

ABSTRACT

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Reduced Incidence and Frequency of Hypoglycemia in an Integrated Analysis of Pooled Data from Clinical Trials of Subjects with Type 1 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 three Phase 2/3 clinical trials in subjects with type 1 diabetes mellitus inadequately controlled (HbA1c > 7.0% and ≤ 11.0%) with standard insulin regimens.

Materials and methods: Subjects were randomized to one of 3 treatment regimens to achieve predefined glycemic goals: TI (n = 614) plus basal insulin; sc insulin (n = 599), which included insulin glargine plus aspart; or “usual care,” with insulin adjustments according to investigator discretion. A structured titration regimen was not enforced. When experiencing hypoglycemia-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 (age 38.4, 38.5 years; disease time since diagnosis 16.5, 16.6 years; baseline HbA1c 8.6%, 8.6%; BMI 26.1, 26.0 kg/m²). Subjects treated with TI had a lower incidence of hypoglycemia compared with subjects treated with other sc insulins: 75.9% vs 81.0% for total hypoglycemia; 75.6% vs 80.8% for mild/moderate hypoglycemia; and 24.3% vs 27.5% for severe hypoglycemia, with the comparison *p* values substantially in favor of TI for total hypoglycemia and mild/moderate hypoglycemia. For frequency, TI had a comparable (not statistically different) number of events, evaluated by event rate (number of events per 100 subject-months), with lower event rates for severe hypoglycemia in the TI group. When evaluated for subjects with blood glucose values ≤ 2 mmol/L, TI also was comparable (not statistically different) to sc insulin treatment with a lower event rate.

Conclusion: TI, in combination with basal insulin, significantly reduced the incidence of total and mild/moderate hypoglycemia with a lower frequency of severe hypoglycemic events than sc insulin comparator under conditions of comparable glycemic control.

Hypoglycemia	Incidence (%)		Odds Ratio	Odds Ratio <i>p</i> Value	Event Rate per 100 Subject Months		Event Rate <i>p</i> Value
	TI + Basal Insulin	Comparator + Basal Insulin			TI + Basal Insulin	Comparator + Basal Insulin	
Mild/Moderate	75.6	80.8	0.743	0.0354	133.2	117.7	0.9097
Severe	24.3	27.5	0.826	0.1576	5.2	6.0	0.5901
Total	75.9	81.0	0.749	0.0413	138.6	124.1	0.9242