IIMPROVED METABOLIC CONTROL IN PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES FOLLOWING THE INITIATION / SWITCHING TO INSULIN GLARGINE (LANTUS®) IN CLINICAL PRACTICE

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ABSTRACT

Effective treatment of diabetes requires the optimization of insulin therapy and the education of patients on diabetes self-management. In this open-label, 9-month, single-center study the effect of insulin glargine (LANTUS®) on glycemic control and weight gain in patients with Type 1 and Type 2 diabetes was investigated. Eighty-nine patients with Type 1 diabetes (mean age 38.7 ± 12.7 years) and 60 patients with Type 2 diabetes (mean age 60.2 ± 8.1 years) were administered insulin glargine, a long-acting insulin analog. Patients were educated on either basal–bolus therapy, if switched from a previous insulin regimen or on initiation of insulin therapy, if not previously treated with insulin. Patients with Type 1 diabetes continued their treatment regimen using insulin glargine as their basal insulin instead of NPH insulin. Patients with Type 2 diabetes started insulin therapy with insulin glargine in addition to their oral treatment or were switched to the basal insulin glargine within their combination regimen. A significant reduction in HbA_{1c} was achieved with insulin glargine and was maintained during the study period. Although there was variability in the weight change over the study duration, weight was reduced overall. No unexpected adverse events or episodes of severe hypoglycemia were detected. Treatment with insulin glargine over a 9-month period significantly improved metabolic control, and induced weight loss in patients with Type 1 and Type 2 diabetes.

INTRODUCTION

- Optimizing existing insulin therapy is central to improving metabolic control in patients with Type 1 and Type 2 diabetes
- Educating patients about the importance of diabetes self-management is an essential component of any diabetes treatment regimen
- NPH insulin has provided the mainstay basal insulin in patients with Type 1 and Type 2 diabetes for many decades[1,2]
- However, the duration of action of NPH insulin is too short for it to provide 24-hour glycemic control[2]
- Insulin glargine (LANTUS®) is a new, long-acting human insulin analog that provides an effective basal insulin supply when administered once daily, shows no pronounced peaks, mimics physiologic basal insulin over a 24-hour period and provides equivalent glycemic control to that of NPH insulin[3–5]
- A single daily dose of insulin glargine is associated with less hypoglycemia than NPH insulin[4]

STUDY OBJECTIVES

- To determine the effect of insulin glargine on glycemic control and body weight in patients with Type 1 or Type 2 diabetes who:
  – were previously taking NPH insulin as their basal insulin therapy, or
  – were not previously receiving insulin therapy (some of the patients with Type 2 diabetes)
- To improve patient education regarding self-management of insulin therapy in order to optimize glycemic control and minimize weight gain

STUDY DESIGN AND METHODS

Patients

- Patients with Type 1 (n=89) and Type 2 (n=60) diabetes received insulin glargine once daily for 9 months

Study design

- This was an open study carried out in a diabetes practice in Germany
- Of the patients with Type 1 diabetes, 72 were pre-treated with NPH insulin (once or twice daily) as their basal insulin therapy. A further 17 patients were pre-treated with NPH insulin once or twice daily and lente insulin at bedtime

- At the beginning of the study (baseline), patients with Type 1 diabetes were switched from their previous basal insulin therapy to once daily insulin glargine. Their pre-existing short-acting insulin regimen was maintained
- Patients with Type 2 diabetes were either initiated on insulin glargine as their basal insulin therapy in addition to their oral treatment, or were switched from their previous basal insulin therapy on to basal insulin glargine within their combination regimen
- Patients were educated about their new insulin glargine treatment and about the concept of basal–bolus therapy prior to commencing the regimen

Efficacy variables

- HbA_{1c} was determined at the start of the study (baseline) and after 9 months of insulin glargine treatment (endpoint)

Body weight

- Body weight was monitored at baseline and endpoint

Insulin dose

- In patients with Type 1 diabetes, the required insulin dose was recorded at baseline and endpoint

Safety measurements

- Patients were asked to report all severe hypoglycemic events that occurred during the study period

Statistical analysis

- All variables were analyzed using descriptive statistics

RESULTS

Patients

- Efficacy data were available for 149 patients with Type 1 or Type 2 diabetes. Baseline characteristics are presented in Table 1

Efficacy

- Insulin glargine caused a significant reduction in HbA_{1c} levels in patients with Type 1 or Type 2 diabetes, which was maintained throughout the study (Figure 1)

Body weight

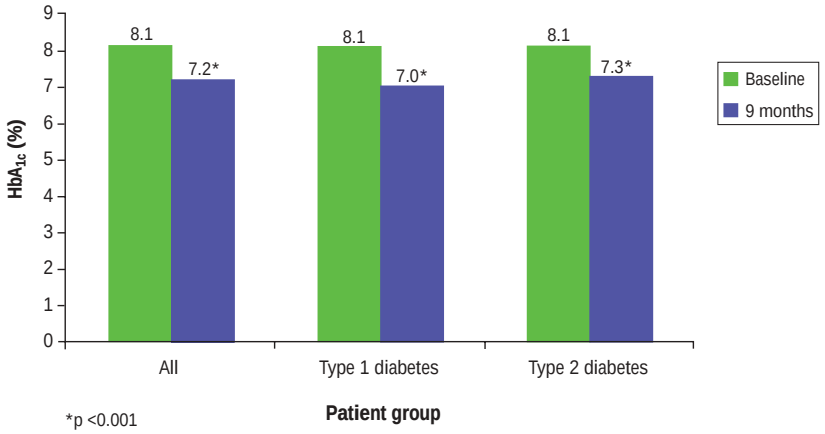
- Although there was variability in weight change over the study duration, insulin glargine caused an overall significant weight reduction (Figure 2)

Please note: The trends in HbA_{1c} level and weight were determined for the pooled data

Table 1. Baseline characteristics of subjects

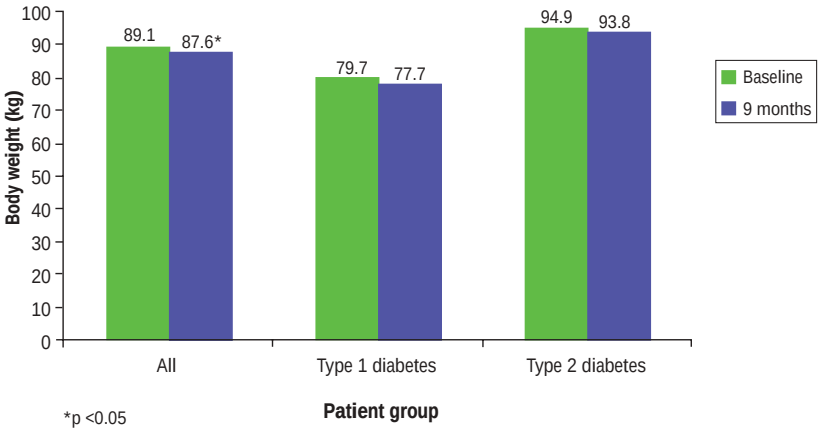
	Total Mean ± SEM	Patients with Type 1 diabetes Mean ± SEM	Patients with Type 2 diabetes Mean ± SEM
Patients (F/M)	149 (67/82)	89 (40/49)	60 (27/33)
Age (years)	47.4 ± 15.3	38.7 ± 12.8	60.2 ± 8.1
HbA_{1c} (%)	8.1 ± 1.4	8.1 ± 1.2	8.1 ± 1.7
Weight (kg)	89.1 ± 18.9	79.7 ± 12.6	94.9 ± 19.8

Figure 1. Reduction in mean HbA_{1c} levels in patients with Type 1 or Type 2 diabetes treated with insulin glargine for 9 months



*p <0.001

Figure 2. Reduction in body weight in patients with Type 1 or Type 2 diabetes treated with insulin glargine over a 9 month period

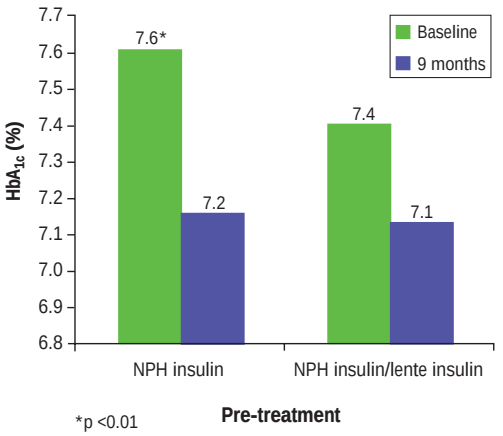


*p <0.05

Efficacy: Type 1 subgroup

- Insulin glargine caused a reduction in HbA_{1c} levels in patients with Type 1 diabetes who were pre-treated with NPH insulin (once or twice daily) or NPH insulin (once or twice daily) combined with lente insulin (at bedtime)
- This reduction was significant in those patients who previously received NPH insulin only (Figure 3)

Figure 3. Reduction in mean HbA_{1c} levels in patients with Type 1 diabetes treated with insulin glargine



*p <0.01

Body weight: Type 1 subgroup

- Insulin glargine caused an overall reduction in body weight in both subgroups of patients with Type 1 diabetes. However, the decrease in weight was not significant (Figure 4)

Insulin dose: Type 1 subgroup

- There was a significant reduction in basal insulin dose in patients with Type 1 diabetes who were switched from either NPH insulin or NPH insulin combined with lente insulin on to insulin glargine at the beginning of the study (Figure 5)

Figure 4. Reduction in body weight in patients with Type 1 diabetes treated with insulin glargine

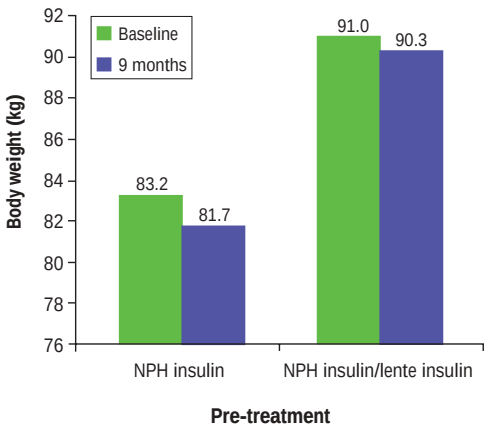
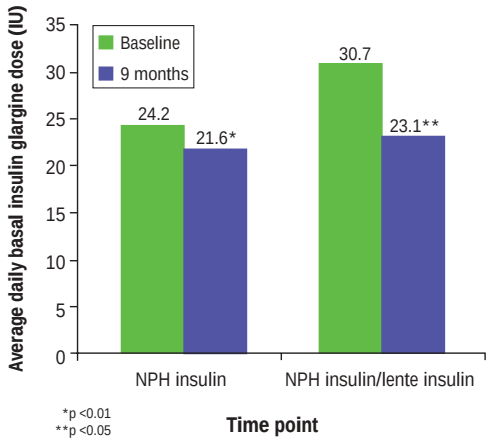


Figure 5. Reduction in daily basal insulin dose in patients with Type 1 diabetes treated with insulin glargine



Safety

- No adverse events or episodes of severe hypoglycemia occurred
- Mild hypoglycemic episodes were not documented

CONCLUSIONS

- Treatment with insulin glargine over a 9 month period significantly improved metabolic control and induced weight loss in patients with Type 1 or Type 2 diabetes
- Improvements in HbA_{1c} levels and weight were observed in all patients, regardless of whether or not they had previously been taking NPH insulin as a basal insulin therapy
- These improvements were not accompanied by adverse events or severe hypoglycemia
- Switching patients with Type 1 diabetes from NPH insulin or NPH insulin plus lente insulin to insulin glargine caused a significant reduction in basal insulin requirements, without compromising glycemic control
- This insulin dose reduction demonstrated that basal hyperinsulinization with the previous basal insulin schemes can be avoided following the switch to insulin glargine
- Educating patients about their treatment regimen and offering them a convenient, once-daily insulin may have been partly responsible for the good efficacy outcomes

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