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A COMPARATIVE CLINICAL INVESTIGATION ON LIPID-LOWERING EFFECTS OF SITAGLIPTIN AND METFORMIN IN TYPE II DIABETIC DYSLIPIDEMIA.

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ABSTRACT

BACKGROUND: Diabetic dyslipidemia is an imbalance of lipid profiles in diabetic patients that exacerbate higher risk of cardiovascular complications. Among anti-diabetic agents Metformin, is first-line biguanide and Sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, are widely utilized owing to its emerging and promising effects on lipid metabolism, nevertheless their comparative and combined outcomes on lipid profiles remains as a major area of investigation. The objective of our study was to evaluate the effects of Metformin as monotherapy and combination of Sitagliptin along with metformin on the lipid profile in type II diabetic patients. **METHODS:** This randomized, prospective controlled study was conducted involving 100 patients diagnosed with type II diabetes. The patients were divided into three treatment groups; group-I had received Sitagliptin 50 mg twice daily; group-II was administered Metformin 500 mg twice daily; and patients in group-III had received combination therapy of Sitagliptin (50 mg once daily) and Metformin (500 mg twice daily) over a period of 36-week. The blood samples were collected at baseline, 18th and 36th week analyzed for biochemical lipid parameters including total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL), very-low-density lipoprotein (VLDL), and low-density lipoprotein (LDL). Statistical analysis was performed using SPSS 24.0, applying two-way ANOVA and paired *t*-test with level of significance set at $p<0.05$**. RESULTS:** Sitagliptin, Metformin, and their combination exhibited significant improvement in lipid profiles in Type II diabetic patients. Both anti-diabetic agents as monotherapy reduced TC, TG, VLDL, and LDL, with significant increase in HDL. Metformin demonstrated a marginally higher reduction in TC and TG levels, while Sitagliptin displayed modest but favorable outcomes. The combination treatment resulted in the most pronounced improvement in all lipid biochemical parameters, suggesting a possible synergistic effect. **CONCLUSION:** This study reveals that the combination of Metformin and Sitagliptin is superior in targeting diabetic dyslipidemia therefore; it may be considered a favorable option in the comprehensive management of type II diabetes.

KEYWORDS: Type II Diabetes Mellitus, Dyslipidemia, Lipid Profile, Metformin, Sitagliptin

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INTRODUCTION

Diabetes mellitus is a metabolic disorder characterized by progressive hyperglycemia resulting from impaired insulin secretion, resistance to peripheral insulin action, or both[1]. Among its major complications, dyslipidemia is a significant concern in the Asian population, marked by aberrations in lipid metabolism, including elevated levels of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG), along with reduced high-density lipoprotein cholesterol (HDL-C)[2.] This condition substantially increases the risk of cardiovascular events, thereby contributing to higher mortality rates among diabetic individuals. Therefore, controlling lipid profile is a critical strategy in the management of diabetes[3].

Metformin, a first-line antidiabetic agent, is widely prescribed in clinical practice for type II diabetes. It reduces hepatic gluconeogenesis, thereby lowering fasting blood glucose levels. Metformin is known for its favorable efficacy and safety profile,[4,5] contributing to modest cardioprotection and improvements in lipid parameters and inflammatory markers[6].

Sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, has also gained considerable clinical use[7]. It augments the action of incretin hormones, thereby suppressing glucagon secretion and improving glycemic control. Beyond its hypoglycemic effects, Sitagliptin also affects lipid metabolism through adiponectin, a hormone that regulates lipid homeostasis and insulin sensitivity. Furthermore, Sitagliptin contribute to the reduction of postprandial lipemia, a key contributor to atherogenesis in diabetic patients[8, 9.] Previous studies have reported its role in normalizing the lipid profile in patients with type II diabetes[10, 11]. Literature also supports the combination of Sitagliptin and Metformin to produce pleiotropic effects. [12]Concerning the global burden of type II diabetes and its complications, it is essential to investigate the comparative effectiveness of widely utilized antidiabetic agents not only in monitoring blood glucose levels but also in modulating lipid profiles. Therefore, the current study aims to perform a comparative clinical evaluation of the lipid-modulating effects as metformin monotherapy and combined effects of Sitagliptin and Metformin in type II diabetes associated dyslipidemia. By analyzing their influence on significant lipid parameters this investigation seeks to offer evidence-based insights that may support an optimal treatment strategy that may provide optimal treatment approaches addressing both glycemic and lipid abnormalities.

METHODS

This randomized, prospective, parallel-group study was conducted from June, 2023, to September, 2024, at Outpatient's Department of Medical Unit-2 of People University of Medical & Health Sciences for Women, Shaheed Benazirabad, (Nawabshah), Sindh-Pakistan.

The study included patients diagnosed with type II diabetes mellitus (T2DM) who also presented with altered lipid profile. A non-probability consecutive sampling technique was employed to recruit participants who met the inclusion criteria, ensuring a sample size of 100 with a 95% confidence interval (CI). Patients were excluded if they were younger than 40 or older than 60 years. Individuals with normal lipid levels or comorbid conditions such as liver disease, endocrine disorders, pulmonary tuberculosis, renal failure, or those already taking medications for diabetes or dyslipidemia were also excluded. Ethical approval for the study protocol was obtained from the Ethical Review Committee, PUMHSW. The study adhered to the Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Participants. All eligible participants provided written informed consent prior to enrollment. Patient

confidentiality was strictly maintained by anonymizing all records and avoiding the collection of any identifying information.
The screening was conducted according to a predefined protocol, including a detailed medical history and clinical examination. Baseline data for each patient including age (years), fasting blood sugar (mg/dL), HbA1c (%), and body mass index (BMI, kg/m²) were recorded. Patients were diagnosed diabetic according to the American Diabetes Association (ADA) guidelines for the diagnosis of diabetes.
The patients were divided into three groups; group-I had received Sitagliptin 50 mg twice daily; group-II was administered Metformin 500 mg twice daily; and patients in group-III had received combination therapy of Sitagliptin (50 mg once daily) and Metformin (500 mg twice daily) over a period of 36-week. All study drugs were taken by oral route. The study subjects were provided with detail instructions regarding medication administration: Metformin was taken with meals to reduce gastrointestinal side effects, while Sitagliptin could be taken with or without food [13, 14].
Blood samples were collected from the antecubital vein after 12 hours of fasting at three time intervals: baseline (week-0), mid-point (18th week), and end-point (36th week). All samples were centrifuged at 3000 rpm for 10 minutes to separate serum, which was stored at -80°C until biochemical analysis. HbA_1C was measured using the tetra-decyl-trimethyl ammonium bromide assay method, while fasting blood sugar was determined using the glucose oxidase method 15. Lipid parameters, including total cholesterol (TC) and triglycerides (TG) were analyzed using a standard enzymatic colorimetric method. Other parameters such as VLDL-C, HDL-C, and LDL-C were also measured using the precipitant technique [16]. All statistical analyses were performed using SPSS software version 24 (SPSS Inc., Chicago, IL). Data was processed in MS-Excel to calculate mean ± standard deviation. A two-way ANOVA was used to compare lipid parameters among the different treatment groups. Additionally, a paired sample *t*-test was applied to examine the changes in biochemical parameters. *P*-value 0.05 was considered as statistically significant.

RESULTS

120 patients were initially screened, out of that 20 patients were excluded because 5 were on anti-hyperlipidemic drugs and the rest could not followed-up. Data was analyzed for the 100 patients whose age ranged from 35 to 65 years (80 males and 20 females). During the initial screening, we have found that their blood glucose levels and HbA1C levels were raised.
Table-1 has outlined the selected patient's demographic characteristics. At baseline the total number of study subjects were 100, who had variable clinical and demographic characteristics between the two treatment groups (Metformin and Sitagliptin). The study participants in the Metformin group were found to be of 52.1 ± 6.2 years, and in the Sitagliptin group they were of 51.7 ± 6.3 years. Body mass index (BMI) of the Metformin group was (29.2 ± 3.0 Kg/m²) and the Sitagliptin group was (29.7 ± 3.4 Kg/m²). We had observed that the fasting blood sugar (FBS) level at baseline was elevated in both the groups, however, the FBS level in Sitagliptin group (336 ± 92 mg/dL) was significantly higher than the Metformin group (256 ± 75 mg/dL). Whereas, the level of HbA1c in patients who had received Sitagliptin (8.3 ± 1.2%) was significantly higher than Metformin group (7.5 ± 1.7%). The mean duration of type II diabetes was 12.4 years.

Table-2, and Figure- 1 showing the baseline total cholesterol level which was 214±28 mg/dL (It was reduced to 198 ± 26 mg/dL with Sitagliptin at 18 weeks and it was further reduced to 187±24 mg/dL at 36 weeks. In the Metformin group, the total cholesterol level was 204 ± 27 mg/dL

at 18 weeks and further decreased to 191±25 mg/dL at 36 weeks. We have observed a highly significant reduction in all the treatment groups with regards to total cholesterol p<0.001 while with the Sitagliptin it showed 1.9% greater reduction than Metformin at the 36 weeks. At baseline serum triglycerides (TG) level was 186±33 mg/dL, but after 18 weeks of Sitagliptin therapy it was reduced to 172±30 mg/dL and which further reduced to 158±27 mg/dL at 36 weeks. The TG levels in the Metformin group were 175± 29 mg/dL at 18 weeks and 163±27 mg/dL at 36 weeks, respectively. Both the treatment groups had achieved progressive reductions in TGs, while Sitagliptin group alone had achieved somewhat greater reduction at 36 weeks.

We have noticed that at baseline, VLDL-C was 38.6±6.5 mg/dL that decreased with the Sitagliptin treatment to 36.7±6.0 mg/dL at the 18 weeks, and further decreased to 34.0 ±5.8 mg/dL at 36 weeks. In comparison with the Metformin, it was found to be 36.5±5.9 mg/dL at 18 weeks and 34.5±5.7 mg/dL at 36 weeks. Sitagliptin showed moderate declines at 36 weeks.

LDL-C level at the baseline was 133±23 mg/dL. With the 18 weeks of Sitagliptin treatment, LDL-C level was observed 121±22 mg/dL. It further reduced to 113±19 mg/dL at 36 weeks. Compared to Metformin, LDL-C level was noted as 126±25 mg/dL at 18 weeks, which further declined to 118±22 mg/dL at 36 weeks. Sitagliptin has reduced LDL-C levels by 3.7% more than Metformin therapy by the 36th week, proving its efficacy in reducing the atherogenic lipids. HDL-C was 45±8 mg/dL at the baseline. We data shows that Sitagliptin had raised HDL-C levels to 48±6 mg/dL at 18 weeks which further raised HDL-C to 50±6 mg/dL at 36 weeks. Contrary to this, Metformin raised HDL-C from 45±8 mg/dL at baseline to 47±8 mg/dL at 18 weeks. This slight increase in HDL-C was found to be 49±7 mg/dL at 36 weeks. It has been proved that both treatment regimens increased HDL-C.S

Table-1 Baseline Parameters of Study Subjects (n=100)

Variables	Metformin	Sitagliptin
Age (years)	52.1 ± 6.2	51.7 ± 6.3
BMI (Kg/m^2)	29.2 ± 3.0	29.7 ± 3.4
FBS (mg/dl)	256 ± 75	336 ± 92
HbA_1C (%)	7.5 ± 1.7	8.3 ± 1.2

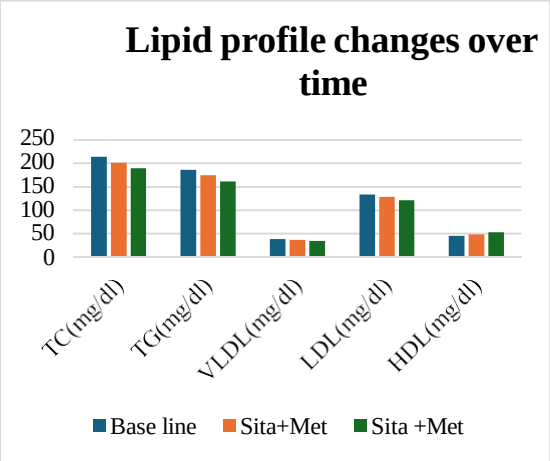
Table-2 The Effects of Sitagliptin and Metformin Treatment on Lipid Parameters.

Parameters	At Baseline (mg/dl)	Sitagliptin (18^{th} week)	Sitagliptin (36^{th} week)	Metformin (18^{th} week)	Metformin (36^{th} week)	*P* value
Total Cholesterol	214± 28	198± 26	187± 24	204 ± 27	191± 25	
Triglycerides	186± 33	172± 30	158± 27	175± 29	163± 27	<0.001
VLDL-C	38.6± 6.5	36.7± 6.0	34± 5.8	36.5± 5.9	34.5± 5.7	
LDL-C	133± 23	121± 22	113± 19	126± 25	118± 22	
HDL-C	45± 8	48± 6	50± 6	47± 8	49± 7	

All values were measured in mg/dl.

*Statistically significant values <0.05 by paired simple *t*-test.

FIGURE 1 COMPARISON OF THE CHANGE OF BIOCHEMICAL PARAMETERS IN THE TWO GROUPS



DISCUSSION

Sitagliptin and Metformin have a documented lipid-regulating effect in diabetic patients, with their therapeutic efficacy well-established in various research studies. This study investigates the effects of these two antidiabetic agents, both as monotherapy and in combination, on the lipid profile in type II diabetic patients. The duration of the study was from 18th to 36th week. The data indicates that add-on therapy was more effective and superior in lipid control. There were significant decreases in all lipid parameters and a favorable change in HDL-C levels compared to single-agent therapy. We found that, as treatment continued over 36 weeks, both Sitagliptin and Metformin showed reduced total cholesterol (TC) levels, separately and in combination. These significant outcomes may be attributed to the complementary mechanisms of the two drugs. Metformin modulates insulin sensitivity and inhibits hepatic cholesterol synthesis, while Sitagliptin stimulates incretin hormones, thereby promoting lipid metabolism[18, 19].

The lipid-regulating effect of add-on therapy is in line with the research reported by Ahmed et al.[20], where Sitagliptin combined with Metformin was more effective in reducing LDL-C and total cholesterol. Hypertriglyceridemia, a hallmark of type II diabetes, is linked to an increased risk of atherogenesis[21]. Here, significant differences in triglyceride (TG) levels were identified in both monotherapy and in combination, with the combination group showing a 7.4% reduction. Since triglyceride metabolism is connected to VLDL-C levels, improvements in TG levels were observed. We observed that both drugs, whether used alone or in combination, led to a reduction in VLDL-C levels, which enhances hepatic clearance of triglyceride-rich lipoproteins, thereby promoting synergistic lipid-lowering effects[22]. In one study, it was reported that diabetic individuals exhibited a significant decline ($p<0.05$) in LDL-C levels, which has been regarded as a critical indicator of cardiovascular complications[23]. Our results are similar to those reported by Wu et al[24]. High-density lipoprotein cholesterol is known for its cardioprotective effects and prevents the risk of plaque formation[25]. Here, the value of HDL-C was recorded to be higher in all treatment groups, particularly in the combination group. Greater HDL-C levels have been linked to improved cardiac health. Derosa, G., et al[26] has also reported similar results. Given that cardiovascular disease represents the major cause of death in diabetes, the combination of Sitagliptin and Metformin is unique in significantly reducing TG, TC, LDL-C, and VLDL-C, while improving HDL-C levels ($p<0.05$). Further, no significant adverse events were reported, signifying good tolerability of the combination regimen. So for as treatment efficacy is concerned, the results of our study revealed that Sitagliptin consistently outperformed Metformin across all atherogenic lipids (TC, TG, LDL-C and VLDL-C) at both 18 and 36 weeks, with the differences most pronounced for LDL-C (15.0% vs. 11.3% reduction) and total cholesterol (12.6% vs. 10.7%) at 36 weeks. We have noted that the maximum lipid improvements occurred at 36 weeks,

confirming the sustained therapeutic efficacy of both drugs. HDL-C elevation progressed linearly with Sitagliptin (+6.7% → +11.1%), whereas Metformin's effect plateaued after 18 weeks (+4.4% → +8.9%). The significant reduction in total cholesterol ($p<0.001$) validates the impact of both treatments on cholesterol metabolism. The observed declines in atherogenic lipids i.e., TC, LDL-C, and VLDL-C which suggest diminish cardiovascular risk, while the concomitant beneficial effects on HDL-C, which enhances reverse cholesterol transport, may further alleviate the atherosclerosis risk.

CONCLUSION

This study confirms that Sitagliptin and Metformin significantly improved the serum lipid profile over 36 weeks, demonstrating progressive reductions in pro-atherogenic parameters (TC, TG, LDL-C, and VLDL-C) and beneficial elevations in cardioprotective HDL-C. Sitagliptin's superior efficacy in LDL-C reduction (−15.0% vs. −11.3%) and HDL-C elevation (+11.1% vs. +8.9%) suggests enhanced metabolic benefits in long-term therapy. The statistically confirmed TC reduction ($p<0.001$) emphasize both agents' value in dyslipidemia management in type II diabetic patients. These outcomes contributes to the therapeutic benefits of combining Metformin with Sitagliptin to target optimized lipid and glucose control and therefore lowers the cardiovascular risk in such kind of patients.

ETHICS APPROVAL: The ERC gave ethical review approval.

CONSENT TO PARTICIPATE: written and verbal consent was taken from subjects and next of kin.

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CONFLICT OF INTEREST: No competing interest declared

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