

Insulin Delivery Devices

22 Insulin Dosing Recommendations: "Over-Basaling" and "Under-Bolusing"

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Objective: To evaluate the correction factor (CF, mg/dL of blood glucose [BG]/U), the carbohydrate-to-insulin ratio (ICR, grams of carbohydrate/U), and the total daily basal insulin dose (TBD, U/d); the formulas from which these factors are derived (ie, total daily insulin dose [TDD, U/d] or weight in kilograms in "well-controlled" patients [ie, glycosylated hemoglobin (A1C) level of <7.0%]); and their relationships using continuous BG monitoring and frequent insulin dosing adjustments under conditions of near-normal glycemia.

Methods: Adults with type 1 diabetes mellitus treated with an insulin pump were included if they had an A1C level of <8.0% and an undetectable C-peptide level and were excluded for any condition that influenced insulin sensitivity. The basal hourly infusion rate was titrated until 80% of BG readings were 70 to 170 mg/dL and <5% were <70 mg/dL. The ICR was determined from the amount of insulin that allowed patients to achieve a postmeal BG level \pm 20% of the premeal level. The CF was determined by the amount of insulin that allowed patients to achieve a BG level of 80 to 120 mg/dL within 4 hours of correction bolus.

Results: All 30 patients achieved BG treatment targets, with TBD = $0.384 \times \text{TDD}$ and $0.185 \times \text{Wt}$ (kg). The formulas for estimating ICR and CF were $(217/\text{TDD}) + 3$ and $(1076/\text{TDD}) + 12$, respectively. Previously published formulas differ markedly. TDD, TBD, ICR, and CF were significantly interrelated, and near-normal glycemia was achieved.

Conclusion: Current dosing formulas overestimate TBD and underestimate bolus dosing. The significant relationship between $1/\text{TBD}$, CF, and glucose infusion rate suggests that a change in one value should be coupled to proportional changes in the others.

23 Technosphere[®]/Insulin Versus Subcutaneous Rapid-Acting Insulin Analogue: A 6-Month Study in Patients with Type 2 Diabetes

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Objective: To compare Technosphere[®]/Insulin (TI) with SC rapid-acting insulin analogue insulin aspart (RAA) in patients with type 2 diabetes mellitus (DM).

Methods: Insulin-treated patients with type 2 DM and glycosylated hemoglobin (A1C) levels of 7.0% to 11.5% were enrolled in a randomized, controlled, 6-month study to compare TI with SC RAA at mealtimes, together with insulin glargine. A1C level, hypoglycemia frequency, weight, and pulmonary function (including forced expiratory volume in 1 second [FEV₁]) were measured at screening, randomization, and 6 months. At screening, the study population (n = 306; TI, 148; RAA, 158) had a mean age of 58 years and body mass index of 30.8 kg/m². Mean baseline A1C values were comparable: TI, 8.85; RAA, 8.99.

Results: A1C values did not change significantly from baseline to 6 months: TI, -0.92 (SD 1.3); RAA, -1.11 (SD 1.1). However, there was a significant difference between groups in the number of patients with ≥ 1 hypoglycemic event (TI, 43%; RAA, 54%) ($P = 0.03$). In the RAA group, mean weight increased by 0.32 kg (SD 2.64), and in the TI group, mean weight decreased by 0.77 kg (SD 2.68) ($P = 0.002$). FEV₁ slightly decreased in both treatment groups: -0.064 L (SD 0.2897) in the TI group and -0.056 L (SD 0.1734) in the RAA group, with no significant difference between groups.

Conclusion: In patients with type 2 DM, TI provided similar glycemic control to RAA over 6 months, with less risk of hypoglycemia.