



MINIMED 640G (2015): SYSTEM USER EVALUATION

STUDY RATIONAL

- Hypoglycaemia is a major burden for people with Type 1 diabetes. It can cause confusion, disorientation, loss of consciousness and in the worst cases coma and even death.
- Automated suspension of insulin delivery, also known as Low Glucose Suspend (LGS), in response to hypoglycaemia detected by continuous glucose monitoring (CGM) when sensors glucose values fall below a pre-set threshold has been shown to reduce the severity and duration of hypoglycaemic events¹. Suspending insulin delivery earlier, in response to predicted hypoglycaemia, may allow patients with type 1 diabetes to further reduce or avoid hypoglycaemia entirely.
- The MiniMed® 640G system with SmartGuard™ technology is the first insulin pump system using Predictive Low Glucose Management (PLGM) to be commercialized. It includes a predictive suspend algorithm and an automatic resumption of insulin delivery when the patient recovered from hypoglycaemia.

OBJECTIVES

- The study aimed to evaluate the user acceptance of the MiniMed® 640G system with SmartGuard™ technology and the associated training materials.

DESIGN AND METHODS

- The study was a non-randomized, interventional trial conducted over 4 weeks at 3 medical centers in Europe (UK, Denmark and Spain).
- Subjects eligibility criteria: Type 1 diabetes for ≥6 months; aged 9 to 65; on Continuous Subcutaneous Insulin Infusion (CSII) therapy for ≥3 months.
- At the start of the study the subjects were trained on the MiniMed® 640G system and feedback questionnaires on the training materials were completed.
- The subjects used the system for 4 weeks at home and were instructed to use the CGM continuously with the PLGM feature turned ON. The low sensor glucose limit threshold was determined according to each subject's characteristics by the physician in consultation with the subject.
- SmartGuard™ is programmed to suspend insulin delivery if the sensor glucose (SG) value is predicted to be at or below the programmed threshold with a +20 mg/dL offset within 30 min and to restart when the SG value is at least 20 mg/dL above the threshold value and predicted to be at least 40 mg/dL above it within 30 min. PLGM suspension lasts a minimum of 30 minutes and a maximum of 2 hours.
- The subjects had the possibility to manually resume insulin delivery at any time during an automatic suspension.
- 4 phone contacts were scheduled with the subject to ensure good system usage and adherence to the study procedure
- At the end of the study feedback questionnaires on the device performance were completed and pump data was downloaded to CareLink™ Data Management Software.

KEYPOINTS

- Following 83% of the PLGM suspension events the pre-set low glucose limit was avoided
- No significant increase in hyperglycaemia
- Subjects assessed MiniMed® 640G was easy to use and helped facilitate their diabetes management

STUDY TYPE

- Multi-center, interventional, non-randomized
- 4 weeks duration
- 40 subjects (aged 9 - 65)

PARAMETERS ASSESSED

- Sensor Glucose values
- User acceptance

REFERENCE

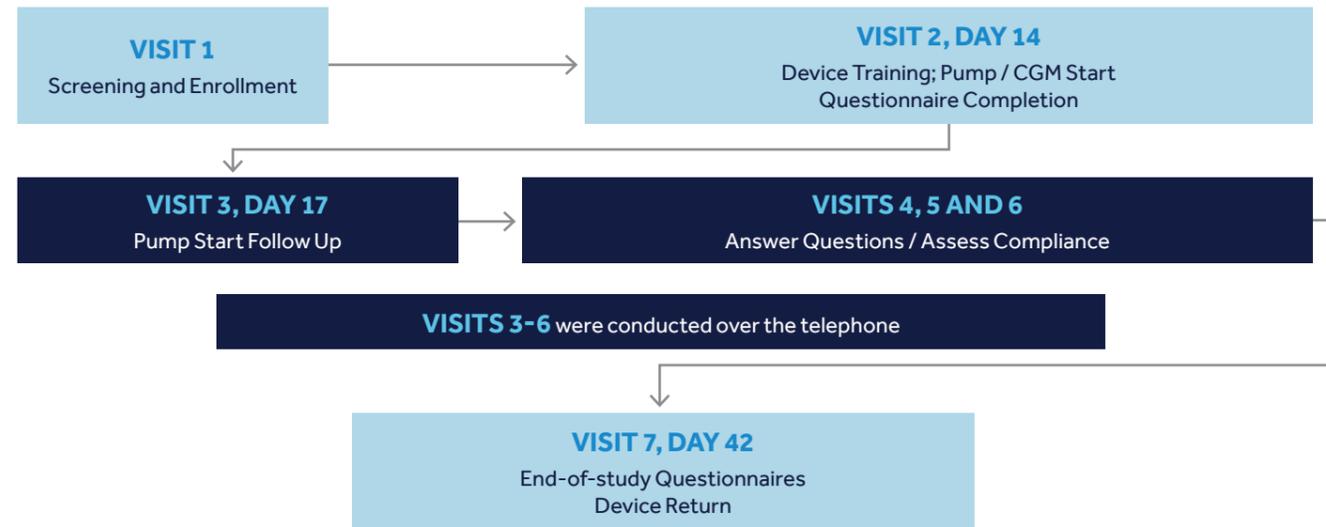
Prevention of hypoglycemia by the predictive low glucose management feature in a user evaluation study. Conget I. et al. EASD Diabetologia Abstracts 58 (1):416, 2015.

FROM THE AUTHORS

"MiniMed 640G system is an important step toward closed-loop systems and can be recommended for best practice routine care"



FIGURE 1: Study Design



RESULTS

- 40 subjects (16 Children aged 9 to 17 and 24 adults aged 19 to 65) were enrolled in the study.
- PLGM suspensions occurred 2.1 events per day with median duration of 57.8 minutes

Hypoglycaemia

- A total of 2322 evaluable PLGM suspension events occurred, which represents a mean rate of 2.1 events per subject-day. In 83% of these PLGM suspensions the SG value did not reach the pre-set low glucose limit (figure 2).
 - The median duration of PLGM suspensions was 57.8 minutes.
 - The most common low glucose limit used was 54 mg/dL (3.0 mmol/L)
 - The median minimum SG value during PLGM suspensions was 69.3 mg/dL (3.85 mmol/L)
 - The median SG value was 161.1 mg/dL (8.95 mmol/L) 2h after insulin delivery restart.
 - Nighttime suspensions lasted longer than daytime suspensions and were less likely to be manually terminated by the subject.
 - The most common time for any PLGM suspension to occur was in the early afternoon. The most common time for a maximum-duration (2-hour) PLGM suspension to occur was at night.

Efficacy

Among PLGM suspensions lasting >90 minutes, insulin delivery was resumed automatically by SmartGuard™ 89% of the time. The mean SG values during and after such suspensions did not reach the pre-set low glucose limit, allowed for a gradual recovery and without any hyperglycaemic rebound, showing that in the majority of incidences there is no need for the subjects to intervene with PLGM suspensions (Figure 3).

Hyperglycaemia

Both sensor glucose and blood glucose values showed no significant increase in hyperglycaemia between before the study and during the study (8.8 vs 9.0 mmol/L and 9.8 vs 9.7 mmol/L, respectively).

User Acceptance

Subjects assessed the MiniMed® 640G system and its automated features were easy to use and felt it helped facilitate diabetes management (Table 1).

FIGURE 2: Hypoglycaemia Prevention by SmartGuard™

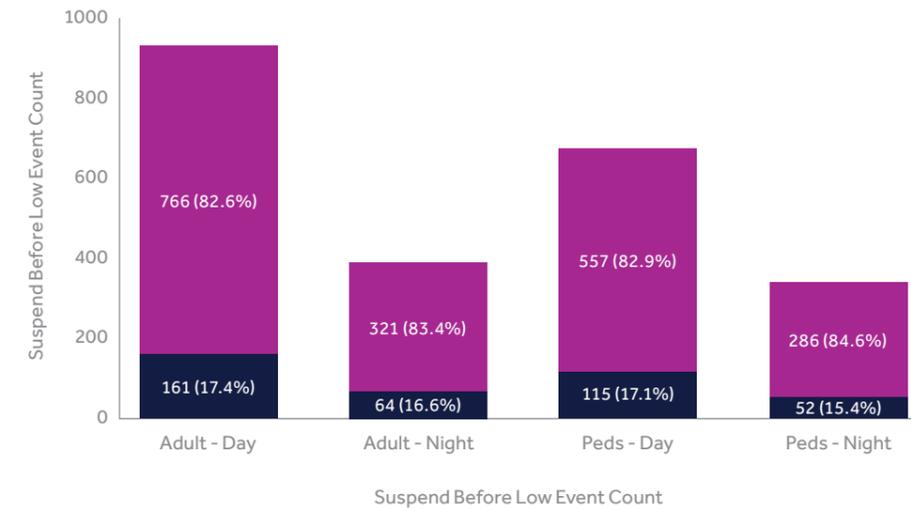


FIGURE 3: Sensor Glucose Trajectories

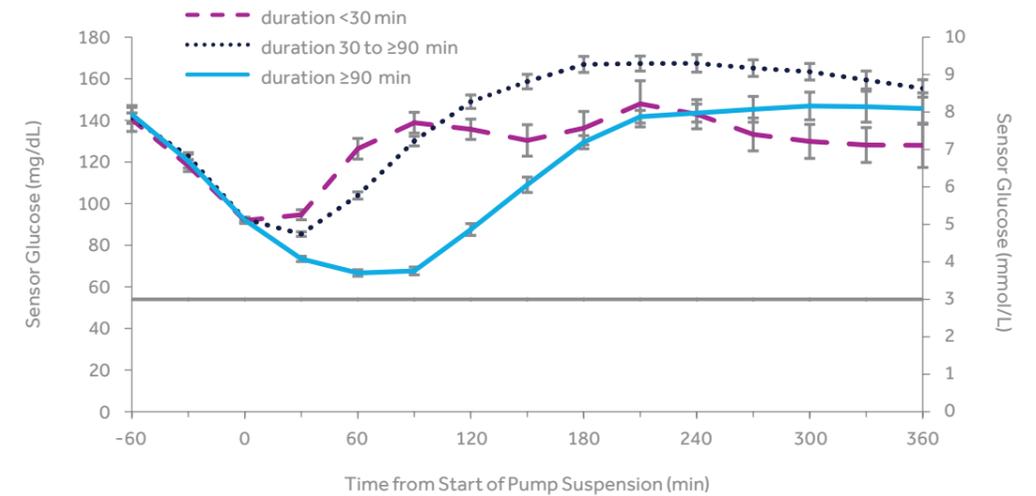


TABLE 1: Selected End-of-Study Questionnaire Responses

QUESTION	ADULT		PEDIATRIC	
	Median	Min, Max	Median	Min, Max
The SmartGuard features are easy to use	6	5, 7	6	4, 7
The SmartGuard features make it easier for me to manage my lows	6	4, 7	6	5, 7
MiniMed 640G helps me achieve better glucose control	6	4, 7	7	3, 7

Allowable answers ranged from 1 ("strong disagreement") to 7 ("strong agreement").

CONCLUSIONS

- MiniMed® 640G system with SmartGuard™ PLGM algorithm can help patients avoid hypoglycaemia, without significantly increasing hyperglycaemia.
- Patients do not need to intervene during a PLGM suspension as results showed that the MiniMed® 640G system was effective in keeping sensor glucose levels within target range when insulin delivery was not resumed manually.
- Subjects assessed that the MiniMed® 640G system was easy to use and helped facilitate their diabetes management
- MiniMed® 640G is the first commercially-available system with the ability to predictively suspend and automatically restart basal insulin delivery based on CGM data

Additional References

1. Threshold-Based Insulin-Pump Interruption for Reduction of Hypoglycemia. Bergenstal R.M. et al. N Engl J Med 369:224-32, 2013.