Technosphere® Insulin: Safety in Type 2 Diabetes Mellitus

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Abstract

The combined pooled analysis presents evidence of safety in patients with type 2 diabetes mellitus (T2DM) from Phase 2/3 clinical trials of Technosphere® (TM) insulin. The 592 patients received Technosphere® insulin alone or in combination with oral agents or subcutaneous basal insulin. The most common adverse event was hypoglycemia, the overall incidence for which was similar in the Technosphere® and comparator groups. In the Technosphere® group, 7/1345 (0.5%) patients were significantly hypoglycemic, compared to 15/1345 (1.1%) of comparator patients. The study results support that Technosphere® insulin is generally safe and effective for patients with type 2 diabetes mellitus (T2DM).

Results

The incidence of hypoglycemia, the overall incidence for which was similar in the Technosphere® and comparator groups. In the Technosphere® group, 7/1345 (0.5%) patients were significantly hypoglycemic, compared to 15/1345 (1.1%) of comparator patients. The study results support that Technosphere® insulin is generally safe and effective for patients with type 2 diabetes mellitus (T2DM).

Conclusions

These Phase 3 trials contributed to the pooled analysis in patients with type 2 diabetes. In total, 1092 patients received Technosphere® insulin alone or in combination with basal insulin. The primary endpoint was the incidence of hypoglycemia (severe or non-severe) in patients with type 2 diabetes. The data were analyzed using a time-to-event approach. The results of the pooled analysis support the efficacy and safety of Technosphere® insulin in patients with type 2 diabetes mellitus (T2DM).

In patients with type 2 diabetes who received Afrezza:

- The most common AEs were hypoglycemia and mild transient cough.
- The incidence of hypoglycemia and of severe hypoglycemia was lower compared with acarbose.
- There was no increase in cardiovascular risk.
- Observed changes in pulmonary function tests were small, non-progressive, and resolved on discontinuation.
- There was no difference in the rate of clinically significant radiological findings in HRCT between groups.

Materials and Methods

In patients with type 2 diabetes who received Afrezza:

- There was a small reduction in pulmonary function that was nonprogressive and resolved on discontinuation.
- Differences in pulmonary function were small, nonprogressive, and disappeared within 3 months of stopping Afrezza.
- The most common adverse event was hypoglycemia, the overall incidence for which was similar in the Technosphere® and comparator groups. In the Technosphere® group, 7/1345 (0.5%) patients were significantly hypoglycemic, compared to 15/1345 (1.1%) of comparator patients. The study results support that Technosphere® insulin is generally safe and effective for patients with type 2 diabetes mellitus (T2DM).

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