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Effects of basal insulin analog (Glargine) on poorly controlled type 2 diabetic patients

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ABSTRACT:

Introduction: This study explores the therapeutic effects of the basal insulin analog Glargine on patients with poorly controlled type 2 diabetes mellitus (T2DM). The aim of the study was to evaluate the effects of Glargine on the body mass index (BMI), lipid profiles, and glycemic control in these patients. Glargine was given to a group of patients with poorly managed type 2 diabetes and they were observed for a predetermined amount of time. **Method:** This cohort study assessed the body mass index (BMI), lipid profile, and glycemic control in patients treated with Glargine. **Results:** Substantial drops in HbA1c levels were indicative of significant improvements in glycemic control. According to the findings, Patients' mean HbA1c decreased, indicating that Glargine was effective in reducing blood sugar levels and improving glycemic stability overall. In addition, the study found that lipid profiles had significantly improved. High-density lipoprotein (HDL) levels rose and total cholesterol and low-density lipoprotein (LDL) levels dropped considerably, indicating a positive effect on cardiovascular risk factors linked to diabetes. It's interesting to note that BMI changes were not significant, despite notable improvements in lipid profiles and glycemic control. This shows that the glycemic and lipid regulatory effects of glargine do not significantly affect body weight, which makes it a good choice for long-term T2DM management without the risk of weight gain, a common side effect of other insulin therapies. **Conclusion:** Glargine effectively manages glucose and lipid parameters without significantly impacting body weight. These findings underscore Glargine's potential as a beneficial treatment in managing poorly controlled T2DM.

Keywords: Glargine, Diabetes, Glycemic control, lipid profile

INTRODUCTION: Type 2 Diabetes mellitus is a pervasive and progressively debilitating metabolic disorder characterized by chronic hyperglycemia due to insulin resistance and relative insulin deficiency [1]. The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030 [2]. Despite advancements in therapeutic interventions, a significant number of patients with type 2 diabetes fail to achieve optimal glycemic control, leading to an increased risk of complications such as cardiovascular disease,

neuropathy, retinopathy, and nephropathy [3, 4]. Among the therapeutic options available, insulin therapy remains a critical component, especially for patients whose condition is poorly controlled with oral antidiabetic drugs and lifestyle modifications alone [5].

Basal insulin analogs, particularly Glargine, have revolutionized the management of type 2 diabetes by providing a more physiologically consistent insulin profile. Glargine, a long-acting insulin analog, is designed to maintain a steady level of insulin in the bloodstream, thereby mimicking the natural basal insulin secretion of the pancreas. This continuous delivery system offers several advantages over traditional NPH (Neutral Protamine Hagedorn) insulin, including a reduced risk of hypoglycemia, especially nocturnal episodes, and a more predictable absorption rate, which translates to more stable blood glucose levels [6].

The introduction of Glargine has been a significant development in diabetes care. Its unique formulation allows for once-daily administration, providing convenience and improving adherence to treatment regimens [7]. Furthermore, clinical trials and real-world studies have demonstrated that Glargine effectively lowers glycated hemoglobin (HbA1c) levels, a key marker of long-term glycemic control, in patients with poorly controlled type 2 diabetes [8]. The reduction in HbA1c is often associated with improvements in other metabolic parameters, including lipid profiles and blood pressure, contributing to a comprehensive cardiovascular risk reduction [9].

However, the efficacy of Glargine in achieving glycemic targets is not uniform across all patient populations. Factors such as duration of diabetes, baseline HbA1c levels, concomitant medical conditions, and patient adherence can influence outcomes. Additionally, while Glargine is associated with a lower incidence of hypoglycemia compared to other insulin formulations, it is not entirely devoid of this risk, necessitating careful titration and monitoring [10]. Moreover,

the economic impact of long-term Glargine use, given its higher cost compared to human insulin, is a consideration for healthcare systems and patients alike [11].

This research aims to delve into the specific effects of Glargine on poorly controlled type 2 diabetic patients, examining its impact on glycemic control, incidence of hypoglycemia, patient adherence, and quality of life. By conducting a thorough analysis of clinical trial data, observational studies, and patient-reported outcomes, the study seeks to provide a nuanced understanding of how Glargine can be optimized in the therapeutic landscape of type 2 diabetes.

MATERIAL 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. 100 Patients of type 2 DM of both gender age between 40- 70 years who had poor glycaemic control on oral hypoglycemic agents were put on basal insulin to achieve desirable glycaemic control. All patients were subjected to basal evaluation of fasting plasma glucose (FPG), postprandial Plasma (PPG) and Glycated hemoglobin (HbA1c) levels. Patients were given 10 units of glargine Subcutaneous at 8 PM daily and the dose was adjusted every 3rd day on basis of fasting plasma glucose. All patients were monitored at 2,4,8 and 12 weeks to optimize glargine dose, when FPG value were in the range of 100-120mg/dl, titration of the dose was stopped. The dose of glargine was increased by 2 units at time. All patients were asked for the symptoms of hypoglycaemia which were documented by self-monitored plasma glucose (SMPG) (glucose < 72 mg/dl) and the dosage was decreased by 2 units. At the end of 12 weeks all patients were monitored for desirable glycaemic control (FPG-100-120 mg/dl, PPG->180mg/dl,RPG->180 mg/ dl and HbA1c <7%).

Data analysis: Mean ± standard deviation (S.D.) was used to express the results. SPSS VERSION 25.0 statistical software was used to analyze the data. Comparing the study group to

the control group was done using the z-test. The following P-values were deemed significant: P <0.001 indicates highly significant, P <0.05 indicates significant.

Observation and Results: Mean and standard deviations (S.D.) of descriptive baseline statistics parameters and efficacy parameters of patients were shown in table 1and 2 respectively. 100 patients, ages 41–69, were included in the study; their mean age was 57.18 ± 6.67 years. The majority, who ranged in age from 56 to 65, had a BMI of over 30.1 (overweight). On oral hypoglycemic medications, all of them had poor glycemic control, indicating a need for a change in treatment. There were 49 men and 51 women in the cohort, and the average duration of diabetes was 13.02 ± 5.86 years. Every patient finished the investigation.

At the start of the study, patients had a fasting blood glucose of 324.81±69.58 mg/dl, which dropped significantly to 119.53±8.86 mg/dl by the end ($p<0.001$). Their postprandial glucose levels decreased from 375.07±69.48 mg/dl to 161.43±26.35 mg/dl ($p<0.001$). HbA1c levels fell from 11.75±1.43% to 7.87±1.17% ($p<0.001$). BMI remained unchanged, from 27.30±4.67 kg/m² to 27.06±0.25 kg/m² ($p=0.76$). Serum total cholesterol dropped from 279.63±68.68 mg% to 224.11±44.22 mg% ($p<0.001$), triglycerides from 239.7±74.92 mg% to 188.8±69.48 mg% ($p<0.001$), and LDL from 191.46±60.72 mg% to 140.69±36.23 mg% ($p<0.001$). HDL increased from 39.4±7.25 mg% to 43.43±5.13 mg% ($p<0.001$).

Table No.1: Descriptive Baseline Statistics of patients

Parameters	**Mean ± S.D.**
Age (years)	57.18 ± 6.67
Duration of Diabetes (years)	13.02 ± 5.86
Duration of Treatment (years)	10.65 ± 5.44
Fasting Blood Glucose (mg/dl)	324.81 ± 69.58
PP Blood Glucose (mg/dl)	375.07 ± 69.48
HbA1c (%)	11.75 ± 1.43
S. Total Cholesterol (mg %)	279.63 ± 68.68
S. LDL (mg %)	191.46 ± 60.72
S. HDL (mg %)	39.4 ± 7.25

S. Triglycerides (mg %)	239.7 ± 74.92
Weight (kg)	69.65 ± 13.16
Height (meters)	1.59 ± 0.007
Body Mass index (BMI) (kg/m^2)	27.30 ± 4.67

Table No.2: Efficacy parameters of Patients

Parameters	Pre-treatment (Mean ± S.D.)	Post-treatment (Mean ± S.D.)	p-value
Fasting plasma glucose (mg/dl)	324.81±69.58	119.53±8.86	<0.001
Postprandial plasma glucose (mg/dl)	375.07±69.48	161±26.35	<0.001
HbA1c	11.75±1.43	7.87±1.17	<0.001
BMI	27.30 ± 4.67	27.06±6.25	0.76
Serum total cholesterol	279.63±68.68	224.11±44.22	<0.001
Serum Triglycerides	239.7±74.92	188.8±69.48	<0.001
Serum Low density lipoprotein	191.46±60.72	140.69±36.23	<0.001
Serum High density lipoprotein	39.4±7.25	43.43±5.13	<0.001

DISCUSSION: This study showed that giving basal insulin analog Glargine to patients with poorly managed type 2 diabetes significantly improved their glycemic control. Glargine's ability to control blood sugar levels is demonstrated by the notable reductions in postprandial (375.07±69.48 mg/dl to 161.43±26.35 mg/dl) and fasting (324.81±69.58 mg/dl to 119.53±8.86 mg/dl) blood glucose levels. These reductions are critical because persistent hyperglycemia increases the risk of diabetes complications. The notable reduction in HbA1c from 11.75±1.43% to 7.87±1.17% indicates how effective Glargine is at improving glucose control over an extended period of time. The goal of diabetes care guidelines is to reduce microvascular and macrovascular problems; therefore, it is imperative to achieve HbA1c levels below 8%. These results align with the enhanced glycemic control documented in clinical investigations conducted by Schreiber SA et al. [12], Fritche A et al.[13], Gordon J. et al.[14] , Hammer H. [14], and Gordon J et al. [15].

Interestingly, the study discovered a significant improvement in lipid profiles. While serum levels of LDL, triglycerides, and total cholesterol all showed significant drops, HDL levels

increased significantly. This alteration is beneficial for cardiovascular health because dyslipidemia increases the risk of cardiovascular disease and is prevalent in diabetic patients. Glycemic control and lipid profiles both improved. These results align with the research conducted by Chaudhuri A et al. [16]. and Tang A et al. [17]

The BMI increased from 27.30±4.67 kg/m² to 27.06±0.25 kg/m², but not significantly. Although weight gain is a common side effect of insulin therapy, this study suggests that, despite glargine's effectiveness for glycemic control, weight may not be significantly affected by it. These results are in line with research conducted by Davies M et al. (18), Rosenstock et al. (19), and Razzaghy-Azar M et al. (20).

Glargine is a safe and effective treatment for poorly managed type 2 diabetes, as evidenced by the fact that the BMI did not significantly change despite the glucose levels being lowered and the lipid profiles being improved. Although the study did not specifically address hypoglycemic events, it is crucial to monitor patients for hypoglycemia because this is a known risk associated with insulin therapy.

CONCLUSION: Basal insulin analog Glargine significantly improves fasting and postprandial blood glucose levels, HbA1c, and lipid profiles in poorly controlled type 2 diabetic patients. These findings indicate that Glargine is an effective and well-tolerated option for enhancing glycemic control and managing dyslipidemia without adversely affecting BMI. Future studies should explore long-term outcomes, potential hypoglycemic events, and quality of life impacts to comprehensively evaluate Glargine’s role in diabetes management.

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