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Comparing the effect of Sitagliptin versus Glimepiride on lipid profile and BMI in known case of Type 2 Diabetes Mellitus

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Abstract

Background: Diabetes mellitus, the most common endocrine disease is represented by metabolic abnormalities due to relative or absolute deficiency of insulin and or insulin resistance. Dyslipidemia which is characterized by increased plasma levels of triglycerides (TG), low-density lipoprotein cholesterol (LDL-C) and decreased level of high-density lipoprotein cholesterol (HDL-C) is commonly seen in patients with type 2 diabetes. Metformin and Sulfonylureas (SU) like Glimepiride are the most commonly used oral antidiabetic agents. However, SU causes hypoglycemia and weight gain and hence, patients are shifted to other antidiabetic agents like Sitagliptin (DPP-4) inhibitor or insulin therapy **Objective:** To study was to assess the effect of Sitagliptin a (DPP-4 inhibitor) oral antidiabetic drug with Glimepiride on, BMI and dyslipidemia in type 2 diabetic patients. **Material and Methods:** This prospective comparative observational study was conducted in general medicine outpatient department at BRIMS teaching hospital, Bidar. The study starts from June 2022 to June 2023. The study period was 24 weeks. Group A**:** 75 Cases will be on Tab Sitagliptin 50 mg OD for 24 weeks. Patients will be asked to come for follow up at 12th week and 24th week. Group B**:** 75 Cases will be on Tab Glimepiride 1mg BD for 24 weeks. **Results:** There was reduction in BMI in Sitagliptin group (25.03 ±4.64 to 23.93 ±3.91) while Glimepiride showed a slight increase in body mass index (25.9± 4.47 to 26.3± 3.96). At 24 weeks, in comparison to Glimepiride group, Sitagliptin group had considerable reduction of Total Cholesterol, Triglycerides, and LDL-C while there was increase in HDL-C levels Speaking of Glimepiride. There was significant difference between both the groups with p value < 0.05 for all the parameters. **Conclusion:** Sitagliptin though primarily used in diabetes mellitus for the control of blood sugar, its favorable effects on BMI, and serum lipid cannot be denied. Hence Sitagliptin seems to be better option than Glimepiride.

Keywords: Sitagliptin, Diabetes Mellitus, Lipid profile, BMI.

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Introduction

Diabetes mellitus, the most common endocrine disease is represented by metabolic abnormalities due to relative or absolute deficiency of insulin and or insulin resistance. The international diabetic federation (IDF) in 2021 reported the countries with the largest number of adults with diabetes aged 20-79 years in 2021 are in China (140.9 million), India (74.2 million), and Pakistan (33 million).{1} Patients with diabetes experience significant morbidity and mortality from microvascular (retinopathy, nephropathy and neuropathy) and macrovascular (heart attacks, stroke, and peripheral vascular disease) complications.{2}

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Dyslipidemia which is characterized by increased plasma levels of triglycerides (TG), low-density lipoprotein cholesterol (LDL-C) and decreased level of high-density lipoprotein cholesterol (HDL-C) is commonly seen in patients with type 2 diabetes {3}

Metformin and Sulfonylureas (SU) like Glimepiride are the most commonly used oral antidiabetic agents. However, SU causes hypoglycemia and weight gain and hence, patients are shifted to other antidiabetic agents like Sitagliptin (DPP-4) inhibitor or insulin therapy {4, 5}

Sitagliptin a dipeptidyl peptidase 4 (DPP-4) inhibitors enhance the function of endogenous incretins causing glucose homoeostasis without the risk of hypoglycemia and weight gain {6}. Sitagliptin reduces HbA1c and delays the need for insulin therapy {7}. Sitagliptin leads to glycagon–like peptidase I (GLP-I) mediated decrease in intestinal lymph flow, inhibition of TG absorption from intestine and reduce very low-density lipoprotein (VLDL) from liver. (8) Altogether decrease of TC, TG, and LDL-C and increase of HDL-C have been reported in many clinical studies (9)

The present study was undertaken with the aim to assess the effect of Sitagliptin on lipid profile and BMI in comparison to Glimepiride in type 2 diabetic patients.

Materials and Methods

This prospective comparative observational study was conducted in general medicine outpatient department at BRIMS teaching hospital, Bidar. The study starts from June 2022 to June 2023. The study period was 24 weeks.

Approval and clearance from institutional ethical committee was obtained,

150 patients who met the inclusion/exclusion criteria and were willing to give inform consent was enrolled for the study.

Sample Size: The sample size had been estimated in consultation with a biostatistician based on previous year's case load and the sample size formula.

From the study by Devarajan TV *et al.*, using 95% Confidence limit and 90% power sample size of 68 was obtained in each group by using the below mentioned formula and Med calc sample size software. With 10% nonresponsive sample size of $68 + 6.8 \approx 74.8 = 75$ cases were included in each group (10)

Group A: 75 Cases will be on Tab Sitagliptin 50 mg OD for 24 weeks. Patients will be asked to come for follow up at 12th week and 24th week.

Group B: 75 Cases will be on Tab Glimepiride 1mg BD for 24 weeks

Inclusion criteria:

1) Patients with age between 40 to 65 years of either sex with type 2 diabetes mellitus attending medicine OPD

2) Patients who are willing to give inform consent

Exclusion Criteria;

1) Patients with type-1 diabetes mellitus.

2) Patients who had renal failure, congestive cardiac failure, severe respiratory diseases, hepatic insufficiency and other terminal illness.

3) A history hypersensitivity to any of the investigational agents and other drugs of their class

4) Alcoholic patients and substance abusive

5) Pregnant and lactating females.

6) Concomitant medications which is known to alter the sugar and lipid levels are not permitted

End points

1. Changes in Lipid profile (total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL), serum triglycerides at baseline and 24th week.

2. Changes in BMI from baseline to end of 24th week.

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Statistical analysis: Data will be entered into Microsoft excel data sheet and will be analyzed using SPSS 22 version software. Categorical data will be represented in the form of Frequencies and proportions. Chi-square will be the test of significance. Continuous data will be represented as mean and standard deviation. Independent t test will be the test of significance to identify the mean difference between two groups. p value <0.05 was considered as statistically significant.

Results

Total 150 participants were divided into 2 groups of 75 each i.e. Sitagliptin group consisting of 75 participants and Glimepiride group consisting of 75 participants respectively.

Table-1 shows the baseline demographics characteristics of age and sex wise distribution along with baseline body mass index of the participants in Sitagliptin and Glimepiride group.

Table 1: Baseline Characteristics

Parameters	**Sitagliptin n = 75**	**Glimepiride n = 75**
Age	58.4±9.78	58.01±6.75
Sex		
Female	33(44%)	39(52%)
Male	42(56%)	36(48%)
Body weight	67.57±8.37	68.33±8.76

Table-2 showed effectiveness of Sitagliptin on serum lipid profile levels in comparison to Glimepiride. When compared with the baseline parameters, at the end of 24 weeks for Sitagliptin group there was reduction of Total Cholesterol (180.97±35.19 to 167.14±24.9), Triglycerides (106.05±43.4 to 98.02±27.8) and LDL-C (105.71±21.42 to 94.12±19.61), while there was increase in HDL-C levels (45.60±10.46 to 49.96±6.89). Speaking of Glimepiride, there was reduction in TC (180.05±31.25 to 176.07±29.18), TG (108.77±36.44 to 107.75±31.84), and LDL-C (104.00±23.92 to 103.21±22.83). HDL-C levels (46.81±9.97 to 47.46±6.12) where meagerly increased. At 24 weeks there was significant difference between both the groups with p value < 0.05 for all the parameters.

Table 2: Effect of Sitagliptin and Glimepiride on serum lipid profile levels

Parameters	**Sitagliptin(n=75)**	**Glimepiride(n=75)**	**P-value**
Total cholesterol(TC)			
Baseline	180.97±35.19	180.05±31.25	0.866
24 weeks	167.14±24.9	176.07±29.18	0.0456
Triglycerides(TG)			
Baseline	106.05±43.4	108.77±36.44	0.678
24 weeks	98.02±27.8	107.75±31.84	0.048
LDL-C			
Baseline	105.71±21.42	104.00±23.92	0.646
24 weeks	94.12±19.61	103.21±22.83	0.0098
HDL-C			
Baseline	45.60±10.46	46.81±9.97	0.469
24 weeks	49.96±6.89	47.46±6.12	0.042*

Table-3 showed that in comparison to baseline, after 24 weeks of treatment, there was reduction in BMI in Sitagliptin group (25.03 ±4.64 to 23.93 ±3.91) while Glimepiride showed a slight increase in body weight (25.9± 4.47 to 26.3± 3.96). However when both the groups were compared there was statistical significance with p-value < 0.05

Table 3: BMI

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BMI	Sitagliptin	Glimepiride	P-value
Baseline	25.03 ±4.64	25.9± 4.47	0.243
24 weeks	23.93 ±3.91	26.3± 3.96	0.0003

Discussion

This study was conducted in 150 patients divided into two groups of 75 each. The study compared the effect of Sitagliptin 50mg OD versus Glimepiride 1mg BD. The results of the study showed decrease in BMI which was statistically significant (p value <0.05) in Sitagliptin group when compared with Glimepiride group. The findings of the study were similar to the study done by Amjad Abrar *et al.* (11)

This revealed significant difference in weight as well as other parameters for glycemic control in the two groups. It was concluded as that Sitagliptin is as efficacious as Glimepiride in reduction of weight. Sitagliptin has neutral or mild weight reducing effect. Moreover it has beneficial effect on serum lipid profile either alone or in combination. Findings in these studies were in accordance with our study

Sitagliptin has neutral or mild weight reducing effect. Moreover it has beneficial effects on serum lipid profile either alone or in combination. Findings in these studies were in accordance with our study. (12-15)

At the end of 24 weeks, it was found that there was reduction in TC, TG, and LDL-C levels while HDL-C increased which were statistically significant with p-value <0.05. These findings from our study were found to be similar to the one done by

W.HELEN and E.BHAVYA (16)

In contrast to the findings from our study, a study conducted by Shigematsu E. *et al.*[17] had shown the changes in lipid profile after Sitagliptin treatment, the HDL level & Triglyceride level were not significantly (p>0.05) reduced after 12 weeks of Sitagliptin treatment from baseline. Another study by Garimella S. *et al.*[18] had reported significant (p<0.05) reduction in triglycerides. Fan M et.al.[19] had concluded that Sitagliptin alone or in combination significantly (p<0.001) improved serum HDL-C levels & serum triglycerides (TGs) in patients with type 2 diabetes mellitus.

Study by Hussain M *et al.*(20) on Sitagliptin started early in diabetics whose lipid profile have not been deranged, then it will not only improve blood sugar but also produces its positive effects on blood pressure and lipid profile, which are cardinal risk factors for cardiovascular disease and its related complications.

Conclusion

Although Sitagliptin is used primarily for glycaemic control in diabetic patients, its favorable effects on blood pressure, body weight, BMI, and serum lipid cannot be denied. With the results from our study and that of findings from other literatures, we can conclude that Sitagliptin has an upper hand in comparison to Glimepiride.

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