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Diabetes Clinical Summaries

MiniMed™ 780G System

ADAPT study - 6 months results

Study rationale

- For many people with type 1 diabetes (T1D), multiple daily injections (MDI) of insulin plus intermittently-scanned continuous glucose monitoring (isCGM) represents the standard of care, while advanced hybrid closed loop (AHCL) systems are the most advanced technology, allowing patients to achieve potentially greater glycemic control.
- The MiniMed™ 780G System is an AHCL system that has been shown to be safe and to significantly improve glycemic control relative to previous generation systems[1,2].
- No data are available on the benefits of initiating the use of an AHCL system in patients using MDI+isCGM for T1D management.

About the MiniMed™ 780G system

- The MiniMed™ 780G system contains an advanced hybrid closed loop (AHCL) algorithm that automates the delivery of both basal and correction insulin boluses every 5 minutes based on sensor glucose values, adapting to the individual's unique insulin needs.
- The AHCL algorithm targets a glucose level which can be adjusted by the user to be 100 (5.5), 110 (6.1) or 120 (6.7) mg/dL (mmol/L) , based on individuals' needs.

Study objectives

- To evaluate the efficacy of MiniMed™ 780G system compared with MDI+isCGM therapy in adults with T1D with suboptimal glucose control.

Get in touch to learn more about how the MiniMed™ 780G system can improve patient outcomes.

Get in touch

Key points

- Differences in favor of AHCL:
  - -1.42% HbA1c
  - +27.6% TIR
  - Treatment satisfaction and fear of hypoglycemia improvement

Study type

- Randomized Controlled Trial
- AHCL vs MDI+isCGM
- 6 months
- 82 subjects
  - Aged ≥18
  - Type 1 diabetes ≥2 years
  - MDI+isCGM ≥3 months
  - HbA1c ≥8.0%

Parameters Assessed

- HbA1c
- Time spent in the glycemic ranges
- Severe hypoglycemic and diabetic ketoacidosis events
- Patient reported outcomes

Reference

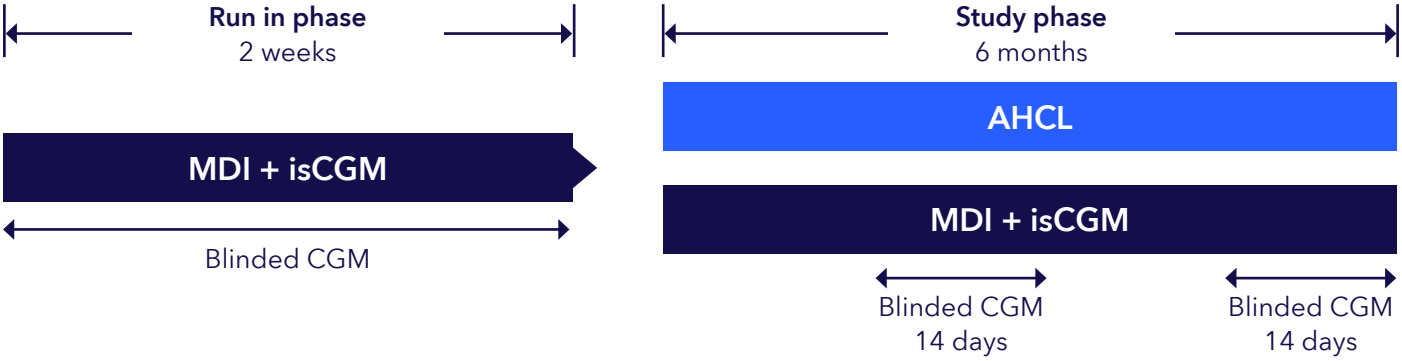
Choudhary P, et al. Advanced Hybrid Closed Loop Study In An Adult Population With Type 1 Diabetes (Adapt): A Randomized Controlled Study. Lancet Diabetes Endocrinol. 2022;10(10):720-731.

Access article online

Study Design and Methods

- This was a randomized controlled trial conducted in 14 sites across 3 European countries (France, Germany and the United Kingdom).
- Patients aged ≥18 years, with T1D duration ≥2 years, HbA1c ≥8.0% and using MDI+isCGM for ≥3 months, were enrolled.
- The protocol has been described previously[3]. It consisted of a 2-week run-in phase followed by a 6-month study phase in which subjects were randomly allocated to either continue with MDI+isCGM or to initiate AHCL. (Figure 1)
- The primary endpoint was the difference in the mean HbA1c change (baseline versus 6 months) between the AHCL group and the MDI+isCGM group. Other endpoints included CGM-derived metrics, including time spent in range (TIR), below range (TBR) and above range (TAR); patient reported outcomes (PROs), including fear of hypoglycemia and treatment satisfaction; and safety, including number of severe hypoglycemic (SH), diabetic ketoacidosis (DKA), and serious adverse events (SAEs).
- The AHCL system used in the study was an investigational version of the MiniMed™ 780G system that did not include the glucose target of 110 mg/dL (6.1 mmol/L), the bluetooth connectivity nor the mobile app.

Figure 1: Study design



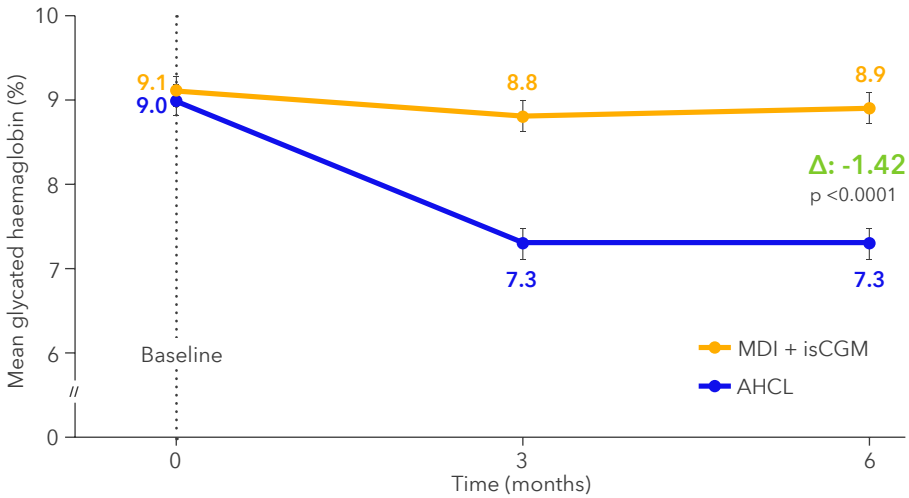
Study results

- 105 patients were screened for eligibility between July 2020 and March 2021; 41 subjects were randomly allocated to each treatment arm. Thirty-six subjects in the AHCL group and 39 subjects in the MDI+isCGM group completed the 6-month treatment phase.
- In the AHCL group, subjects used the CGM sensor 92.2% of the time and spent 95.8% of the time in AHCL. They experienced 0.9 AHCL exits per week and performed a mean of 3.8 self-monitoring of blood glucose (SMBG) measurements per day. The glucose target of 100 mg/dL and an active insulin time (AIT) of 2h were used for 68.3% and 54.4% of the time, respectively.

HbA1c

- At 6 months, the mean±SD change from baseline in HbA1c was −1.54±0.73% in the AHCL group and −0.20±0.80% in the MDI+isCGM group, resulting in a model-based treatment effect of −1.42%; P<0.0001) in favor of the AHCL group (Figure 2).
- No subjects (0%) in the MDI+isCGM group achieved the glycemic treatment goal of HbA1c <7.0% at 6 months compared to 27.8% of subjects in the AHCL group (Figure 4).

Figure 2: Results of HbA1c



CGM-derived metrics

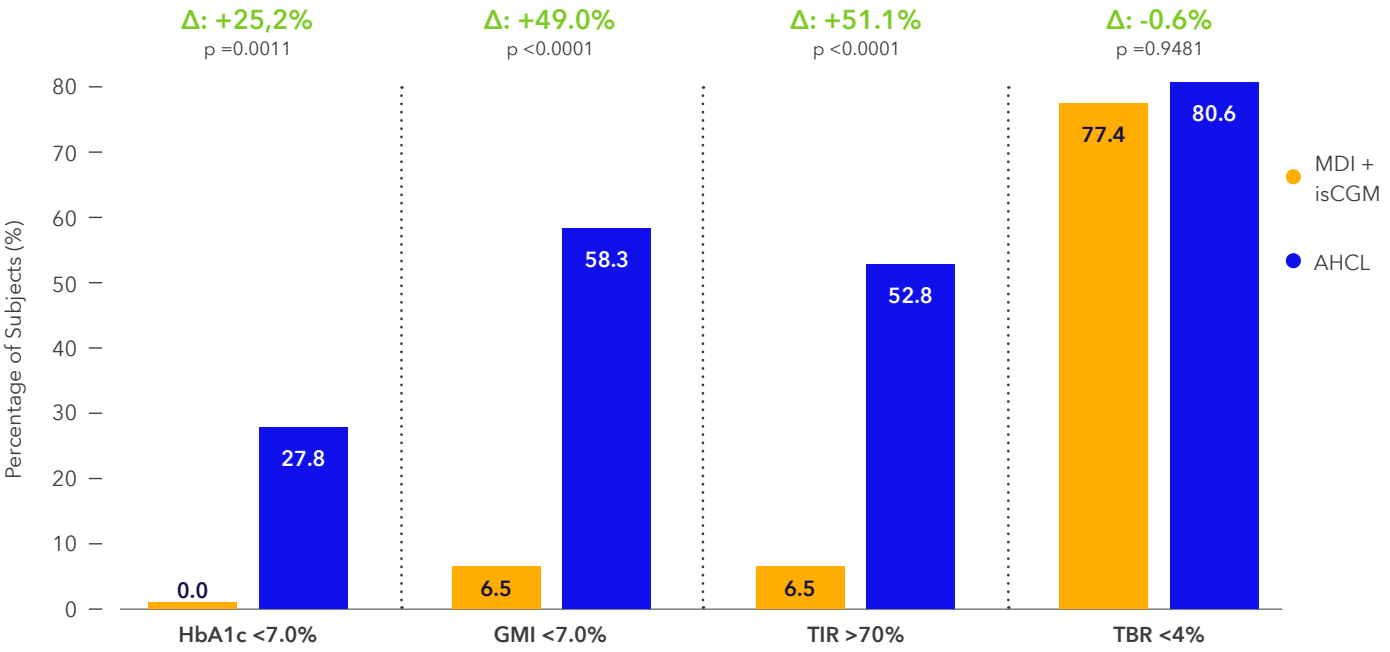
- Subjects in the AHCL group spent a significantly greater proportion of TIR compared with the MDI+isCGM group (TIR: 70.6% and 43.6%, respectively) resulting in a model-based treatment effect of +27.6% (p<0.0001) (Figure 3). This increase corresponded to an increment of 6.6 hours per day spent within the target range.
- The improvement in glycemic levels was associated with no increase in sensor-detected nor clinical hypoglycemia. TBR remained below the recommended threshold of 4% for both treatment groups (Figure 3).
- Mean SG improved significantly in the AHCL group to 152.2 ±16.5 mg/dL (8.5 ±0.9 mmol/L) compared to the MDI+isCGM group (p<0.0001), corresponding to a GMI of 7.0 ±0.4% (Figure 3).
- At 6 months, a significantly higher percentage of subjects in the AHCL group, compared to the MDI+isCGM group, achieved the glycemic treatment goals of TIR>70% (52.8% vs 6.5%, respectively) (Figure 4).

Figure 3: Results of CGM-derived metrics

	MDI + isCGM		AHCL		Δ	*p*
	Baseline	Study Phase	Baseline	Study Phase		
Mean SG, mg/dL	195.1 ± 23.8	194.7 ± 29.5	208.8 ± 29.0	152.2 ± 16.5	-44.9	<0.0001
Mean SG, mmol/L	10.8 ± 1.3	10.8 ± 1.6	11.6 ± 1.6	8.5 ± 0.9	-2.5	<0.0001
CV of SG, %	37.8 ± 5.6	35.9 ± 5.7	35.4 ± 5.8	35.5 ± 4.5	0.6	0.571
GMI, %	8.0 ± 0.6	8.0 ± 0.7	8.3 ± 0.7	7.0 ± 0.4	-1.1	<0.0001

*non-inferiority met

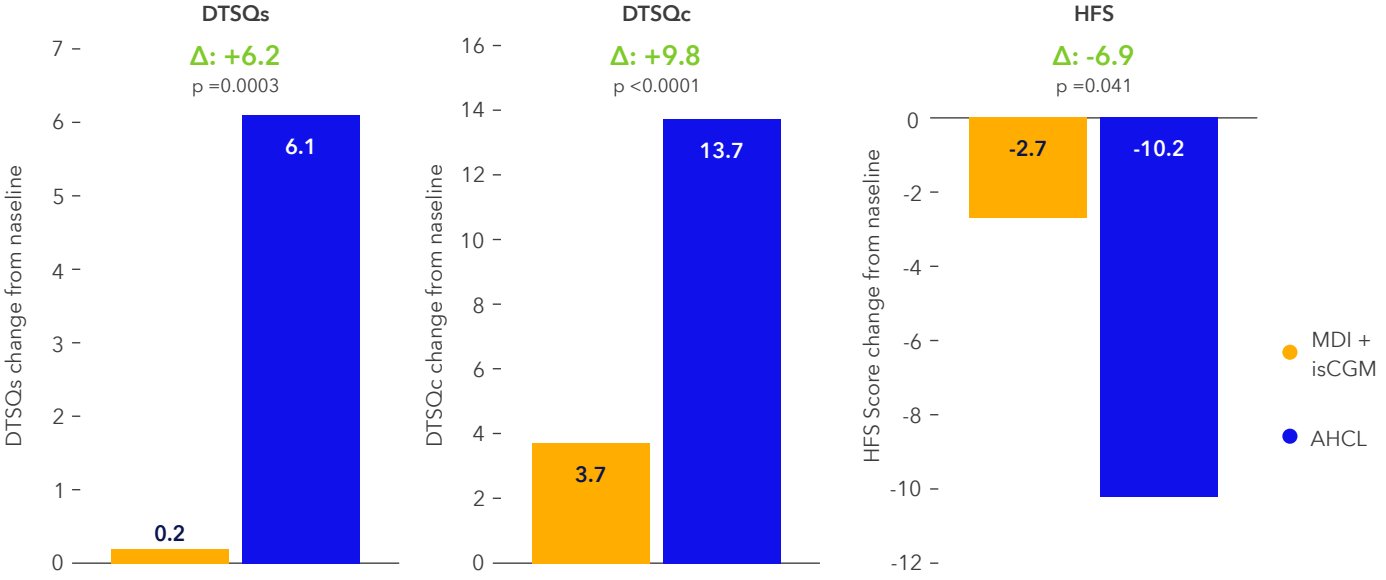
Figure 4: Percentage of subjects achieving the glycemic treatment goals.



Patient reported outcomes

- AHCL improved treatment satisfaction with a significant increase in the mean Diabetes Treatment Satisfaction Questionnaire Status (DTSQs) score in the AHCL group after 6 months compared with the MDI+isCGM group (p=0.0003) (Figure 5).
- Fear of hypoglycemia (HFS total score) decreased from baseline in both groups, but the magnitude of the decrease was greater in the AHCL group (p=0.0409).

Figure 5: Patient reported outcomes scores



Safety

- No SH or DKA event occurred during the 6-month study phase.
- 2 SAEs, not related to the study devices, occurred during the study phase (one in each treatment group).

Conclusion

- In people with T1D using MDI+isCGM and with HbA1c ≥8·0%, the use of AHCL confers benefits in terms of glycemic control and user satisfaction beyond those that can be achieved with MDI+isCGM therapy.
- These data support wider and earlier access to AHCL in people with T1D not at target glucose levels.

Additional References

1. Carlson AL, et al. Safety and Glycemic Outcomes During the MiniMed™ Advanced Hybrid Closed-Loop System Pivotal Trial in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther. 2022;24(3):178-189.
2. Silva JD,et al Real-World Performance of the MiniMed™ 780G System: First Report of Outcomes from 4120 Users. Diabetes Technol Ther. 2022;24(2):113-119.
3. De Portu S, et al. "A Randomised Controlled Trial of Advanced Hybrid Closed-Loop Study in Adult Population with Type 1 Diabetes (ADAPT): Study Protocol and Rationale". BMJ Open 2022 ; 12(2):e050635.

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