Metabolic and weight benefits following long-term administration of insulin glargine (Lantus®) in patients with type 2 diabetes in clinical practice.

Schreiber S, Rußmann A. *Diabetes Metabolism* 2003; 29(Spec No 2):Abstract 2212.

STUDY DESCRIPTION

This was a single center, long-term observational study. The findings described in several abstracts have been combined and summarized. Patients (mean age 60.2 years, mean body weight 94.9 kg) receiving treatment with OHA only (n=16), OHA plus insulin (n=11), conventional insulin therapy (CIT)(n=10) or intensified conventional insulin therapy (ICT) (n=23) were switched to receive insulin glargine once-daily in conjunction with continued OHA and/or prandial insulin for 18 months. Patients were enrolled based on either inadequate glycemic control (FBG>140mg/dL), or on the basis that their previous insulin treatment regimen was considered by the patient to be too rigid. Patients either took part in a formal educational program on insulin and diet at baseline and/or underwent routine physician consultations throughout the course of this study.

OBJECTIVES

To determine the long-term efficacy and safety of insulin glargine in a clinical practice in persons with T2DM who were poorly controlled or dissatisfied on their current treatment regimen.

OUTCOME VARIABLES

Primary variables

- Changes in the HbA_{1c} level from baseline at 9 and 18 months
- Changes in body weight from baseline at 9 and 18 months

Secondary variables

- Patient reported episodes of severe hypoglycemia

KEY FINDINGS

- Overall, patients switched to treatment with insulin glargine experienced a significant decrease from baseline in HbA_{1c} at 9 months (reduction from 8.1 to 7.3%, $p<0.001$) and 18 months (reduction from 8.1% to 6.9%, ($p<0.0003$) (Figure 116).
- Patients previously treated with insulin as ICT or CIT showed no change in glycemic control. With ICT, the HbA_{1c} was 6.0, 7.1 and 6.7 % at baseline, 9 and 18 months respectively. With CIT, the HbA_{1c} was 7.0, 7.0 and 6.9 % at baseline, 9 and 18 months respectively (Figure 116).
- Patients who had previously received OHA monotherapy achieved a significant reduction in HbA_{1c} at 9 months (-1.4%; $p<0.05$) to 7% and was maintained at 18 months (Figure 116).
- Patients who had previously received OHA in conjunction with insulin also achieved significant reductions in HbA_{1c} at 9 months (-2.1%; $p<0.05$) to 7.2% and was maintained at 18 months (Figure116).
- For all patients, the mean weight loss at 9 and 18 months was 1.1kg and 8.2 kg respectively (Figure 117).
- In patients previously treated with ICT, there was a mean weight loss of 1.5 kg and 14 kg at 9 and 18 months respectively. With CIT, the mean weight loss was 0.3kg at 9 months and 7.7 kg at 18 months (Figure 117).
- In patients pre-treated with OHA with or without insulin, there was minimal weight change over the 18 months study period (Figure 117).
- No episodes of severe hypoglycemia were reported by the patients during the study period.

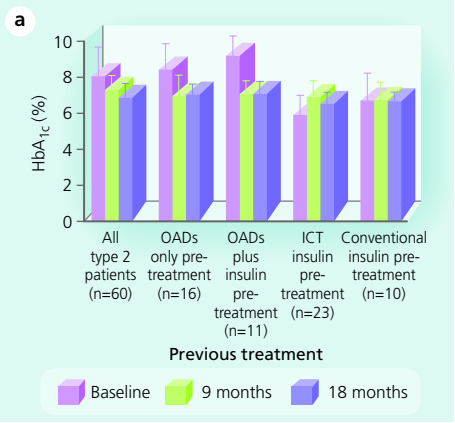

Figure 116. Baseline to endpoint changes in HbA_{1c}.

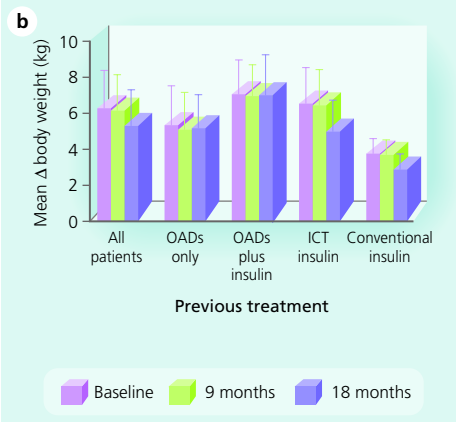

Figure 117. Baseline to endpoint changes in body weight.

EDITORS COMMENTARY

In this long-term study, insulin glargine treatment in association with an "insulin and diet" education program was successful in achieving and/or maintaining good glycemic control in patients previously treated either with OHA alone, or with insulin, as a conventional treatment (CIT) or as intensified conventional therapy (ICT). Both the improvement in glycemic control and the significant weight loss recorded reflect the expertise of a specialized diabetes center, with an emphasis on dietary and lifestyle intervention.

Those patients on OHA alone or OHA in conjunction with insulin had a reduction in HbA_{1c} of 1.4% and 1.1%, with end-of-treatment means of HbA_{1c} of 7% and 7.2%, respectively, and accompanied by a 1.4 kg and 1.0 kg change in body weight over 18 months. In patients who had previously received insulin as CIT or as ICT, HbA_{1c} was maintained at below 7% in both groups at 18 months. In these groups, a significant weight loss was observed. Weight loss has always been very difficult to accomplish in clinical practice. In the absence of a control group, no definitive conclusions can be strongly stated. Nonetheless, insulin glargine appeared to be an effective tool to facilitate implementation of glycemic control and weight loss in a structured diabetes program, presumably due to the reckless profile and reduced risk of hypoglycemia without the need for supplemented caloric intake.

This study confirms the efficacy of insulin glargine as a basal insulin supplement in a "real world" clinical setting. Insulin glargine therefore offers patients under intensive insulin therapy a less rigid and equally effective insulin treatment regimen.

Additional References

1. Schreiber S, Rußmann A. Long-term administration of insulin glargine (LANTUS®): Metabolic and weight benefits in patients with type 2 diabetes in clinical practice. *Diabetes* 2003; 52(Suppl 1):A455 Abstract 1972.

2. Schreiber S, Rußman A. Improved metabolic control with a favourable weight profile in patients with type 2 diabetes treated with insulin glargine in clinical practice. *Diabetes* 2002; 51(Suppl 1):A114 Abstract 464-P.

3. Schreiber S, Rußman A. Improved metabolic control in patients with type 1 and type 2 diabetes following the initiation/switching to insulin glargine in clinical practice. *Diabetes* 2002; 51(Suppl 1):A114 Abstract 465-P.