

Multi-Study Evaluation of Changes in Body Weight with Use of Inhaled Technosphere Insulin (TI) Versus Rapid Acting Analogue (RAA) Insulin

BACKGROUND

- Technosphere Insulin (TI) is a rapid acting inhaled human insulin indicated to improve glycemic control in adult patients with diabetes mellitus¹
- TI lowers blood sugar levels by stimulating peripheral glucose uptake by skeletal muscle and fat, and by inhibiting hepatic glucose production¹
- TI absorption into the blood starts in less than one minute²

CONCLUSIONS

- Across three trials in participants with type 1 diabetes, **TI was associated with a neutral weight profile** while participants on rapid-acting analog insulin experienced weight gain.

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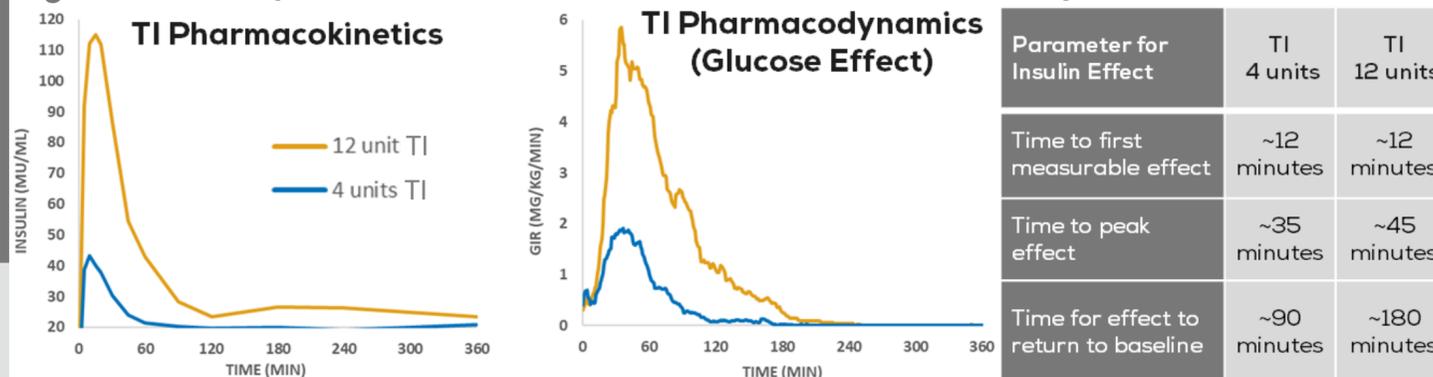
Presenting Author: Deb Malkoff-Cohen[†], MS, RD, BC-ADM, CDCES, CDN

Additional Authors: Joanne Rinker[‡], MS, RDN, BC-ADM, CDCES, FADCES; Joseph Sylvan[‡]; Johanna Ulloa; Sharyse Watanabe[‡]; Chioma Friday[‡]

[†]Nutrition by DMC [‡]MannKind Corporation, Westlake Village, CA

Background

Figure 1. Technosphere Insulin (TI) Pharmacokinetics and Pharmacodynamics Profile¹



Methods

Body weight was measured at the start and end of clinical trials in participants with type 1 diabetes using either TI or injectable RAA insulins.

Results

Across the Affinity-1³, STAT⁴, and INHALE-3^{5,6} trials, treatment difference between groups favored the TI arm. Two trials reported no weight gain in the TI group, while the third showed only a minimal increase of 0.1 kg.

INHALE-3 demonstrated potentially directional differences based on a participant's insulin modality before starting TI treatment.

AFFINITY-1

24-week phase 3 trial which evaluated the efficacy and safety of TI versus insulin aspart

Table 1. Weight Change

	TI (N=132)	Control (N=153)
Weight Change (24 weeks) Mean ± SD	-0.4 ± 5.0 kg	0.9 ± 5.5 kg
Treatment Difference	-1.3 kg (p=0.01)	

STAT

4-week phase 4 trial which evaluated glycemic management of TI versus insulin aspart

Table 2. Weight Change

	TI (N=26)	Control (N=34)
Weight Change (4 weeks) Mean ± SD	-0.2 ± 1.3 kg	0.8 ± 1.3 kg
Weight Change Difference	-1.0 kg (p=0.006)	

INHALE-3

17-week phase 4 RCT trial which evaluated the efficacy and safety of TI compared to usual care [multiple daily injections (MDI), automated insulin delivery (AID) and sensor augmented pumps (SAP)]

Table 3. Weight Change, All Participants

	TI (N=56)	Control (N=57)
Weight Change (17 weeks) Mean ± SD	0.1 ± 2.8 kg	1.4 ± 3.1 kg
Treatment Difference	-1.3 kg (p=0.03)	

Table 4. Weight Change, AID Participants

AID at Start of Study	TI (N=28)	Control (N=19)
Weight Change (17 weeks) Mean ± SD	0.4 ± 2.9 kg	1.3 ± 3.5 kg

Table 5. Weight Change, MDI/SAP Participants

MDI/SAP at Start of Study	TI (N=28)	Control (N=20)
Weight Change (17 weeks) Mean ± SD	-0.3 ± 2.7 kg	1.5 ± 2.7 kg

¹Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation. Danbury, CT; February 2023. ²Data on File (PDC-INS-0002). MannKind Corporation. ³Bode BW, et al. Diabetes Care. 2015;38(12):2266-73. ⁴Akturk HK, et al. Diabetes Technol Ther. 2018;20(10):639-647. ⁵Hirsch IB, Beck RW, Marak MC, et al. Diabetes Care. vol 48,3 (2025): 353-360. ⁶Hirsch IB, Beck RW, Marak MC, et al. Diabetes Care. Vol 47,9 (2024): 1682-1687.