Treatment with insulin glargine of patients with type 2 diabetes in clinical practice: metabolic control over 30 months.

Schreiber S, Russmann A. *Diabetes* 2004; 53(Suppl 2):Abstract 2043-PO.

STUDY DESCRIPTION

This is an additional analysis of a single center, long-term observational study assessing patients with T2DM treated with insulin glargine. This particular analysis was conducted on a group of patients (n=46) with near-normal weight (mean body weight 86.3 ± 17.7 kg) who failed on their current therapy of OHA or insulin and then were given insulin glargine, once-daily, for 30 months in clinical practice. As previously described, patients were enrolled based on either inadequate glycemic control with FBG>140mg/dL (7.8 mmol/L), or on the basis that their previous insulin treatment regimen was regarded by the patient to be too rigid. In this analysis, the patients were investigated according to their previous treatment, with OHAs (n=18) or insulin only (n=28). Subjects' metabolic control was assessed at 9, 18, 24 and 30 months. The dose of insulin glargine was titrated according to the morning FBG. Subjects involved in the study either took part in a formal educational program on insulin and diet at baseline and/or underwent routine physician consultations during the course of this study.

KEY FINDINGS

- Significant reductions from baseline HbA_{1c} (8.14% ± 1.7%) were observed at 9 and 30 months in all the patients (reductions from baseline of -0.69% ($p<0.002$) and -0.96%, respectively ($p<0.001$)) (Table 12; Figure 118).
- The patients treated previously with OHAs experienced greater reductions from a higher baseline HbA_{1c} of 9.16% ± 1.7% [-1.88% at 9 months ($p<0.002$) and -2.26 % at 30 months ($p<0.001$)] (Table 12; Figure 118).
- The insulin-only pre-treated group experienced smaller but significant reductions from a baseline of 7.59 ± 1.5% (-0.09% at 9 months ($p<0.001$) and 0.38% at 30 months ($p<0.001$) (Table 12; Figure 118).
- There was no change in weight from baseline to endpoint.
- No unexpected adverse events or episodes of severe hypoglycemia were observed.

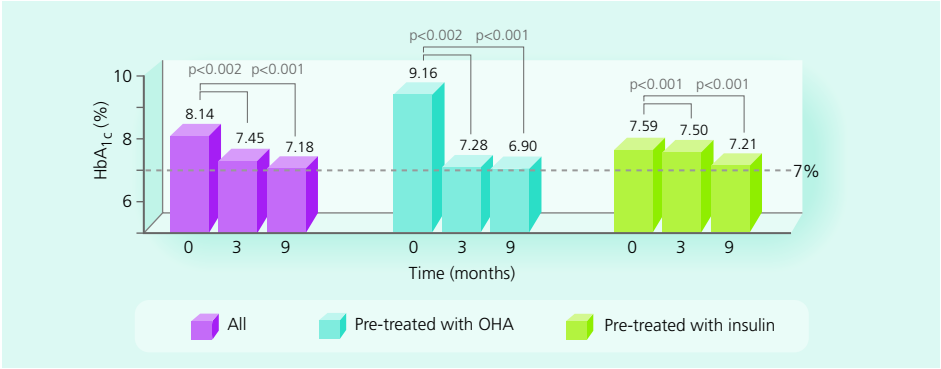

Figure 118. Changes in mean HbA_{1c} during the 9 month study

	All patients	Previous OHA	Previous insulin only
Baseline	8.14 ± 1.7	9.16 ± 1.7	7.59 ± 1.5
9 months	7.45 ± 0.9	7.28 ± 1.0	7.50 ± 1.0
Δ at 9 months	–0.69 (p<0.002)	–1.88 (p<0.002)	–0.09 (p<0.001)
30 months	7.18 ± 0.9	6.90 ± 0.3	7.21 ± 1.1
Δ at 30 months	–0.96 (p<0.001)	–2.26 (p<0.001)	–0.38 (p<0.001)

Table 12. Summary of the findings of the 30 month observational study. Difference (Δ) and p values are shown.

EDITORS COMMENTARY

This uncontrolled study has clear limitations, but provides some valuable long term observations indicating sustained glycemic effects and no weight gain when insulin glargine is part of an integrated diabetes management program in clinical practice. In combination with educational support, the addition of insulin glargine to persons inadequately controlled or dissatisfied with their current insulin therapy significantly improved their glycemic control over a period of 30 months.

As expected, the greatest reduction in HbA_{1c} was seen in those subjects previously treated with OHA alone, with a mean value less than target at 30 months. It is important to note that none of the subjects were recorded as having experienced unexpected adverse events, episodes of severe hypoglycemia and no weight gain was evident in these patients who entered this long-term study with near-normal body weight.