Abstract

Insulin glargine in type 2 diabetes: An observational study of everyday practice.

Schreiber S.A, Schneider K, Schweitzer MA. *Diabetes* 2004; 53(Suppl 2):Abstract 2043-PO.

STUDY DESCRIPTION

This 9-month, uncontrolled study, is the largest observational trial (n=12,216) reported. The study enrolled patients with T2DM inadequately controlled on their current OADs to assess the effect of add-on insulin glargine treatment. This was a "real world" study conducted in the setting of general clinical practice without any strict rigorous protocol. Decisions regarding insulin glargine dosing including changes on OAD treatment were made at the discretion of the attending physician and reflecting everyday practice. Almost half the patients (47%) had T2DM for more than 5 years duration and 39% of the patients had T2DM for 1-5 years. Interestingly, 10% of the patients had T2DM for <1 year and the remaining 4% were recently diagnosed.

OBJECTIVES

The aim of this observational study was to investigate the effect of adding insulin glargine basal therapy to OHAs in patients with T2DM in the setting of everyday practice.

OUTCOME VARIABLES

- Baseline, 3-month and 9-month changes in:
  - HbA_{1c}
  - FBG
  - Insulin dose
  - Body weight and BMI
- Adverse drug reactions, including hypoglycemia

KEY FINDINGS

- After 3 months of treatment, reductions in HbA_{1c} were apparent (8.7 ± 1.4% reduced to 7.2 ± 0.9%) and this was maintained at 9 months (7.0 ± 1.0%)(Table 13; Figure 125a).
- FBG was substantially reduced from baseline levels (202 ± 56 mg/dL, 11.2 ± 3.1 mmol/L) at 3 months (133 ± 32 mg/dL, 7.4 ± 1.8 mmol/L) with little additional reduction at 9 months (131 ± 34 mg/dL, 7.3 ± 1.9 mmol/L)(Table 13; Figure 125b).
- No weight gain occurred with the addition of insulin glargine. BMI was reduced slightly from 29.0 ± 4.7 to 28.7 ± 4.5 kg/m²

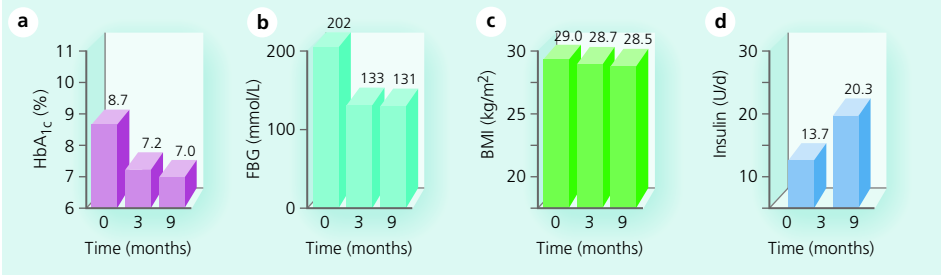

Figure 125. Summary of main findings during 9 month study period (**a**) Change in mean HbA_{1c} (**b**) Change in mean fasting blood glucose (**c**) Change in mean BMI (**d**) Increase in mean insulin dose.

during the 3-month treatment period (Table 13; Figure 125c).
- BMI was reduced slightly to 28.5 ± 4.8 kg/m^2 during the 9-month treatment period (Table 13; Figure 125c).
- The mean starting dose of insulin glargine (13.7 ± 7.0 U) increased to 20.3 ± 9.6 U at 9 months (Figure 125d).
- Adverse drug reactions were documented in 26 patients (0.21%). Only 19 of 47 adverse events documented were due to hypoglycemia.

	HbA_{1c} (%)	FBG (mg/dL)	BMI (kg/m^2)
Baseline	8.7 ±1.4 (n=11,511)	202 ± 56 (n=12,100)	29.0 ± 4.7 (n=11,090)
3 months	7.2 ±0.9 (n=11,296)	133 ± 32 (n=11,872)	28.7 ± 4.5 (n=10,692)
9 months	7.0 ±1.0 (n=6031)	131 ± 34 (n=6335)	28.5 ± 4.8 (n=5324)

Table 13. Summary of main findings from large observational study.

EDITORS COMMENTARY

The uncontrolled design of this large study prevents definitive conclusions but nevertheless, the translational message appears clear regarding the clinical value of insulin glargine. These data suggest that, in daily clinical practice, insulin glargine in combination with OHAs is a simple and highly effective strategy to achieve good glycemic control in patients with T2DM inadequately controlled on OHAs alone. This is consistent with the results seen in many clinical trials. The mean HBA_{1c} recorded at 9 months documented that the target of ≤7% was achieved. Considering the magnitude of this study conducted in more than 12000 patients, it is surprising that only 19 adverse events due to hypoglycemia were reported and there was no overall change in body weight despite significant improvements in glycemic control.