups using a computer-generated random number table. Both inpatients and outpatients from the general medicine department were considered.

Data collection procedure

Data were collected using a standardized patient data form. The following parameters were recorded at three time points: baseline (initial visit), 3rd month, and 6th month:

- Fasting Blood Sugar (FBS)
- Post-Lunch Blood Sugar (PLBS)
- Glycated Hemoglobin (HbA1c)
- Serum Creatinine (Cr)
- Triglycerides (TG)

Participants were followed up through reminders and regular hospital visits to ensure timely laboratory assessments.

Ethical considerations

The study protocol was reviewed and approved by the Institutional Human Ethics Committee (IHEC) of Geethanjali College of Pharmacy (Ref no: GCPK/PD24/09). Written informed consent was obtained from all participants prior to enrollment. Confidentiality and data privacy were maintained throughout the study.

Statistical analysis

All collected data were entered into Microsoft Excel (version 2412) and analyzed using SPSS version 27 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were presented as frequencies and percentages.

- Independent *t* - tests were used to compare mean values between the two treatment groups at each visit.
- Paired *t* - tests were used for within-group comparisons across time points (initial, 3rd, and 6th months).
- Chi-square test was used to analyze categorical variables (e.g., gender distribution).

A *p* - value of <0.05 was considered statistically significant.

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Results

Response rate

Here in inquiry, 182 forms were distributed, with 91 forms allocated to regimen1, 91 forms to regimen2. 86 forms were returned from regimen 1, 86 forms from regimen 2, resulting in 172 forms returned. This shows a pace of responsiveness of approximately 94.56%, suggesting a strong engagement from participants in both groups Table 1, Figure 1.

Table 1: Dissemination of subjects by sex.

		Number	Percentage
Gender	Male	95	55
	Female	77	45
Total		172	100

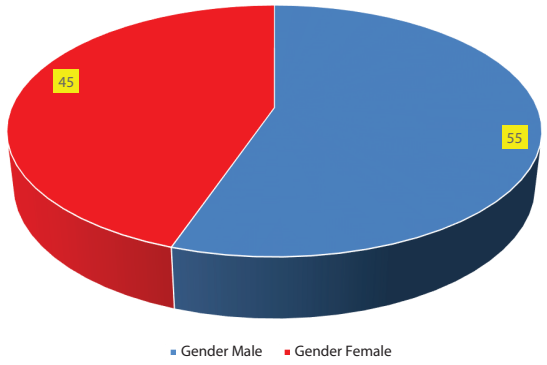

Figure 1: Dissemination of subjects by sex.

Table 2: Distribution of Gender among 2 treatment groups.

		Group				Total		Chi-square	p value
		Vildagliptin + Metformin		Sitagliptin + Metformin					
		No.	%	No.	%	No.	%		
Gender	Male	45	47	50	53	95	55	.588[a]	0.443
	Female	41	53	36	47	77	45		
Total		86	50	86	50	172	100		

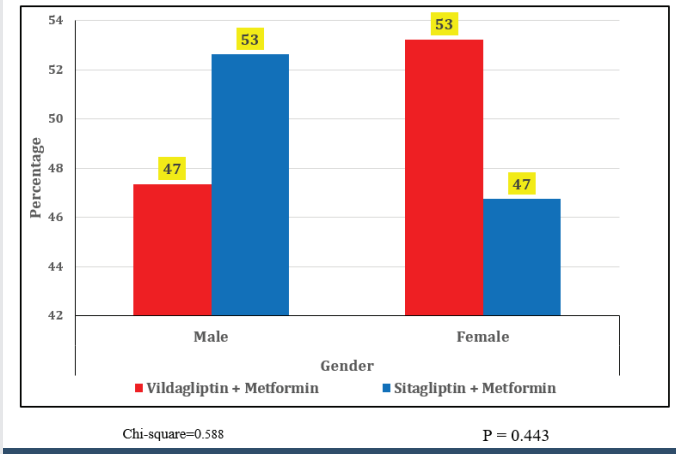

Figure 2: Distribution of Gender among 2 treatment groups.

Table 3: Distribution of Age among 2 Treatment Groups.

		N	Mean	Std. Deviation	"t" Value	*p* value
Age in Years	Vildagliptin + Metformin	86	57.41	12.01409	1.348	0.179
	Sitagliptin + Metformin	86	59.86	11.85120		

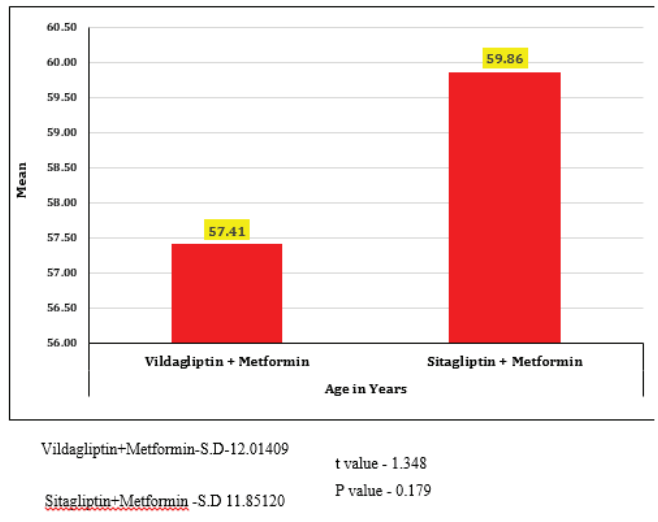

Figure 3: Distribution of Age among 2 treatment Groups.

Discussion

The study included a total of 172 participants, with a gender distribution of 55% male (95 participants) and 45% female (77 participants). This distribution is reflective of the general population in diabetes studies, where males often have a higher prevalence of T2DM.

Participants were divided into two treatment groups: Vildagliptin + Metformin and Sitagliptin + Metformin. Both groups showed significant improvements in FBS, PLBS, HbA1c,Cr,TG over the 6-month period.

Table 2, Figure 2 - represents the distribution of participants in the two treatment groups: Vildagliptin + Metformin and Sitagliptin + Metformin, along with their respective sex breakdowns. Both treatment groups had a similar gender distribution, The Chi-square value of 0.588 and a *p* - value of 0.443 indicate no significant difference in gender distribution between the two groups.

Table 3, Figure 3 the mean age for the Vildagliptin + Metformin group was 57.41 years, while the Sitagliptin + Metformin group had a mean age of 59.86 years. The t-value of 1.348 and *p* - value of 0.179 suggest no significant difference in age between the two groups.

In Table 4, Figure 4 Initial visit parameters, the Vildagliptin + Metformin group exhibited a FBS of 146.49 mg/dL and a PLBS of 214.95 mg/dL, with an HbA1c of 7.36%, creatinine at 1.01 mg/dL, and TG at 198.91 mg/dL. In comparison, the Sitagliptin + Metformin group had an FBS of 142.53 mg/dL, PLBS of 208.01 mg/dL, HbA1c of 7.40%, Cr at 1.08 mg/dL, and TG at 248.36 mg/dL. These initial values indicate that both groups started with similar metabolic profiles, allowing for a fair comparison of treatment efficacy over time.

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Table 4: Glycemic and Biochemical Outcomes at the Initial Visit.

			N	Mean	Std. Deviation	"t" Value	p value
1st month visit	FBS	Vildagliptin + Metformin	86	146.49	33.208	0.747	0.456
		Sitagliptin + Metformin	86	142.53	36.138		
	PLBS	Vildagliptin + Metformin	86	214.95	43.450	0.959	0.339
		Sitagliptin + Metformin	86	208.01	51.185		
	HbA1c	Vildagliptin + Metformin	86	7.36	0.689	0.331	0.741
		Sitagliptin + Metformin	86	7.40	0.784		
	Cr	Vildagliptin + Metformin	86	1.01	0.276	1.544	0.125
		Sitagliptin + Metformin	86	1.08	0.352		
	TG	Vildagliptin + Metformin	24	189.79	100.992	1.308	0.198
		Sitagliptin + Metformin	22	248.36	192.553		

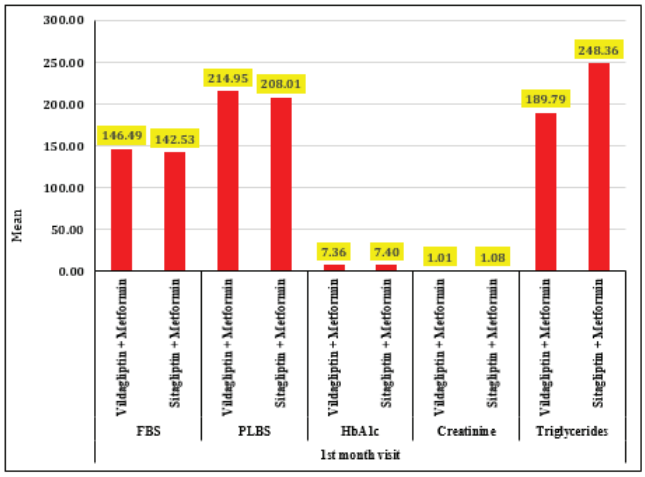

Figure 4: Glycemic and Biochemical Outcomes at the Initial Visit.

Table 5: Glycemic and Biochemical Parameters at 1st Follow-Up (3rd Month).

Group			N	Mean	Std. Deviation	"t" Value	p value
3rd month visit	FBS	Vildagliptin + Metformin	85	131.64	33.388	0.015	0.988
		Sitagliptin + Metformin	86	131.56	36.088		
	PLBS	Vildagliptin + Metformin	85	194.61	43.701	0.287	0.774
		Sitagliptin + Metformin	86	192.57	49.101		
	HbA1c	Vildagliptin + Metformin	85	7.18	0.661	0.901	0.369
		Sitagliptin + Metformin	86	7.28	0.788		
	Cr	Vildagliptin + Metformin	85	0.98	0.250	1.443	0.151
		Sitagliptin + Metformin	86	1.03	0.259		
	TG	Vildagliptin + Metformin	22	162.50	107.909	0.528	0.601
		Sitagliptin + Metformin	22	180.82	121.959		

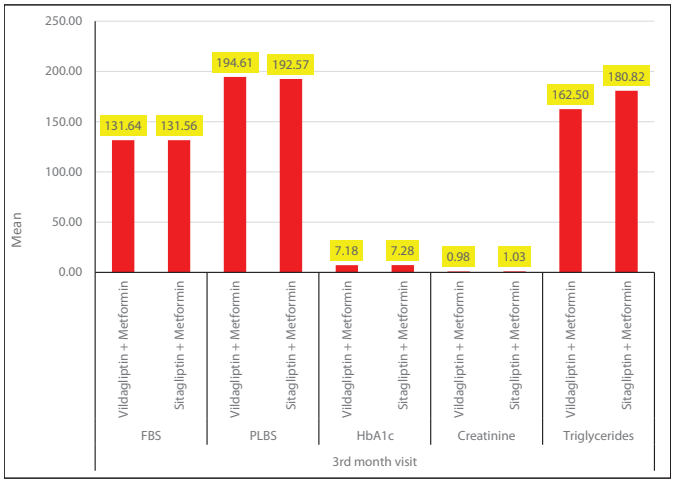

Figure 5: Glycemic and Biochemical Parameters at 1st Follow-Up (3rd Month).

In Table 5, Figure 5 - By the third month, both treatment groups showed significant improvements in metabolic parameters. The Vildagliptin + Metformin group recorded an FBS of 131.64 mg/dL (10.14% decrease), PLBS of 194.61 mg/dL (9.48% decrease), HbA1c of 7.18% (2.45% decrease), and Cr at 0.98 mg/dL (2.97% decrease). TG decreased to 162.50 mg/dL (18.25% decrease). The Sitagliptin + Metformin group also improved, with an FBS of 131.56 mg/dL (7.69% decrease), PLBS of 192.57 mg/dL (7.39% decrease), HbA1c of 7.28% (1.62% decrease), Cr at 1.03 mg/dL (4.63% decrease), and TG at 180.82 mg/dL (27.14% decrease). These results indicate effective management of diabetes in both groups. But overall, the Vildagliptin + Metformin group demonstrated superior reductions in FBS, PLBS, and HbA1c.

In Table 6, Figure 6 - At the sixth-month visit, the Vildagliptin + Metformin group demonstrated further improvements, with an FBS of 121.38 mg/dL (17.14% decrease), PLBS of 172.76 mg/dL (19.59% decrease), HbA1c of 7.01%

Table 6: Glycemic and Biochemical Parameters at 2nd Follow-Up (6th Month).

Group			N	Mean	Std. Deviation	"t" Value	p value
6th month visit	FBS	Vildagliptin + Metformin	50	121.38	33.298	0.767	0.445
		Sitagliptin + Metformin	57	126.16	31.103		
	PLBS	Vildagliptin + Metformin	50	172.76	42.910	0.645	0.521
		Sitagliptin + Metformin	57	178.33	46.054		
	HbA1c	Vildagliptin + Metformin	50	7.01	0.662	1.094	0.276
		Sitagliptin + Metformin	57	7.16	0.775		
	Cr	Vildagliptin + Metformin	50	0.93	0.233	0.007	0.994
		Sitagliptin + Metformin	57	0.93	0.236		
	TG	Vildagliptin + Metformin	14	111.07	61.782	0.037	0.971
		Sitagliptin + Metformin	17	110.35	46.579		

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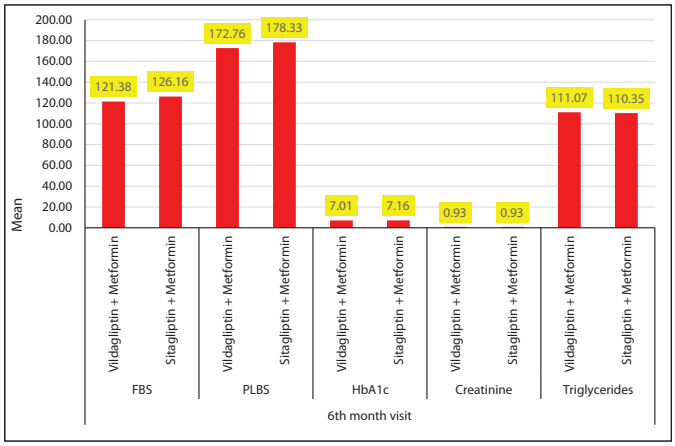

Figure 6: Glycemic and Biochemical Parameters at 2nd Follow-Up (6th Month).

(4.76% decrease), and stable Cr at 0.93 mg/dL (7.92% decrease). TG were recorded at 111.07 mg/dL (44.04% decrease). The Sitagliptin + Metformin group also showed favorable results, with an FBS of 126.16 mg/dL (11.48% decrease), PLBS of 178.33 mg/dL (14.26% decrease), HbA1c of 7.16% (3.24% decrease), Cr at 0.93 mg/dL (13.89% decrease), and TG at 110.35 mg/dL (55.66% decrease). While both groups showed improvements, the Vildagliptin + Metformin group maintained superior control over FBS, PLBS, HbA1c.

Table 7, Figure 7 - summarizes the mean values, standard deviations, t-values, and *p* - values for various parameters at different visits for the Vildagliptin + Metformin group. Significant reductions were observed in FBS, PLBS, HbA1c, Cr, and TG, with *p* - values < 0.001 indicating strong statistical significance. These results underscore the efficacy of Vildagliptin + Metformin in managing diabetes and improving metabolic health, suggesting it may be a preferred treatment option for patients.

Table 8, Figure 8 - Similar to Table 7, this table summarizes the results for the Sitagliptin + Metformin group. Significant reductions were also noted across all parameters, with *p* - values < 0.001 for most comparisons. However, the magnitude of improvement was generally less than that observed with Vildagliptin + Metformin.

This indicates that while Sitagliptin + Metformin is effective, Vildagliptin + Metformin demonstrates superior efficacy in managing key metabolic parameters.

Conclusion

This study evaluated the efficacy of two treatment regimens, Vildagliptin + Metformin, and Sitagliptin + Metformin, in managing T2DM over a six-months period.

The results demonstrated that both treatment groups significantly improved key metabolic parameters, including FBS, PLBS, HbA1c, Cr, and TG.However, the Vildagliptin + Metformin group consistently exhibited superior outcomes compared to the Sitagliptin + Metformin group.

Specifically, Vildagliptin + Metformin achieved greater

Table 7: Impact of Vildagliptin + Metformin on FBS, PLBS, HbA1c, Creatinine, and Triglyceride Levels over Initial Visit, 3rd, and 6th months.

Vildagliptin + Metformin		Mean	N	Std. Deviation	"t" Value	*p* value
FBS	Initial Visit	146.31	85	33.361	22.555	<0.001
	3rd Month Visit	131.64	85	33.388		
PLBS	Initial Visit	215.42	85	43.487	35.038	<0.001
	3rd Month Visit	194.61	85	43.701		
HbA1c	Initial Visit	7.37	85	0.689	25.125	<0.001
	3rd Month Visit	7.18	85	0.661		
Cr	Initial Visit	1.01	85	0.278	3.831	<0.001
	3rd Month Visit	0.98	85	0.250		
TG	Initial Visit	198.91	22	100.575	5.817	<0.001
	3rd Month Visit	162.50	22	107.909		
FBS	3rd Month Visit	133.54	50	34.887	25.836	<0.001
	6th Month Visit	121.38	50	33.298		
PLBS	3rd Month Visit	194.44	50	43.074	23.801	<0.001
	6th Month Visit	172.76	50	42.910		
HbA1c	3rd Month Visit	7.19	50	0.677	12.860	<0.001
	6th Month Visit	7.01	50	0.662		
Cr	3rd Month Visit	0.96	50	0.237	2.178	0.034
	6th Month Visit	0.93	50	0.233		
TG	3rd Month Visit	148.46	13	61.424	7.441	<0.001
	6th Month Visit	114.62	13	62.806		
FBS	Initial Visit	147.50	50	35.319	44.896	<0.001
	6th Month Visit	121.38	50	33.298		
PLBS	Initial Visit	214.44	50	43.149	96.308	<0.001
	6th Month Visit	172.76	50	42.910		
HbA1c	Initial Visit	7.38	50	0.702	26.555	<0.001
	6th Month Visit	7.01	50	0.662		
Cr	Initial Visit	1.00	50	0.280	4.384	0.034
	6th Month Visit	0.93	50	0.233		
TG	Initial Visit	189.00	14	70.585	11.951	<0.001
	6th Month Visit	111.07	14	61.782		

Figure 7: Impact of Vildagliptin + Metformin on FBS, PLBS, HbA1c, Creatinine, and Triglyceride Levels over Initial Visit, 3rd, and 6th months.

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Table 8: Impact of Sitagliptin + Metformin on FBS, PLBS, HbA1c, Creatinine, and Triglyceride Levels over Initial visit, 3rd, and 6th months.

Sitagliptin + Metformin		Mean	N	Std. Deviation	"t" Value	*p* value
FBS	Initial Visit	142.53	86	36.138	171.478	<0.001
	3rd Month Visit	131.56	86	36.088		
PLBS	Initial Visit	208.01	86	51.185	9.374	<0.001
	3rd Month Visit	192.57	86	49.101		
HbA1c	Initial Visit	7.40	86	0.784	18.882	<0.001
	3rd Month Visit	7.28	86	0.788		
Cr	Initial Visit	1.08	86	0.352	3.145	0.002
	3rd Month Visit	1.03	86	0.259		
TG	Initial Visit	248.36	22	192.553	3.145	0.005
	3rd Month Visit	180.82	22	121.959		
FBS	3rd Month Visit	133.91	57	33.454	8.733	<0.001
	6th Month Visit	126.16	57	31.103		
PLBS	3rd Month Visit	194.44	57	47.829	8.425	<0.001
	6th Month Visit	178.33	57	46.054		
HbA1c	3rd Month Visit	7.35	57	0.833	6.937	<0.001
	6th Month Visit	7.16	57	0.775		
Cr	3rd Month Visit	1.04	57	0.276	4.553	<0.001
	6th Month Visit	0.93	57	0.236		
TG	3rd Month Visit	164.59	17	118.005	2.450	0.026
	6th Month Visit	110.35	17	46.579		
FBS	Initial Visit	144.91	57	33.524	20.899	<0.001
	6th Month Visit	126.16	57	31.103		
PLBS	Initial Visit	210.68	57	48.957	28.507	<0.001
	6th Month Visit	178.33	57	46.054		
HbA1c	Initial Visit	7.46	57	0.833	10.952	<0.001
	6th Month Visit	7.16	57	0.775		
Cr	Initial Visit	1.08	57	0.352	4.742	<0.001
	6th Month Visit	0.93	57	0.236		
TG	Initial Visit	207.00	17	159.171	3.098	0.007
	6th Month Visit	110.35	17	46.579		

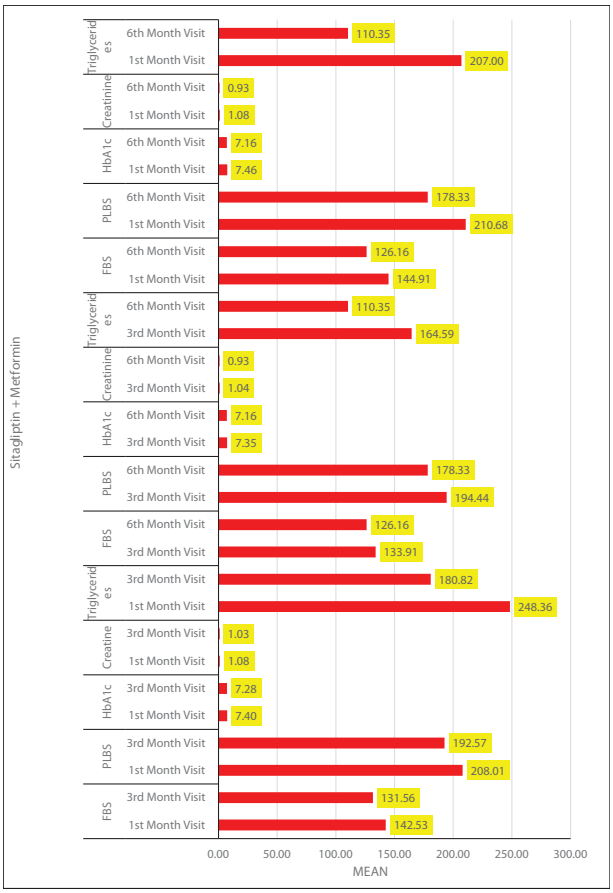

Figure 8: Impact of Sitagliptin + Metformin on FBS, PLBS, HbA1c, Creatinine, and Triglyceride Levels over Initial visit, 3rd, and 6th months.

reductions in FBS, PLBS, as well as a more significant decrease in HbA1c levels, achieving optimal glycaemic control and improving metabolic health in patients with type 2 diabetes.

Sitagliptin + Metformin demonstrated a modest improvement in triglyceride and serum creatinine levels compared to Vildagliptin+Metformin. However, the differences in renal and lipid parameters were minimal and not clinically significant.

Overall, the results support the continued use of both Vildagliptin + Metformin and Sitagliptin + Metformin in clinical practice, with a recommendation for Vildagliptin + Metformin as a preferred choice for enhanced metabolic control.

Acknowledgement

This dissertation, entitled "The Glycemic Outcomes of Metformin with Add-on Vildagliptin or Sitagliptin in T2DM," has been completed in R.V.M. Hospital & GCPK, Hyderabad.

We would like to express our heartfelt gratitude to all those who have supported and guided us throughout the completion of our thesis work.

Firstly, we extend our sincere thanks to our college Secretary Sir, Mr. G. Ravinder Reddy, for his constant encouragement and support.

Our deepest gratitude also goes to our esteemed Principal, Dr. M. Ravi Kumar, M.Pharm, Ph.D, PDF (USA), for his guidance and support during the course of our study.

We are extremely grateful to our HOD, Dr. Abdul Nazer Ali, M. Pharm Ph.D. (Clinical Pharmacy) Professor and HOD of Pharmacy Practice, GCPK for his invaluable guidance and for being a constant source of support. His wisdom and expertise guided us at every step of our research, helping us overcome challenges and refine our work.

We would also like to express our profound appreciation to our Internal Guide, Dr. Mohammed Abubakar, for his exceptional guidance, encouragement, and motivation. His unwavering support and in-depth knowledge were critical in shaping our work, and we are deeply thankful for his patience and dedication throughout this process.

A special thank you to our Clinical Guide, Dr. B. Sashidhar Reddy (MBBS, DNB, MNAMS, INT MED) Associate Professor, Department of General Medicine RVM Hospital, whose expertise, insightful suggestions, and continuous support have been indispensable throughout our research journey.

We are also thankful to the hospital staff for their cooperation and assistance, and to the patients who participated in this study, without whom this research would not have been possible. Their contribution has been vital in making this project a success.

Finally, we would like to thank all those who helped us in various ways during this research, whose names we may not be

Citation: Abubakar M, Priya BS, Himaja YS, Harini N. The Glycemic Outcomes of Metformin with Add-on Vildagliptin or Sitagliptin in T2DM. Glob J Obes Diabetes Metab Syndr. 2025;12(1):016-025. Available from: https://dx.doi.org/10.17352/2455-8583.000068

able to mention here. Your encouragement, support, and help have been invaluable, and we will always be grateful.

Strengths

The study compares vildagliptin and sitagliptin with metformin, offering insights into their efficacy and safety.

Emphasizing follow-up reminders improves medication adherence, leading to better therapeutic outcomes.

The study highlights outcomes that matter to patients, like blood sugar control and side effects, offering a clearer understanding of how treatment affects quality of life.

Limitations

The study may not have fully considered variations in lifestyle factors such as diet, and physical activity, which could have an impact on glycaemic outcomes.

Conducting the study in a single hospital limits the applicability of the findings to broader populations or different healthcare settings.

The restrictive inclusion and exclusion criteria, such as excluding alcoholic patients, may reduce the relevance of the results to real-world diabetic populations.

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