MINIMED™ 670G PIVOTAL TRIAL: TIMING OF MEAL BOLUS PLAYS A CRITICAL ROLE IN POSTPRANDIAL GLUCOSE CONTROL

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Introduction

The Auto Mode feature of the Medtronic MiniMed™ 670G system with SmartGuard™ technology automatically adjusts basal insulin delivery every 5 minutes based on sensor glucose (SG) values. Patients are required to calibrate the sensor, enter meal carbohydrate estimates, and notify the system of exercise. The MiniMed™ 670G system pivotal trial data[1,2] were analyzed to study the effect of the timing of meal boluses on postprandial SG levels.

Methods

Pivotal Trial Study Design:

1. Sites: 9 in US & 1 in Israel
2. 124 Type 1 patients (A1C <10%)
3. Pump use ≥6 months (+/- CGM)
4. **Run-in Phase**: Open loop (Manual Mode) for 2 weeks
5. **Study Phase:** Closed loop (Auto Mode) for 3 months

Postprandial Analysis:

1. A total of 3,708 postprandial periods were analyzed
2. Two meal cohorts were analyzed based on the user-announced carbohydrate content: (a) **Small meals**: ≤20 grams and (b) **Medium-to-Large meals**: >20 grams

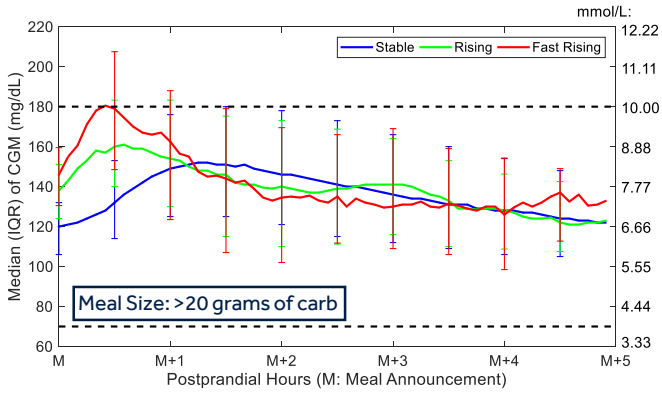
Postprandial Analysis (Cont.):

3. Both cohorts were divided into 3 groups based on sensor rate of change (ROC) at meal announcement:
   - **Stable (ROC <0.5 mg/dL/min)** – assuming bolus is delivered prior to meal consumption
   - **Rising (ROC >1 mg/dL/min)** – assuming bolus is delivered after/during meal consumption
   - **Fast Rising (ROC >2 mg/dL/min)** – assuming bolus is delivered after/during meal consumption
4. Meal events following another meal entry within 5-hour timeframe were discarded

Results

	Stable (ROC <0.5 mg/dL/min)	Rising (ROC >1 mg/dL/min)	Fast Rising (ROC >2 mg/dL/min)
Small Meals: ≤20 grams			
Number of meal events	673	78	15
Mean carb-to-insulin ratio, grams/unit	9.4 ± 3.2	8.7 ± 3.0	8.3 ± 2.7
Mean postprandial SG peak, mg/dL	174 ± 35	177 ± 28	178 ± 34
Mean postprandial SG AUC >180 mg/dL, min×mg/dL	524 ± 1,502	666 ± 1522	713 ± 2,095
Mean postprandial SG time >180 mg/dL, min	25 ± 46	28 ± 50	30 ± 57
Medium-to-Large Meals: >20 grams			
Number of meal events	2,634	323	63
Mean carb-to-insulin ratio, grams/unit	9.4 ± 3.7	9.0 ± 3.2†	8.6 ± 3.1‡
Mean postprandial SG peak, mg/dL	190 ± 41	203 ± 43†	216 ± 43‡
Mean postprandial SG AUC >180 mg/dL, min×mg/dL	1,557 ± 3,011	1,949 ± 3561†	2,624 ± 4083‡
Mean postprandial SG time >180 mg/dL, min	45 ± 60	55 ± 63†	67 ± 70‡

All values, except 'Number of meal events', are shown as mean ± SD.
† Indicates significance in p-value, between Stable (ROC <0.5 mg/dL/min) and Rising (ROC >1 mg/dL/min) groups.
‡ Indicates significance in p-value, between Stable (ROC <0.5 mg/dL/min) and Fast Rising (ROC >2 mg/dL/min) groups.



- Medium-to-Large meal cohort:
  - For the **Stable** group: postprandial SG-peak, AUC >180 mg/dL, and time spent >180 mg/dL were significantly lower compared to those of the other two groups
  - Although meal boluses in the two **Rising** groups were more aggressive, better postprandial outcome was observed in the **Stable** group due to pre-meal timing of boluses
- Small meal cohort: No significant differences were observed among the three groups

Conclusions

- This analysis demonstrates that meal-bolus timing for meals >20 grams of carbohydrate, during real-world use of the MiniMed™ 670G system, has a significant influence on postprandial glycemic outcome
- The data also suggests that pre-meal bolusing is potentially more impactful in producing tighter postprandial control than a more aggressive carb-to-insulin ratio
- Initiating meal bolus delivery prior to meal consumption remains the recommendation for MiniMed™ 670G when the Auto Mode feature is enabled

References

1. Garg SK, et al. *Diabetes Technol Ther*. 2017;19:155-163.
2. Bergenstal R., et al. *JAMA*. 2016; 316: 1407-1408.

· **WARNING**: Indicated for type 1 diabetes patients ≥14 years. Prescription required. Medtronic performed an evaluation of the MiniMed™ 670G closed-loop system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin does of 8 units per day because the device requires a minimum of 8 units per day to operate safely.

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