

DIABETES CLINICAL SUMMARIES



CARELINK™ DATA MINING REAL LIFE USE OF CGM

STUDY RATIONALE

- It has been shown in clinical studies that Sensor Augmented Pump (SAP) therapy is associated with improved glycaemic control and a decrease in hyperglycaemic events^{1,2} and duration. Clinical studies are conducted in a controlled environment and the transposition of these results into real life remains to be established.
- Additionally, the clinical evidence showed that when Continuous Glucose Monitoring (CGM) was used for at least 70% of the time patients experienced optimum benefits^{1,2}. This level of adherence is rare in real life and there is a lack of clinical data demonstrating which factors are associated with long-term CGM adherence.
- A retrospective analysis of data from Medtronic CareLink™ – a self-uploaded database including patients receiving insulin pump therapy (without CGM: Continuous Subcutaneous Insulin Infusion (CSII) therapy; or with CGM: SAP therapy) with blood glucose meters – was performed.

OBJECTIVES

- The study aimed to analyse blood glucose control according to CGM usage and identify factors associated with CGM continuation

DESIGN AND METHODS

- The study was a retrospective analysis of CareLink™ data of 10'501 subjects with Type 1 or Type 2 diabetes mellitus in Western Europe, Israel and Canada collected between 01 September 2011 and 31 October 2013.
- All subjects included in the analysis had at least 6 months of downloadable data and at least one CGM reading in CareLink™.
- Data were analysed according to the extent of CGM usage (< 25%, 25–49%, 50–74% and ≥ 75% of time). In order to exclude anecdotal and transient diagnostic use of the CGM, subjects without a minimum of 15 days of CGM usage within any 6-month period were defined as non-CGM users.
- Measures of glycaemic variability were derived from Self-Monitoring of Blood Glucose (SMBG) measurements, rather to CGM values, to allow a greater consistency in the number of measurements between groups.
- Blood glucose measurements were also used to estimate HbA1c levels and the proportion of subjects achieving HbA1c level <53 mmol/mol (7.0%).
- Hypoglycaemic events were defined as blood glucose values below 2.8 (50), 3.3 (60) and 3.9 mmol/L (70 mg/dL). Two low blood glucose measurements within 20 minutes were regarded as one event.
- Time to discontinuation of CGM was also analysed in new CGM users (defined as individuals with a date of first consistent CGM use later than 01 October 2011). CGM discontinuation was defined as less than 15 days of CGM use within any 6-month period.

KEYPOINTS

- Increased usage of CGM is associated with:
 - ✓ Greater chance of achieving HbA1c <7%
 - ✓ Greater reduction of hypoglycaemia
- Usage of CGM during the first month is strongly associated with long-term adherence

STUDY TYPE

- Retrospective analysis of CareLink™ database (patient self-uploaded electronic database)
- 10'501 subjects with Type 1 or Type 2 diabetes
- 26-month data collection period

PARAMETERS ASSESSED

- Time of CGM usage (%)
- Blood glucose levels
- Time to CGM discontinuation (for new CGM users)

REFERENCE

Routine use of continuous glucose monitoring in 10 501 people with diabetes mellitus. Battelino et al. Diabetic Med., published online July 14, 2015. doi:10.1111/dme.12825.



RESULTS

Out of the 10'501 subjects included in the analysis, 7'916 had at least 15 days of CGM use within a 6-month period and were classified as CGM users.

Glycemic Control

- The mean proportion of blood glucose values within the target range (3.9 – 10 mmol/L) increased significantly with CGM usage (Table 1).
- Subjects using CGM >75% of the time have a significantly increased chance to achieve HbA1c <7% (Table 1).

Hypoglycaemia

- Occurrence of hypoglycaemic events below 2.8 mmol/L (50 mg/dL) decreased as CGM usage increased. Subjects using CGM >75% of time had 33% less hypoglycaemic events compared to non-sensor users (Figure 2).
- Significant reductions in the number of hypoglycaemic events were also observed with higher sensor glucose thresholds: 34% and 27% reduction in the number of events below 3.3 (60) and 3.9 mmol/L (70 mg/dL), respectively.

CGM Continuation Factors

- Out of the 3028 new CGM users, 25.4% discontinued CGM during the observation period.
- The risk of discontinuation was related to the degree of CGM use (Table 1).
- CGM usage during the first month of therapy was an important predictor of subsequent discontinuation: only subjects using CGM >75% of the time during the first month of SAP therapy were less likely to discontinue CGM (Figure 3).

TABLE 1: Characteristics according to CGM usage group

	NON-CGM USERS	<25% TIME	25-49% TIME	50-74% TIME	≥75% TIME
Subjects, n	2585	2782	1789	1585	1760
Mean SMBG per week, n	33.9	31.5	32.2	34.5	37.4
Mean BG values, %					
< 2.8 mmol/L	2.0	1.9	1.6	1.4	1.2
< 3.9 mmol/L	9.1	8.5	7.7	7.0	6.3
3.9 – 10.0 mmol/L	53.4	54.1	54.7	55.3	57.6
> 10.0 mmol/L	37.6	37.3	37.6	37.7	36.1
Subjects reaching HbA1c target <7%, n (%)	803 (31.06)	849 (30.52)	555 (31.02)	509 (32.11)	699 (39.72)
CGM discontinuation, n (%)	NA	1407 (50.6%)	241 (13.5%)	29 (1.8%)	5 (0.3%)

FIGURE 2: Number of hypoglycaemic events per patient-day

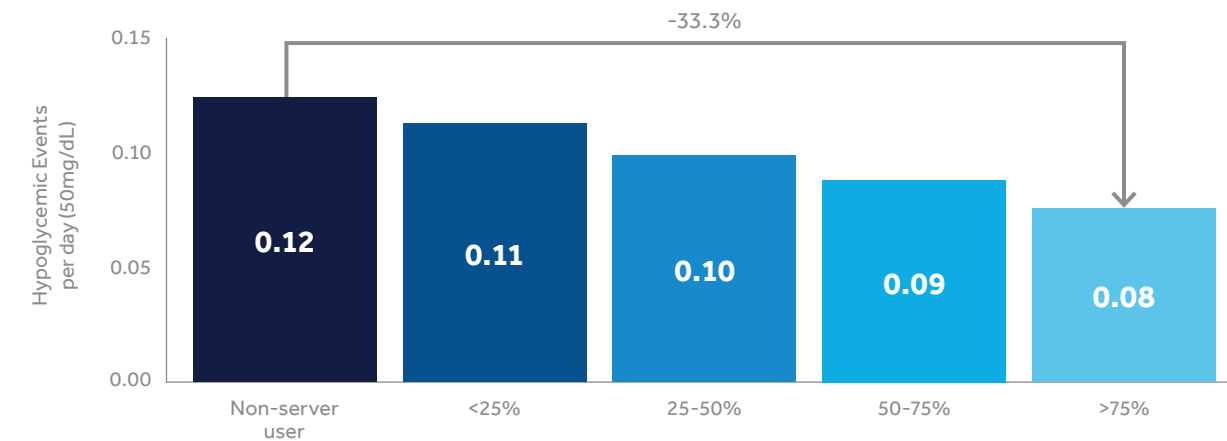
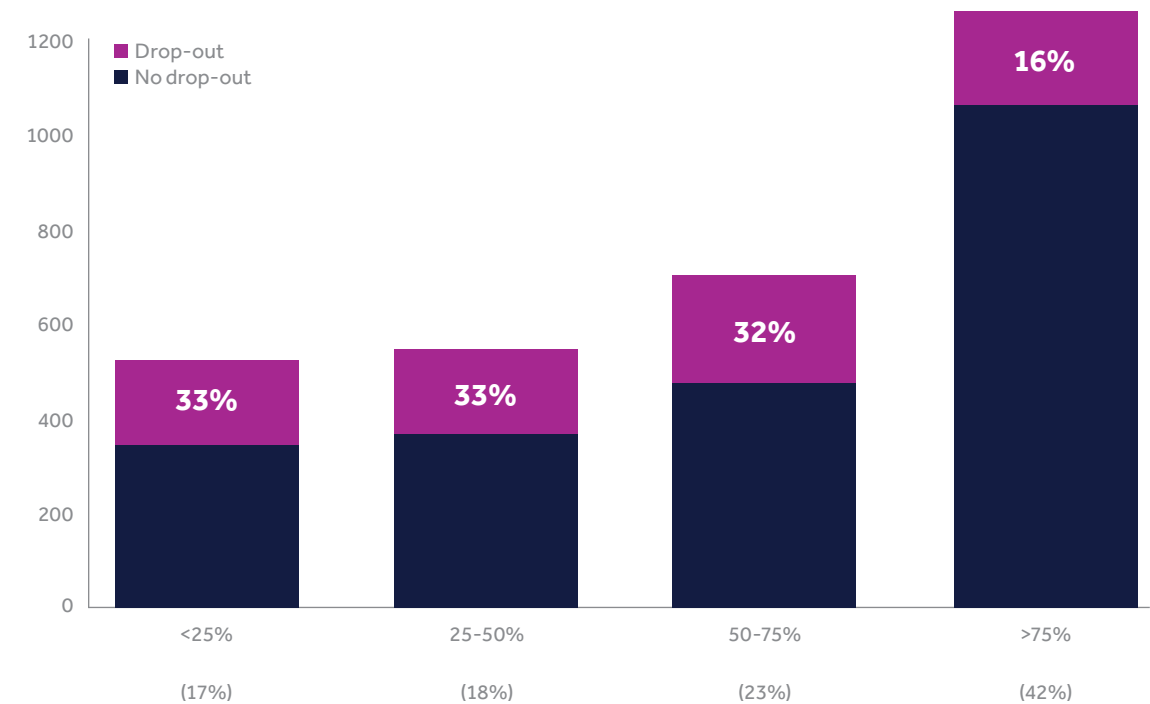


FIGURE 3: CGM discontinuation rate by CGM usage during the first month of SAP therapy



CONCLUSIONS

- The routine use of CGM with CSII was associated with significant improvement in metabolic control and reduction in the number of hypoglycaemic events.
- CGM usage during the first month of SAP therapy was strongly associated with long-term adherence. Patient education and training may be helpful in achieving this.

Additional References

1. Effectiveness of Sensor-Augmented Insulin Pump Therapy in Type 1 Diabetes. Bergenstal RM, et al. N Engl J Med 363:311-20, 2010.
2. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomized controlled trial. Battelino T, et al. Diabetologia 55:3155-3162, 2012.