

# ABSTRACT

## Poster Presentation 918

### Reduced Incidence and Frequency of Hypoglycemia in an Integrated Analysis of Pooled Data from Clinical Trials of Subjects with Type 2 Diabetes Using Prandial Inhaled Technosphere® Insulin

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**Background and aims:** Technosphere® Insulin (TI) is a rapid-acting insulin with a pharmacokinetic profile well suited for early control of postprandial plasma glucose. This integrated analysis includes the pooled data from six phase 2/3 clinical trials in subjects with type 2 diabetes mellitus inadequately controlled (HbA1c  $\geq$  6.6% and  $\leq$  12.0%) despite insulin with or without oral antihyperglycemic therapy.

**Materials and methods:** Subjects were randomized to treatment regimens to achieve predefined glycemic goals: TI (N = 1795) or sc insulin (N = 942), which included biphasic insulin aspart 70/30, or insulin aspart and “usual care,” with insulin adjustments according to investigator discretion in five trials and forced titration in one trial. A structured titration regimen was not enforced. When experiencing hypoglycemic-like symptoms, subjects were instructed to confirm the event with a blood glucose reading. Subjects experiencing a severe hypoglycemic episode were required to report the details of third-party assistance (if needed), the presence of neurologic symptoms, and the specifics of treatment.

**Results:** Mean baseline characteristics were similar for TI and sc insulin comparator (age 56.2, 55.6 years; disease time since diagnosis 10.8, 12.4 years; baseline HbA1c 8.8%, 8.8%; BMI 31.1, 31.1 kg/m<sup>2</sup>). Subjects treated with TI experienced statistically significantly fewer hypoglycemic episodes in regard to both incidence and frequency compared with subjects treated with sc insulins. For incidence, significantly fewer subjects reported hypoglycemia with TI: 31.8% vs 49.6% for total hypoglycemia; 31.6% vs 49.4% for mild/moderate hypoglycemia; and 2.8% vs 7.5% for severe hypoglycemia, with the three comparison *p* values <0.0001. For frequency, TI also had significantly fewer events, evaluated by event rate (number of events per 100 subject months): 23.9 vs 38.8 for total hypoglycemia (*p* <0.0001); 23.2 vs 37.3 for mild/moderate hypoglycemia (*p* <0.0001); and 0.66 vs 1.37 for severe hypoglycemia (*p* <0.0184).

**Conclusion:** TI, often in combination with a basal insulin, consistently reduced the incidence and frequency of both mild/moderate and severe hypoglycemic events under conditions of comparable glycemic control. The reduction in the risk of hypoglycemia in patients with type 2 diabetes under inadequate control may facilitate the introduction of insulin therapy.

Hypoglycemia	Incidence (%)		Odds Ratio	Odds Ratio <i>p</i> Value	Event Rate per 100 Subject Months		Event Rate <i>p</i> Value
	TI	SC Insulin			TI	SC Insulin	
Mild/Moderate	31.6	49.4	0.466	<0.0001	23.2	37.3	<0.0001
Severe	2.8	7.5	0.359	<0.0001	0.66	1.37	0.0184
Total	31.8	49.6	0.466	<0.0001	23.9	38.8	<0.0001