

## Corrections

The following abstracts were presented at the Insulin Congress (The Evolving Science and Practice of Insulin Therapy) held November 10–12, 2006, in Washington, DC, but did not appear in Volume 2, Supplement A of *Insulin*.

### The Efficacy of Long-Term Insulin Glargine and Oral Antidiabetic Therapy in Patients with Type 2 Diabetes Mellitus in Clinical Practice

Stephan A. Schreiber, *Diabeteszentrum Schreiber, Quickborn, Germany*

**Background:** Maintaining target glycosylated hemoglobin (A1C) levels (<7.0%) in patients with type 2 diabetes mellitus (DM) reduces the risk of late DM-associated complications. Previously reported results of a 9-month, uncontrolled observational study (N = 12,216) found that the addition of insulin glargine, a basal insulin analogue, to existing oral antidiabetic drug (OAD) therapy was associated with reductions in A1C to target levels.

**Objective:** To further investigate the effects of long-term, once-daily insulin glargine plus OAD therapy on glycemic control in patients with type 2 DM in a 32-month extension of the original observational study in 1915 patients. Dosing decisions, including changes to OAD therapy, were made at the physicians' discretion, reflecting everyday clinical practice.

**Results:** At baseline, patients' mean (SD) age was 63.5 (11.3) years, A1C was 8.6% (1.5%), fasting blood glucose (FBG) was 11.1 (3.2) mmol/L, and body mass index (BMI) was 29.0 (4.8) kg/m<sup>2</sup>. Reductions in A1C and FBG levels were observed after 9 months of treatment with insulin glargine plus OADs, and these reductions were maintained at 32 months (**Table**). Only 2 hypoglycemic episodes were reported in the extension phase.

**Table.**

Time Point	A1C, %*	FBG, mmol/L*	BMI, kg/m <sup>2</sup> *	Insulin Dose, U*
Baseline	8.6 (1.5) (n = 1816)	11.1 (3.2) (n = 1874)	29.0 (4.8) (n = 1761)	14.1 (7.4) (n = 1909)
9 Months	7.0 (0.9) (n = 1776)	7.2 (1.8) (n = 1869)	28.5 (4.7) (n = 1634)	20.1 (9.5) (n = 1908)
32 Months	7.0 (1.0) (n = 1817)	7.2 (2.0) (n = 1813)	28.7 (4.7) (n = 1655)	23.7 (10.9) (n = 1761)

A1C = glycosylated hemoglobin; FBG = fasting blood glucose; BMI = body mass index.

\*Mean (SD).

**Conclusion:** These data suggest that, in daily practice, the introduction of insulin glargine plus OADs can facilitate both the attainment and maintenance of target A1C levels, irrespective of BMI, in patients with type 2 DM.

**Acknowledgments:** This study was supported by sanofi-aventis. This abstract was presented as a poster at the American Diabetes Association Annual Congress, 2006/S. Schreiber, *Diabetes*. 2006;55(Suppl 1):A134. Abstract 562-P.

### A Randomized Trial Comparing Initiation of Basal Insulin Individually and in Groups in Type 2 Diabetes Mellitus

Hannele Yki-Järvinen, *University of Helsinki, Helsinki, Finland*; Michael Alvarsson, *Karolinska Sjukhuset, Stockholm, Sweden*; Tord Bystedt, *Karolinska Sjukhuset, Stockholm, Sweden*; Ian Caldwell, *Swan Lane Medical Center, Bolton, United Kingdom*; Melanie Davies, *University of Leicester, Leicester, United Kingdom*; Leena Juurinen, *University of Helsinki, Helsinki, Finland*; Sanni Lahdenpera, *sanofi-aventis, Helsinki, Finland*; Giel Nijpels, *VU University Medical Center, Amsterdam, The Netherlands*; and Markku Vähätalo, *Turku Health Center, Turku, Finland*

**Background:** Initiation of insulin is often unnecessarily delayed for years.

**Objective:** To determine whether equivalent glycemic control can be achieved by initiating insulin individually versus in groups.

**Methods:** A total of 121 patients with type 2 diabetes mellitus and poor glycemic control despite maximal doses of oral agents were randomized to receive either individual or group (n = 4–8/group) education, with visits during screening and at weeks 0, 6, 12, and 24, and phone calls preceded by electronic transfer of fasting glucose levels at weeks 1, 2, 4, 8, 16, and 20. The goal was to encourage self-adjustment of the insulin dose (insulin glargine at bedtime; every 3 days increase by 2 IU to target fasting glucose of ≤100 mg/dL [5.5 mmol/L]).

**Results:** Baseline characteristics and results are shown in the **table**.

**Conclusion:** We concluded that initiation of insulin in groups was as effective in terms of glycemic control as initiation of insulin individually; it improved treatment satisfaction similarly but reduced the time spent by 49%.

**Acknowledgments:** This study was supported by sanofi-aventis. This abstract was given as an oral presentation at the American Diabetes Association Annual Congress, 2006/H. Yki-Järvinen, *Diabetes*. 2006;55(Suppl 1):A134. Abstract 562-P.

Table.					
Characteristic	Individual (n = 63)	Group (n = 58)	Characteristic	Individual (n = 63)	Group (n = 58)
Sex (M/F), %	65/35	59/41	Insulin dose week 24, IU/kg	0.59 (0.02)	0.59 (0.01)
Age, y	58 (1)	58 (1)	Fasting glucose <72 mg/dL, % of patients	58	62
BMI, kg/m <sup>2</sup>	31.5 (0.7)	31.2 (0.9)	Symptomatic, % of patients	44	40
2 OADs, %	82	76	Weight change, kg	2.2 (0.4)	3.7 (0.6) <sup>†</sup>
A1C week 0, %	8.7 (0.1)	8.8 (0.1)	DTSQ week 0	27 (1)	26 (1)
A1C week 24, %	6.9 (0.1)*	6.8 (0.1)*	DTSQ week 24	32 (1)*	31 (1)*
Insulin dose week 24, IU	54 (2)	57 (2)	Total time spent by HCPs, h	4.2 (0.2)	2.2 (0.1) <sup>†</sup>

M = male; F = female; BMI = body mass index; OAD = oral antidiabetic drug; A1C = glycosylated hemoglobin; DTSQ = diabetes treatment satisfaction questionnaire (total treatment satisfaction score).  
\**P* < 0.001 week 24 versus week 0.  
<sup>†</sup>*P* < 0.001 for difference between treatments.

H.Y.-J. has acted as a consultant or speaker for Amylin, Astra-Zeneca, Aventis, Lilly, Merck, MSD, and Pfizer and received grant support for investigator-initiated trials from Astra-Zeneca, Aventis, Lilly, Novartis, and Roche. M.D. has acted in a consultancy capacity and as a speaker for Novartis, Novo Nordisk, sanofi-aventis, and Eli Lilly and has received grants in support of investigator and internal trials from Servier, Novartis, Novo Nordisk, Pfizer, and sanofi-aventis. S.L. is an employee of sanofi-aventis.

### Equivalence of Basal Insulin Glargine Versus Prandial Insulin Lispro for Glucose Control in Type 2 Diabetes Mellitus Patients on Oral Agents: Results of the APOLLO Study

Karim El-Haschimi, sanofi-aventis, Berlin, Germany; Thomas Linn, Third Medical Department & Policlinic, University Hospital Giessen, Giessen, Germany; and Reinhard G. Bretzel, Third Medical Department & Policlinic, University Hospital Giessen, Giessen, Germany; for the APOLLO Study Group

**Background:** When initiating insulin therapy in patients with type 2 diabetes mellitus (DM), it is unclear whether to target postprandial glucose (PPG) with short-acting insulins or fasting blood glucose (FBG) with basal insulins.

**Objective:** To present the results of a 44-week, parallel, open-label, randomized, multinational study comparing the efficacy and safety of an oral antidiabetic drug (OAD) regimen plus either once-daily insulin glargine (n = 174) or mealtime insulin lispro (n = 174) in type 2 DM patients failing oral treatment (APOLLO).

**Results:** Glycosylated hemoglobin significantly improved in both groups; equivalence was within the preestablished 0.4% limit for noninferiority (0.157; 95%CI, 0.35–0.05). Insulin glargine provided significantly better control of FBG (*P* < 0.001) and nocturnal blood glucose (*P* < 0.002; **Table**); insulin lispro provided better PPG control, particularly after lunch and dinner (both, *P* < 0.001). The mean number of overall hypoglycemic events was significantly lower with insulin glargine versus insulin lispro (5.4 vs 24.4 events/patient-year), and daily insulin doses at end point were similar (42.1 [25.9] vs 45.1 [25.6] IU).

Table.	Insulin Glargine, mean (SD)		Insulin Lispro, mean (SD)	
	Baseline	End Point	Baseline	End Point
A1C, %	8.71 (0.95)	6.96 (0.67)	8.64 (0.95)	6.77 (0.83)
FBG				
mg/dL	186 (36)	111 (27)	179 (41)	145 (34)
mmol/L	10.3 (2.0)	6.2 (1.5)	9.9 (2.7)	8.0 (1.9)
Nocturnal blood glucose				
mg/dL	177 (44)	118 (39)	177 (53)	129 (33)
mmol/L	9.8 (2.4)	6.5 (2.2)	9.8 (2.9)	7.2 (1.8)

A1C = glycosylated hemoglobin; FBG = fasting blood glucose.

**Conclusions:** An OAD regimen using the long-acting insulin analogue glargine to target FBG offers glucose control equivalent to that with the short-acting insulin analogue lispro to target PPG in type 2 DM. However, insulin glargine was associated with a reduced risk of hypoglycemia, fewer insulin injections, and less self-monitoring of blood glucose versus insulin lispro. Thus, the insulin glargine regimen may improve patient treatment satisfaction and compliance versus the insulin lispro regimen.

**Acknowledgments:** This study was supported by sanofi-aventis. This abstract was given as an oral presentation at the American Diabetes Association Annual Congress, 2006/R. Bretzel, *Diabetes*. 2006;55(Suppl 1):A76. Abstract 326-OR, and as an oral presentation at the European Association for the Study of Diabetes Annual Congress, 2006/R. Bretzel, *Diabetologia*. 2006;49(Suppl 1). Abstract 0145.

K.E.-H. is an employee of sanofi-aventis; R.G.B. has served on advisory panels and as a consultant for Eli Lilly and sanofi-aventis, and holds stock in sanofi-aventis.

### Patients with Type 2 Diabetes Mellitus Inadequately Controlled on Premixed Insulin: Effect of Initiating Insulin Glargine plus Oral Agents on Glycemic Control in Daily Practice

Harm Hammer, *Facharzt für Innere Medizin, Hausärztliche Versorgung, Bremen, Germany*; and Karim El-Haschimi, *sanofi-aventis, Berlin, Germany*

**Background:** Currently, there is limited information regarding next-step therapy options for type 2 diabetes mellitus (DM) patients whose disease is inadequately controlled with premixed insulin.

**Objective:** To document the effect of initiating once-daily insulin glargine plus oral antidiabetic drugs (OADs) in everyday clinical practice in a 3-month observational study.

**Methods:** Dosing decisions for insulin and concomitant OADs were at the physicians' discretion, reflecting everyday practice. Glimperide was recommended as the OAD at baseline.

**Results:** In total, 5045 type 2 DM patients (mean [SD]: age, 64.0 [10.9] years; duration of DM, 8.7 [5.9] years; poorly controlled glycosylated hemoglobin [A1C], 8.3% [1.2%]) were switched from premixed insulin (35 [15] U) to insulin glargine (22.1 [10.6] U) plus OADs. There was a trend toward an increase in proportion of patients taking OADs (metformin, 42% vs 55% at start of observation vs 3 months; glimepiride, 16% vs 41%; glibenclamide, 11% vs 11%; other, 3.1% vs 5.4%). Significant reductions were observed in A1C, fasting blood glucose, and body weight (Table). The mean insulin glargine dose at 3 months was 26.5 (11.5) U. Adverse drug reactions were reported in 14 patients; 13 of these were hypoglycemia.

**Table.**

	A1C, % (n = 4965)	FBG, mg/dL ([mmol/L]) (n = 4815)	Body Weight, kg (n = 4958)
Start of observation	8.3 (1.2)	178 (48) [9.9 (2.7)]	85.2 (14.4)
3 Months	7.1 (0.8)	124 (26) [6.9 (1.4)]	83.6 (14.1)
Change	-1.1 (1.0)*	-55 (45) [3.1 (2.5)]*	-1.6 (3.2)*

A1C = glycosylated hemoglobin; FBG = fasting blood glucose.

\* $P \leq 0.001$  (Wilcoxon signed rank test).

**Conclusions:** These data confirm that transferring patients with type 2 DM from premixed insulin to insulin glargine plus OADs can improve metabolic control in daily practice and provides a convenient and effective treatment option.

**Acknowledgments:** This study was supported by sanofi-aventis. This abstract was presented as a poster at the American Diabetes Association Annual Congress, 2006/H. Hammer, *Diabetes*. 2006;55(Suppl 1):A115. Abstract 481-P.

H.H. is on the speaker bureau for sanofi-aventis; K.E.-H. is an employee of sanofi-aventis.

## ***Correction***

One of the authors of an abstract that appeared in the March 2007 Supplement (2007;2[Suppl A]:S25–S26) has informed us that the name of a coauthor—Colleen M. McCormick—was misspelled. The spelling is correct as it appears below.

### **43 Shared Medical Appointments Are an Effective Intervention in High-Risk, Traditionally Nonadherent Veterans Who Might Benefit from Multiple-Injection Insulin Therapy**

*Brian V. Burke, MD, Dayton VAMC, Wright State University; SC Boonshoft; Colleen M. McCormick; Sara Howard, NP, Veterans Affairs Medical Center, Dayton, Ohio*