

ABSTRACT

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Pulmonary Function Tests Remain Similar in Patients Who Received Technosphere® Insulin and in Patients Currently Receiving Standard Antidiabetic Therapy

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Background and aims: Previous controlled clinical studies have demonstrated that regimens of basal insulin plus Technosphere® Insulin (TI) were as effective as basal insulin plus rapid-acting sc insulin in patients with diabetes. In previously reported studies, we have been unable to detect a consistent change in pulmonary function tests (PFTs). Small but clinically nonsignificant differences have been observed. This clinical trial was designed to assess the changes in pulmonary function after cessation of TI therapy and resumption of standard antidiabetic treatment in patients with type 1 or type 2 diabetes.

Materials and methods: Adults with diabetes who participated in any of four controlled clinical trials of TI were invited to participate in this follow-up trial to evaluate changes in PFTs after completing the study and being switched to usual antidiabetic therapy without TI. Patients were followed for a total of 3 months after cessation of study therapy. PFTs were assessed at the end of the parent trial and 1 and 3 months after subjects completed the parent trial.

Results: Of 649 patients in this study, 315 subjects (121 with type 1 diabetes, 194 with type 2 diabetes) received TI and 334 subjects (129 with type 1 diabetes, 205 with type 2 diabetes) received the antidiabetic regimen without prandial TI during the parent trials. Small, nonprogressive treatment group differences in mean changes from Baseline in forced expiratory volume in 1 second (FEV₁) and carbon monoxide diffusing capacity (DL_{CO}) observed during the comparative phase of the controlled trials disappeared when comparing the two groups at 3 months after cessation of TI therapy and resumption of standard antidiabetic therapy (FEV₁: -0.08 L in the TI group, -0.11 L in the non-TI group [$p = 0.1388$]; DL_{CO}: -1.29 mL/min/mm Hg in the TI group, -1.37 mL/min/mm Hg in the non-TI group [$p = 0.9360$]). In addition, there was no statistical difference in FEV₁ between the two groups when examining subjects with type 1 and type 2 diabetes ($p = 0.6158$ and $p = 0.1795$, respectively).

Conclusion: These data suggest that the pattern and magnitude of PFT changes associated with the use of TI in subjects with type 1 and type 2 diabetes are not likely due to any structural alterations in the lungs and are not clinically meaningful.

