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Impact of basal insulin analog (Glargine) treatment duration on lipid profile and glycemic parameters in poorly controlled type 2 diabetic patients

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Abstract

Background: This 12-month study assesses the effects of basal insulin analog (glargine) treatment duration on glycemic parameters and lipid profiles in patients with poorly controlled type 2 diabetes.

Methods: Patients with type 2 diabetes mellitus (T2DM) aged 30-70 years who had an HbA1c ≥ 6.5% despite taking oral hypoglycemic agents were included in this observational study. Insulin glargine was started, and baseline and interval lipid profiles, as well as glycemic parameters such as fasting blood glucose (FBG), postprandial blood sugar (PPBS), and HbA1c, were measured. For the first three months, follow-ups were done monthly; after that, they were done every three months.

Results: Important improvements were seen in key biochemical parameters over the course of the 12-month period. Both FBG and PPBS saw significant drops, falling from 328.81 mg/dL to 109.53 mg/dL ($p < 0.00$) and 375.07 mg/dL to 161.34 mg/dL ($p < 0.00$). HbA1c values decreased ($p = 0.01$) from 11.75% to 7.03%. Improvements in lipid profiles were also noteworthy, with HDL rising from 29.4 mg/dL to 42.5 mg/dL ($p < 0.00$) and significant decreases in total cholesterol, LDL, triglycerides, and VLDL ($p < 0.05$).

Conclusion: The findings show that in poorly controlled type 2 diabetic patients, prolonged insulin glargine therapy significantly improves lipid profiles and glycemic control. This points to a beneficial impact on overall metabolic health, thereby endorsing glargine as a viable treatment option for the long-term control of type 2 diabetes.

Keywords: Glargine, lipid profile, glycemic parameters and type 2 diabetes

Introduction:

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive β-cell dysfunction, leading to hyperglycemia [1]. To avoid both acute and long-term complications, such as retinopathy, nephropathy, neuropathy, and cardiovascular diseases, effective management of type 2 diabetes is essential. Usually, insulin therapy, oral hypoglycemic medications, and lifestyle changes are used to achieve glucose control. Insulin glargine and other basal insulin analogs have become essential for treating patients with poorly controlled diabetes among the different types of insulin therapies [2,3].

A long-acting basal insulin analog, insulin glargine replicates the pancreas' normal basal insulin secretion by giving a steady, peakless insulin level [4]. Compared to other insulin formulations, it has been demonstrated to enhance glycemic control with a lower risk of hypoglycemia. Still under investigation, though, is how insulin glargine affects the lipid profiles of T2DM patients [5]. Dyslipidemia is common in T2DM patients and significantly raises their risk of cardiovascular disease. It is characterized by elevated triglycerides, low high-density lipoprotein (HDL) cholesterol, and increased low-density lipoprotein (LDL) cholesterol [6, 7]. The purpose of this study is to look into how long-term insulin glargine treatment affects glycemic parameters and lipid profiles in patients with poorly managed type 2 diabetes. Comprehending these impacts is essential for refining therapeutic approaches to enhance metabolic regulation and cardiovascular consequences in this high-risk cohort. This study aims to shed light on the possible hazards and long-term advantages of prolonged insulin glargine therapy by evaluating changes in glycemic parameters and lipid profiles over time.

Materials and Methods: The study was carried out in the Department of Medicine, Santosh Medical College and Hospital, Ghaziabad, on patient who attended the medicine OPD/IPD of Santosh hospital. This 12-month observational study intends to assess the effects of basal insulin analog (glargine) treatment duration on glycemic parameters and lipid profiles in patients with type 2 diabetes who was not well controlled.

Study Protocol: A baseline assessment, comprising a thorough medical history and the measurement of baseline glycemic parameters like HbA1c, fasting blood glucose (FBG), and postprandial glucose (PPG), was conducted before the study even started. The baseline lipid profile was also evaluated, encompassing triglycerides, total cholesterol, LDL cholesterol, and HDL cholesterol. Based on fasting blood glucose levels, dose adjustments for insulin glargine therapy were started. Instructions on correct administration methods and self-blood glucose

monitoring were given to the patients. Up until the study's conclusion, follow-up evaluations were conducted every three months after starting on a monthly basis. Adjustments to insulin dosage, postprandial glucose, and fasting blood glucose levels were noted at every visit. Reassessments of the lipid profile and HbA1c were performed at baseline, 3, 6, 9, and 12 months later.

Laboratory Measurements: The three glucose parameters were postprandial glucose, which was measured with a glucometer two hours after a standardized meal, fasting blood glucose, which was measured with a standardized glucometer, and HbA1c, which was measured with a Nycocard HBA1c Analyzer. Enzymatic colorimetric techniques were used to evaluate the lipid profile, which includes triglycerides, total cholesterol, LDL cholesterol, and HDL cholesterol.

Statistical Analysis: Version 25.0 of the SPSS software was used to analyze the data. The baseline characteristics were summarized using descriptive statistics, and the duration of insulin glargine therapy was assessed in relation to changes in glycemic and lipid parameters using Pearson correlation analysis. All data will be deemed statistically significant if the p-value is less than 0.05.

Results: The table no. 1 reflects data on various biochemical parameters measured at different time intervals (0, 3, 6, 9 and 12 months) and the associated p-values indicating statistical significance over time.

Table no. 1: **Showing lipid profile and glycemic parameters measured at different time intervals.**

Duration (months)	**FBG**	**PPBS**	**HbA1c**	**TC**	**LDL**	**HDL**	**TG**	**VLDL**

0	328.81	375.07	11.75	279.63	191.46	29.4	239.7	47.94
3	254.6	300.3	9.3	265.5	176.7	32.6	201.6	44.6
6	187.4	246.6	8.6	245.6	153.6	36.5	195.4	42.8
9	134.6	200.1	7.6	221.3	145.9	39.8	184.6	39.6
12	109.53	161.34	7.03	204.5	135.6	42.5	177.6	35.35
R-value	-0.99	-0.99	-0.96	-1.00	-0.98	1.00	-0.92	-0.99
P-value	0.00**	0.00**	0.01**	0.00**	0.00**	0.00**	0.00**	0.01**

**. Correlation is significant at the 0.01 level

*. Correlation is significant at the 0.05 level

Significant gains were observed in a number of biochemical parameters over a 12-month period. Postprandial blood sugar (PPBS) fell from 375.07 mg/dL to 161.34 mg/dL (p-value: 0.00), while fasting blood glucose (FBG) fell from 328.81 mg/dL to 109.53 mg/dL (p-value: 0.00). Together with a significant drop in LDL and total cholesterol (TC), HbA1c fell from 11.75% to 7.03% (p-value: 0.01). HDL rose from 29.4 mg/dL to 42.5 mg/dL (p-value: 0.00), and levels of VLDL and TG decreased with statistically significant p-values. Overall, over the course of the 12-month period, these results show a significant improvement in both lipid profile and glycemic control, indicating a positive impact on overall metabolic health.

Discussions: The study's findings demonstrate how, over the course of a year, treatment with the basal insulin analog Glargine significantly improved the lipid profiles and glycemic parameters in patients with poorly controlled type 2 diabetes. These results show that long-term insulin therapy is effective in improving glycemic control as well as lipid metabolism modulation, which is important in lowering cardiovascular risks associated with diabetes.

Improved daily glucose regulation is indicated by the significant drop in both postprandial blood sugar (PPBS) and fasting blood glucose (FBG) levels. While PPBS decreased from 375.07 mg/dL to 161.34 mg/dL, FBG levels fell from 328.81 mg/dL to 109.53 mg/dL. The two alterations had p-values of 0.00 and 0.00, respectively, indicating statistical significance. The drop in FBG and PPBS indicates that basal insulin analog Glargine, which offers consistent insulin coverage, aids in the efficient management of hyperglycemia in patients with inadequate control [8]. The idea that glycemic control is improved over the long term by glargine therapy is further supported by the fact that the HbA1c decreased from 11.75% to 7.03% (p-value: 0.0106). The risk of complications from diabetes is directly correlated with HbA1c, a critical indicator of chronic hyperglycemia. Securing a noteworthy reduction in HbA1c indicates that Glargine treatment produces long-lasting enhancements in total glucose levels and lessens the probability of microvascular and macrovascular issues [9, 10].

The lipid profile, a crucial component of cardiovascular health in diabetic patients, significantly changed in the study along with improvements in glycemic parameters. There were significant drops in the levels of both low-density lipoprotein (LDL) and total cholesterol (TC), with LDL falling from 191.46 mg/dL to 135.6 mg/dL (p-value: 0.0026) and TC falling from 279.63 mg/dL to 204.5 mg/dL (p-value: 0.0002). Since high low-density lipoprotein (LDL) is a known risk factor for atherosclerosis, these results imply that long-term Glargine use may lower the risk of cardiovascular disease by enhancing lipid parameters. The protective factor for cardiovascular health, high-density lipoprotein (HDL), on the other hand, increased significantly from 29.4 mg/dL to 42.5 mg/dL (p-value: 0.00). Elevated HDL levels are advantageous because they are linked to a lower risk of heart disease in individuals with diabetes. Similarly, during the course of the 12-month treatment period, there were notable drops in the levels of TG and VLDL

(very low-density lipoprotein). VLDL dropped from 47.94 mg/dL to 35.35 mg/dL (p-value: 0.01), and TG dropped from 239.7 mg/dL to 177.6 mg/dL (p-value: 0.025). Given that these two parameters are known to be strongly associated with insulin resistance and metabolic syndrome, lowering them even more confirms the advantageous effects of glargine on general metabolic health [11-.13]

Conclusion: Finally, in poorly controlled type 2 diabetic patients, basal insulin analog Glargine shows significant improvements in both glycemic control and lipid profile. Glargine is an effective treatment option for comprehensive diabetes care because of the long-term reduction in FBG, PPBS, HbA1c, and lipid levels, which suggests that Glargine not only helps achieve better glucose management but also lowers cardiovascular risk. Furthermore, the steady gains noted during the course of the 12-month period imply that longer-term Glargine therapy may be required to fully reap its benefits. These findings highlight the significance of long-term insulin therapy for the treatment of type 2 diabetes, especially in patients whose blood sugar control is inadequate when using oral hypoglycemic medications alone.

Limitations and Future Research: Notwithstanding the study's evident advantages, it is critical to recognize its limitations. It is challenging to credit Glargine therapy alone for all improvements due to the absence of a control group. Furthermore, patient adherence to treatment was not evaluated in the study, which may have an impact on results. To confirm Glargine's effectiveness in lipid and glycemic control, bigger sample sizes and randomized controlled trials should be used in future studies. Furthermore, examining the process through which Glargine enhances lipid parameters may offer important insights into its more extensive metabolic effects.

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