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A Comparative Retrospective Study of Vildagliptin 100mg SR OD and Sitagliptin 100 mg in Subjects with Type 2 Diabetes Mellitus

Dr. K. Vamsi Krishna[1], Dr Sanjeet Kumar Jaiswal[2], Dr Subodh Jain[3], Dr Syed Haroon Iqubal[4], Dr. Sona Warrier[5], Dr. Ashish Prasad[6], Dr. Ashish Birla[7], Mr. Vinod More[8], Dr. Ravindra Mote[9]

[1]Department of Endocrinology and Diabetology, SevenHills Hospital, Visakhapatnam, India

[2]Consultant Diabetologist and Endocrinologist, HORMONE, The Diabetes, Thyroid and Endocrine Clinic, Raipur, India

[3]Physician and Diabetologist, Diabetes Care Centre, Allahabad, India

[4]Consultant Physician, Diabetologist, Critical Care Specialist, Mediwin Polyclinic, Bareilly, UP, India

[5, 6, 7]Scientific Services, USV Private Limited, Mumbai, Maharashtra, India

[8, 9]Department of Clinical Research, Mediclin Clinical Research, Mumbai, India

*Corresponding Author
Dr. Sona Warrier, Scientific Services, USV Private Limited, Mumbai, Maharashtra, India
Email: *drsonawarrier[at]gmail.com*

Abstract: ***Diabetes mellitus is a chronic metabolic disorder characterized by insufficient insulin secretion from β - cells of pancreatic islet leads to increased blood glucose level and cause damage to the cardiovascular system, kidneys, eyes, and nerves. Dipeptidyl peptidase 4 (DPP - 4) inhibitors are the drugs that inhibit degradations of incretin hormones which enhance insulin secretion. Vildagliptin and Sitagliptin are oral DDP - 4 inhibitors that aid to control blood glucose levels in type 2 diabetes mellitus. An assessment of efficacy was performed by measuring the post - treatment glycosylated hemoglobin (HbA1c) levels. This was a Single - centre, Retrospective, Comparative Clinical Study that recruited a total number of 340 subjects fulfilling study criteria. Subjects who were on stable doses of metformin and with HbA1c values between ≥8% to <11% were included. The study consists of two treatment groups, Vildagliptin 100 mg SR Tablets (Treatment A) and Sitagliptin 100 mg Tablets (Treatment B), and HbA1c, Fasting blood glucose (FBG), and post - prandial blood glucose (PPBG) levels from baseline to week 16 were compared. The study endpoints were to estimate the mean change in HbA1c, FBG, and PPBG from baseline to week 16 (Visit 3). Statistical data analysis was done using SAS 9.4. Descriptive statistical analysis was expressed as the means ± standard deviation. A total of 340 subjects suffering from T2DM were included and analyzed; of which 174 were in the Vildagliptin group and 166 were in the Sitagliptin group. After 16 weeks of treatment with study drugs, it was found that a significant reduction was observed in HbA1c, FBG, and PPBG levels in the Vildagliptin group as compared to the Sitagliptin group. Results of this retrospective study revealed that Vildagliptin and Sitagliptin showed comparable efficacy profiles for controlling the levels of various glucose parameters.***

Keywords: Retrospective, Type 2 Diabetes mellitus, Vildagliptin, Sitagliptin, Dipeptidyl peptidase - 4 inhibitor

1. Introduction

The World Health Organization (WHO) describes diabetes mellitus as a chronic metabolic condition marked by high blood glucose levels that, over time, cause damage to the blood vessels, heart, eyes, kidneys, and nerves.[1] Type 2 Diabetes Mellitus (T2DM), a disorder characterized by insufficient insulin secretion from β - cells of the pancreatic islet, tissue insulin resistance (IR), and poor compensatory insulin secretory response.[2, 3] As the disease condition advances, insulin secretion becomes unable to keep glucose levels in balance, leading to hyperglycemia. Subjects with T2DM are typically obese or have a greater body fat percentage, which is primarily distributed in the abdomen area. Adipokine dysregulation and increased release of free fatty acids are two inflammatory mechanisms used by adipose tissue to enhance insulin resistance in this disease. The prevalence and incidence of T2DM have quadrupled as a result of population aging, sedentary lifestyles, high - calorie diets, and global obesity rates.[1, 4]

The International Diabetes Federation estimated that there were 537 million people worldwide with T2DM in 2021, and that number will rise to 783 million by 2045. At 74.2 million people, India was forecast to have the second - largest T2DM population in the world in 2021. By 2045, that number is expected to rise to 124.9 million.[5]

Although the treatment options for T2DM are expanding, changing one's way of life continues to be the cornerstone of its management. Metformin monotherapy was the initial focus of medication for T2DM. Early combination therapy was effective in subjects with greater glycosylated haemoglobin (HbA1c), but it is now also available for those with lower HbA1c levels.[6, 7]Although increasing the dosage of metformin monotherapy has improved glycemic control, the prevalence of gastrointestinal side effects has decreased patient compliance.[7]

As a result, the drawbacks of the stepwise increased therapy method call for new therapeutic approaches. Early adoption

of more aggressive combination therapy can be a successful strategy before responsiveness to monotherapy starts to decrease.[7]This strategy may offer two benefits: Greater glycemic control and the capacity to target several disease pathways implicated in glucose dysregulation. Additionally, early therapies help to reduce the development of T2DM illness and the related macrovascular and microvascular consequences.[8]

Therefore, numerous possible medications have been created to regulate glucose levels and lessen severe hypoglycemia. Vildagliptin and Sitagliptin are two members of a new class of antihyperglycemic drugs that help control blood glucose levels by blocking the enzyme dipeptidyl peptidase 4 (DPP - 4), which stops the breakdown of incretin hormones that promote insulin release. DPP - 4 inhibitors are oral medications that increase α - and β - cell activity, have a neutral effect on weight, have a low risk of hypoglycemia, and address numerous shortcomings of conventional therapy.[9, 10]

T2DM is treated with medications that target several different systems.[11] The incretins, specifically gastric inhibitory polypeptide (GIP) and glucagon - like peptide - 1 (GLP - 1) are inactivated by the gliptins, a relatively new class of oral antidiabetics when DPP - 4 is inhibited.[12] Improved glucose management and enhanced α - and β - cell sensitivity to glucose are the end results of extended incretin action.[13, 14] This makes this new class a strong option for use as an additional therapy to metformin to improve glycaemic control without producing weight gain or hypoglycemia episodes.[15] Sitagliptin and Vildagliptin, the two most commonly used gliptins, are chemically diverse species with differing properties for binding to DPP - 4: whereas the former is a competitive inhibitor, the latter acts as a substrate for the enzyme forming a reversible covalent complex with the catalytic site of DPP - 4 that dissociates slowly, eliciting prolonged DPP - 4 inhibition despite a rather short half - life of about 2 to 3 hours.[16]This increases intact GLP - 1 levels both after meals and during fasting, maintains suppressed glucagon levels, and reduces hepatic glucose synthesis overnight.[11, 17]

In this retrospective study, we sought to compare Vildagliptin 100 mg SR Tablets and Sitagliptin 100 mg Tablets directly among subjects with T2DM who were not adequately managed by metformin alone.

Vildagliptin's sustained - release formulation was developed to release 100 mg of the medication for an extended time at a programmed rate by using a polymer matrix structure that promotes the medications - controlled release. Drug release from tablets with a hydrophilic matrix occurs largely by diffusion as opposed to erosion. When fluid comes into contact with the tablet's surface during the diffusion process, the surface turns into a gel. The active pharmaceutical ingredient (API) then enters a state of dissolution once the gel creates a barrier to its diffusion. As a result, when the polymer matrix is hydrated, the gelation moves closer to the tablet's center.1[8]In vildagliptin 100 mg SR OD, microcrystalline cellulose (MCC) PH 112 serves as the polymer matrix. For sustained - release drug delivery systems, the MCC has been extensively used in the development of multi - particulate and matrix tablet dosage forms. MCC reported zero - order release profiles. This has been shown to not affect the variables utilized to make matrix tablets for drug release.[19] The polymer matrix system has fewer side effects, eliminates peak - to - trough fluctuations, and is not severely impacted by hydrodynamic or stomach pH conditions. Due to the regulated steady drug delivery, the normal peak and troughs of multiple dosing observed in the IR formulations can be completely bypassed.[20 - 23]

2. Materials and Methods

This was aSingle - centre, Retrospective, Comparative Clinical Study that reviewed subjects who had been diagnosed with type 2 diabetes mellitus at Seven Hills Hospital, Visakhapatnam, India. A total number of 340 subjects fulfilling the study criteria were recruited. The study was approved by Shah Lifeline Hospital and Heart Institute EC, Thane, Maharashtra, India. (CTRI Number: CTRI/2023/08/056116)

Adult subjects meeting all the following conditions will be included in the study: male or female subjects of >18 years of age diagnosed with T2DM, subjects who were on metformin at a stable dose for at least one month before enrolment, and subjects with HbA1c value between ≥8% to<11%. Subjects with a history of Type 1 Diabetes Mellitus and known hypersensitivity to any of the components of the formulation were excluded.

Subjects were enrolled in Treatment A (Vildagliptin 100 mg SR Tablets) (N=174) or Treatment B (Sitagliptin 100 mg Tablets) (N=166). The metabolic parameters were compared in terms of mean change of HbA1c, FBG, and PPPG from baseline to week 16.

Study Endpoints: The primary endpoint was to estimate the mean change in HbA1c from baseline to week 16 (Visit 3). The secondary endpoints were to evaluate the mean change in FBG and PPBG from baseline to week 16 (Visit 3).

Statistical data analysis was done using SAS 9.4. Descriptive statistical analysis was expressed as the means ± standard deviation. Continuous variables of the Treatment A= Vildagliptin group and the Treatment B= Sitagliptin group were compared and analyzed. A paired test was used for within - group analysis and Two - sample t - tests were used for between - group analysis. Statistical significance was considered at $p<0.05$.

3. Results

Baseline characteristics:

A total number of 340 subjects suffering from T2DM were included and analyzed; of which 174 subjects were in Treatment A (Vildagliptin group) and 166 subjects were in Treatment B (Sitagliptin group). Demographics and baseline characteristics of both groups are presented in Tables 1, 2, 3&4. The baseline HbA1cof subjects was 8.96 % ± 0.76 in Treatment A (Vildagliptin group) and 9.02% ± 0.72 in Treatment B (Sitagliptin group) ($P^{\#}$= 0.4233). The baseline FPG of subjects was 169.44 mg/dl ± 33.56in Treatment A

(Vildagliptin group) and 170.98 mg/dl ± 34.97in Treatment B (Sitagliptin group) ($P^{\#}$= 0.6789). The baseline PPBG of subjects was 255.16 mg/dl ± 50.85in Treatment A (Vildagliptin group) and 251.52 mg/dl ± 48.15 in Treatment B (Sitagliptin group) ($P^{\#}$= 0.4980). At baseline, no statistically significant differences were observed in all parameters between both treatments.

Change in the glycemic parameters after 16 weeks of treatment

After 16 weeks of treatment, all glucose parameters significantly decreased compared to baseline in both groups (Table 2, 3& 4). The mean reduction of HbA1c from baseline to visit 3 was 0.64 ± 0.23in Treatment A (Vildagliptin group) and 0.48 ± 0.22in Treatment B (Sitagliptin group) ($P^{\#}$= <.0001) (Table2). The mean reduction of FBG from baseline to visit 3 was16.26 ± 6.24 mg/dL in Treatment A (Vildagliptin group) and 13.31±3.47 mg/dL in Treatment B (Sitagliptin group) ($P^{\#}$= <.0001) (Table3). The mean reduction of PPBG from baseline to visit 3 was 43.67 ± 7.46 in Treatment A (Vildagliptin group) and 41.79 ± 7.82 in Treatment B (Sitagliptin group) ($P^{\#}$= 0.0238) (Table 4).

4. Discussion

Type 2 diabetes mellitus patients need long - term, chronic treatment, typically for many years. Considerable patient exposure is expected given the prevalence of diabetes. As a result of this, medicines approved for aiding these patients with glycemic control should have well - characterized safety profiles based on shorter - term research, while some potential concerns might not be discovered until after longer - term studies. To fully evaluate the drug's longer - term safety profile, the safety database of a novel antidiabetic medication for type 2 diabetes mellitus should also include a significant number of patients exposed to the treatment for longer periods. Additionally, patients with type 2 diabetes mellitus frequently have comorbid diseases as well as effects linked to diabetes (such as chronic renal disease and cardiovascular disease). To enhance glycemic control, it is crucial to assess the safety of novel medications in the patient group that will use them, which includes a significant number of patients with underlying cardiovascular disease, chronic kidney disease, and elderly people.[24]

This retrospective study compared the effects of Vildagliptin 100mg SR OD and Sitagliptin 100mg on various glucose metabolic parameters. The use of DPP - 4 inhibitors in combination with metformin has obtained attention because of its weight neutrality, modest efficacy, and safety. Moreover, DPP - 4 inhibitors act by increasing GLP - 1 and GIP and this leads to additional glucose - lowering effects. The efficacy of Vildagliptin and Sitagliptin were directly compared based on various glycemic parameters over 16 weeks of treatment. We found that Vildagliptin 100 mg SR Tabletsare more efficacious as compared to Sitagliptin 100 mg Tablets for glucose control in T2DM. Our study demonstrates better glycemic control with Vildagliptin as compared to Sitagliptin since the observed significant reduction in HbA1c, FBG, and PPBG levels was higher in Treatment A than in Treatment B.

In the present study, a total of 340 subjects were enrolled and divided into Treatment A (N=174) and Treatment B (N=166). Subjects were administered Vildagliptin 100 mg SR Tablets (Treatment A) and Sitagliptin 100 mg Tablets (Treatment B) once daily throughout 16 - week periods. The study observed the effect of vildagliptin and sitagliptin on various glucose metabolic parameters likeHbA1c, FBG, and PPBG. We observed the effect of study interventions within groups and between groups after 16 weeks of treatment and found that vildagliptin significantly reduced HbA1c level compared to sitagliptin from baseline to week 16. A 16 - week treatment study also explore the effect of investigational drug products within groups and between groups and found that there was a significant reduction in FBG and PPBG levels after treatment with vildagliptin as compared to sitagliptin.

This study has limitations because it is a retrospective study with a relatively short duration i. e.16 weeks only and was limited to a small sample size. We could not exclude the possibility of differences in drug compliance between the two medications. To gather more proof of the advantages of DPP - 4 inhibitors, long - term follow - up studies of diabetes are required.

5. Conclusion

This 16 - week research on T2DM patients resulted in a notable and clinically significant decrease in blood glucose levels. The findings of this retrospective study revealed that Vildagliptin and Sitagliptin have comparable efficacy profiles for controlling the level of various glucose parameters like HbA1c, FBG, and PPBG. Both drugs were well tolerated and were associated with low rates of hypoglycemia.

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Table 1: Demographic characteristics at baseline

Parameter	Treatment A	Treatment B
Total Number of Subjects	174	166
Age (Year)	55	55
Male	82 (47.12%)	80 (48.19%)
Female	92 (52.88 %)	86 (51.81%)
HbA1c (%)	8.96 ±0.76	9.02 ± 0.72
FBG (mg/dL)	169.44 ± 33.56	170.98 ± 34.97
PPBG (mg/dL)	255.16 ± 50.85	251.52 ± 48.15

Table 2: Mean change in HbA1C from baseline to Visit 3 (Week 16)

Visit	Statistics	Treatment (A)	Treatment (B)	P# value
Baseline	N	174	166	0.4233
	Mean	8.96	9.02	
	SD	0.76	0.72	
	(Min, Max)	(8.00, 10.80)	(8.00, 10.60)	
Visit 3	N	174	166	0.0090
	Mean	8.32	8.54	
	SD	0.80	0.77	
	(Min, Max)	(6.90, 10.10)	(6.90, 10.20)	
Mean Reduction from Baseline to Visit 3 (Week 16)	N	174	166	<.0001
	Mean	0.64	0.48	
	SD	0.23	0.22	

	SE	0.02	0.02	
	CI	(0.60, 0.67)	(0.44, 0.51)	
	p^+ - value	<.0001	<.0001	

Note: p^+ - value are calculated using paired tests for within - group analysis and $P^\#$ values are calculated using Two - sample t - tests for between - group analysis
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets

Table 3: Mean change in FBG from baseline to visit 3 (week 16)

Visit	Statistics	Treatment (A)	Treatment (B)	P# value
Baseline	N	174	166	0.6789
	Mean	169.44	170.98	
	SD	33.56	34.97	
	(Min, Max)	(129.50, 263.00)	(130.10, 265.00)	
Visit 3	N	174	166	0.2155
	Mean	153.18	157.66	
	SD	31.93	34.68	
	(Min, Max)	(115.30, 253.00)	(110.40, 251.80)	
Mean Reduction from Baseline to (Visit 3)	N	174	166	<.0001
	Mean	16.26	13.31	
	SD	6.24	3.47	
	SE	0.47	0.27	
	CI	(15.32, 17.19)	(12.78, 13.85)	
	p+/ - value	<.0001	<.0001	

Note: p+ - value are calculated using paired tests for within - group analysis and P# values are calculated using Two - sample t - tests for between - group analysis
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets

Table 4: Mean change in PPBG from baseline to visit 3 (week 16)

Visit	Statistics	Treatment (A)	Treatment (B)	$P^\#$ value
Baseline	N	174	166	0.4980
	Mean	255.16	251.52	
	SD	50.85	48.15	
	(Min, Max)	(164.50, 398.00)	(149.70, 395.20)	
Visit 3	N	174	166	0.7335
	Mean	211.49	209.73	
	SD	48.48	47.01	
	(Min, Max)	(140.30, 356.80)	(130.20, 359.10)	
Mean Reduction from Baseline to (Visit 3)	N	174	166	0.0238
	Mean	43.67	41.79	
	SD	7.46	7.82	
	SE	0.57	0.61	
	CI	(42.56, 44.79)	(40.59, 42.99)	
	p^+ - value	<.0001	<.0001	

Note: p^+ - value are calculated using paired tests for within - group analysis and $P^\#$ values are calculated using Two - sample t - tests for between - group analysis
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets

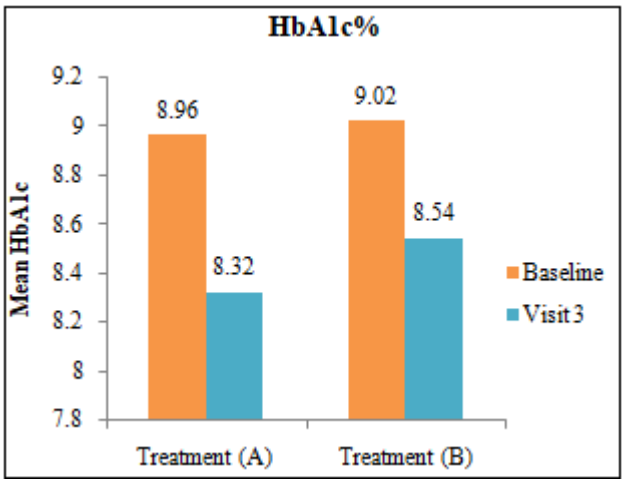

Figure 1: Change in HbA1C from baseline to Visit 3 (Week 16)
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets

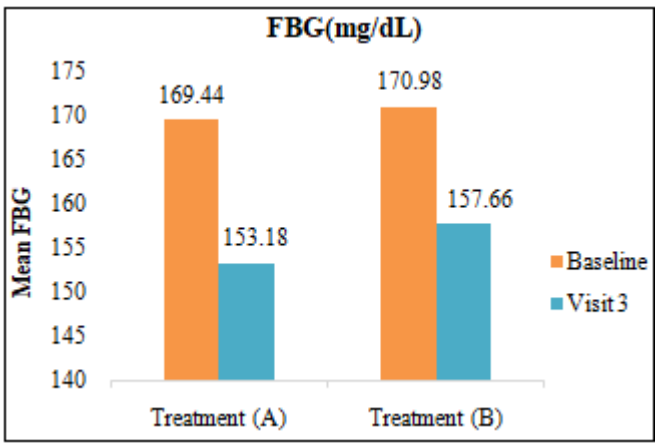

Figure 2: Change in FBG from baseline to visit 3 (week 16)
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets

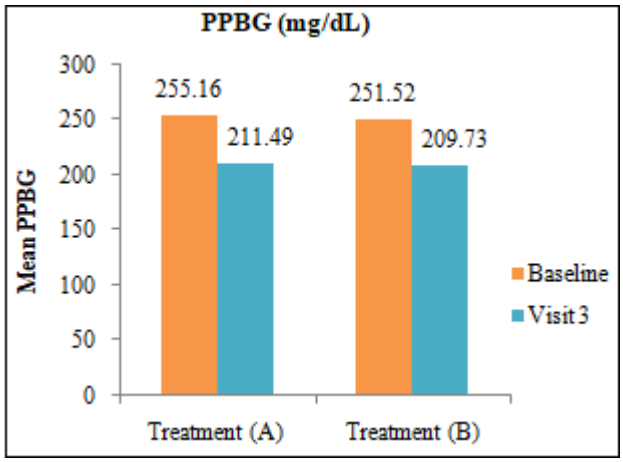

Figure 3: Change in PPBG from baseline to visit 3 (week 16)
Treatment A= Vildagliptin 100 mg SR Tablets Treatment B= Sitagliptin 100 mg Tablets