

Witthaus E, Ashwell SG, Johnston P, Stephens J, Home PD and Bradley C (2004) Quality of Life is improved with Insulin Glargine + Lispro Compared with NPH Insulin + Regular Human Insulin in Patients with Type 1 Diabetes. *Diabetologia* 47: [Suppl 1]:A306, Abstract 849.

Abstract for poster presented at the 40<sup>th</sup> Annual Meeting of the EASD, Munich, Germany, September 5-9, 2004.

### **Quality of Life is Improved with Insulin Glargine + Lispro Compared with NPH Insulin + Regular Human Insulin in Patients with Type 1 Diabetes**

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**Background and Aims:** Diabetes has a significant, negative impact on the quality of life (QoL) of patients, thus, the protection and improvement of QoL is an important goal of diabetes care. The Audit of Diabetes-dependent Quality of Life (ADDQoL) is a questionnaire that measures present QoL and average weighted impact (AWI) of diabetes on QoL across 18 individual life domains, including work, social life and enjoyment of food. One of the objectives of this study was to show, using the ADDQoL, that the perceived negative impact of diabetes on QoL is reduced in patients on a combination of insulin glargine (LANTUS<sup>®</sup>) + insulin lispro (Humalog<sup>®</sup>), as compared with NPH insulin + regular human insulin.

**Materials and Methods:** This was a 32-week, multicenter, open-label, randomized crossover clinical trial comparing once-daily insulin glargine + insulin lispro with once- or twice-daily NPH insulin + regular human insulin, in patients with Type 1 diabetes. Patients (n=48; 62.5% female; mean age 42 ± 11.4 years) were randomized to receive either Treatment Sequence A (insulin glargine + lispro followed by NPH insulin + regular human insulin; n=22) or Treatment Sequence B (NPH insulin + regular human insulin followed by insulin glargine + lispro; n=26). The ADDQoL was used initially, and after each treatment period. In addition, treatment satisfaction was assessed using the Diabetes Treatment Satisfaction Questionnaire (DTSQ).

**Results:** For all patients combined, the mean present QoL baseline score was 1.3, reflecting 'good' (rather than 'very good' or 'excellent') present QoL. Present QoL improved significantly with insulin glargine + lispro but did not change with NPH insulin + regular human insulin (p=0.014; 95% confidence interval [CI]: 0.07; 0.55; Table). The mean AWI score was -1.8 initially, indicating a mean negative impact (actual range -6 to +3) of diabetes on QoL. After the total treatment period, the mean AWI score improved by 0.4 with insulin glargine + lispro and by 0.1 after NPH insulin + regular human insulin, indicating a beneficial effect of insulin glargine + lispro (p=0.033). Moreover, treatment satisfaction for the total treatment period was markedly improved after treatment with insulin glargine + lispro compared with NPH insulin + regular human insulin (mean: 32.2 ± 3.4 vs 23.9 ± 7.2; p<0.0001).

**Conclusion:** This study shows that insulin glargine + lispro improves treatment satisfaction, reduces the negative impact of diabetes on QoL, and improves QoL *per se*.

ADDQoL scores (mean ± SD)	Present QoL		Average weighted impact score	
	Sequence A: insulin glargine + lispro/NPH insulin + regular	Sequence B: NPH insulin + regular/ insulin glargine + lispro	Sequence A: insulin glargine + lispro/NPH insulin + regular	Sequence B: NPH insulin + regular/ insulin glargine + lispro
Baseline	1.4 ± 0.8	1.2 ± 1.3	-1.6 ± 1.2	-1.9 ± 1.3
End of treatment period 1	1.6 ± 0.8	1.2 ± 1.2	-1.2 ± 0.6	-1.8 ± 1.2
End of treatment period 2	1.3 ± 0.8	1.6 ± 0.9	-1.5 ± 1.2	-1.6 ± 1.2
	Insulin glargine + lispro	NPH insulin + regular	Insulin glargine + lispro	NPH insulin + regular
Total treatment period	1.6 ± 0.8*	1.3 ± 1.0	-1.4 ± 0.9 <sup>†</sup>	-1.7 ± 1.2

\*p=0.014 vs NPH insulin + regular; <sup>†</sup>p=0.033 vs NPH insulin + regular

**Keyword (Complete):** 29 Insulin therapy