Dexcom®
CONTINUOUS GLUCOSE MONITORING

The HypoDE Study[1]

Dexcom Continuous Glucose Monitoring (CGM)* Significantly Reduces Hypoglycaemia in Patients on Multiple Daily Injections (MDI)

Optimising Glucose Control While Decreasing Hypos

CGM clinical trials to date have largely excluded individuals with severe hypoglycaemia (SH) or impaired hypoglycaemic awareness (IHA). This study examines the impact of the Dexcom G5® Mobile CGM System use in patients on multiple daily injections (MDI) insulin therapy with a history of SH or IHA. The evidence was clear - CGM use demonstrated significant reduction in hypoglycaemic events while improving glycaemic control, including:

Reduction of Overall Hypoglycaemia

Reduced Glycaemic Variability

Study Objective & Methods

Objective:
Evaluate the effectiveness of CGM in reducing hypoglycaemic events† among high-risk individuals with Type 1 Diabetes treated with MDI.

Research Design/Method:

- *Randomised, controlled trial conducted in 12 diabetes practices throughout Germany*
- *30-week study that included a 4-week baseline data collection period, a 22-week intervention phase, and a 4-week evaluation period (weeks 22-26) to collect CGM data*
- *Adults with Type 1 Diabetes treated on MDI (n=149); randomised to CGM use (n=75) with the Dexcom G5 Mobile CGM System, or a control group using self-monitoring of blood glucose (SMBG) (n=74)*
- *History of IHA (Clarke score‡≥4) or recent severe hypoglycaemic event*
- *Average baseline HbA1c of 7.5%*

*Baseline glucose data for all participants and the glucose data in the follow-up period for the SMBG group were collected using the Dexcom G4® PLATINUM CGM System, which uses the same software algorithm as the Dexcom G5 Mobile CGM System. Subjects in the CGM group used the Dexcom G5 Mobile in the treatment phase and the follow-up period. All CGM data collected in the baseline period and in the control group in the intervention period was blinded.

† Hypoglycaemic event defined as glucose values ≤3.0 mmol/L sustained for at least 20 minutes, preceded by a minimum of 30 minutes with glucose values >3.0 mmol/L. Number of hypoglycaemic events in baseline and follow-up phases were recorded for each patient and standardised to an incidence of hypo events per 28 days.

‡ The Clarke score measures hypo awareness, based on a response to 8 questions characterising an individual's exposure to moderate and severe hypo events. Scores ≥4 indicate IHA.

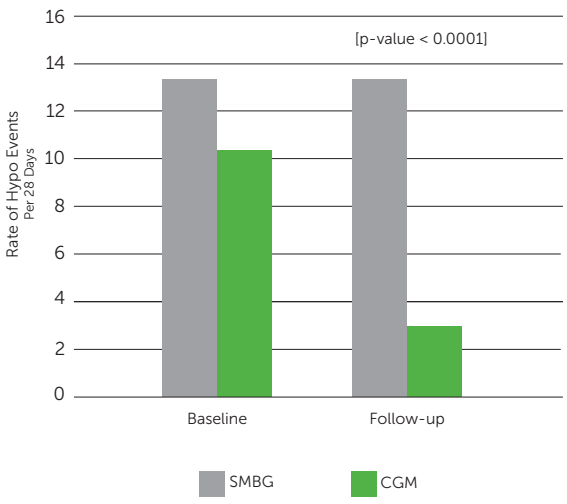
Results

Dexcom CGM Use Reduced Exposure to Hypoglycaemia

Primary Outcome:
Comparison of frequency of average number of hypoglycaemic events per 28 days (≤3.0 mmol/L for at least 20 minutes) in the CGM group to the control group.

- *Dexcom CGM group reduced the average number of hypo events by 72%§ from baseline (incidence rate ratio of 0.28).*
- *SMBG group showed minimal reduction of hypo events (13.5 events at baseline; 13.2 events at follow-up).*

CGM use reduced frequency of hypoglycaemic events compared to SMBG in individuals with MDI-treated Type 1 Diabetes.



§ Adjusted for baseline differences.

HypoDE Study[1]

Dexcom CGM Significantly Reduces Hypoglycaemia in MDI Patients

Secondary Hypoglycaemia Outcomes:

Reduced Hypo Events at Night

The average rate of hypo events at night dropped by more than half in the Dexcom CGM group from a rate of 2.3 events (per 28 days) at baseline to 1 event at follow-up.

The SMBG group saw an increase from an average of 2.4 night-time hypo events per 28 days at baseline to an average of 2.7 events at follow-up.

Significant Reduction of Hypoglycaemia

8-fold reduction of median daily duration of glucose <3.0 mmol/L - from 24.1 minutes at baseline to 3.8 minutes.

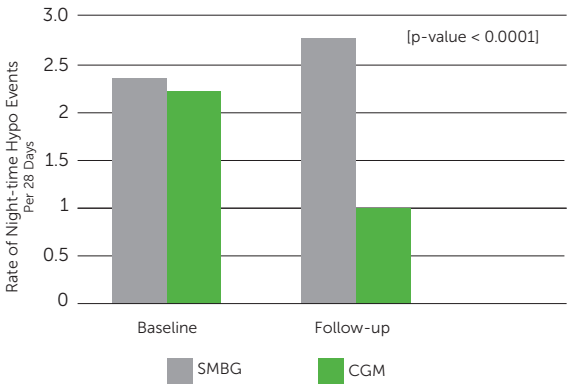
SMBG group showed a modest decrease of 9% (from 36.3 minutes to 32.9 minutes)

Reduced Risk of Severe Hypo

Average incidence of SH in SMBG group was 2x the rate of the CGM group. (1.18 vs. 0.64 SH events# per patient year)

SH events defined as number of hypoglycaemic events requiring third-party assistance (with or without medical assistance).

Reduced Night-time Hypo Events in Dexcom CGM Group¶



¶ between 00:00 and 06:00

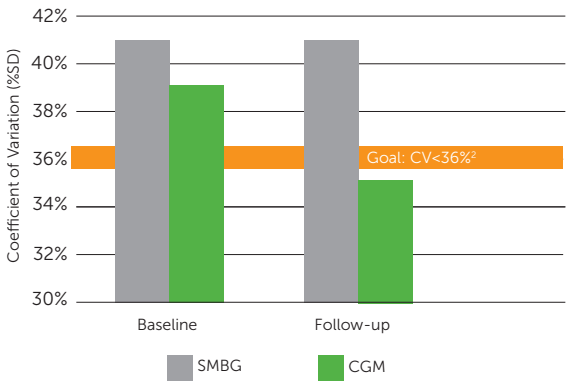
Dexcom CGM Use Improved Glucose Control

Dexcom CGM group saw an average reduction in glycaemic variability:from a coefficient of variation (CV) of 39.3% at baseline to a CV of 34.1% at follow-up. (A CV<36% is considered a goal for glucose variability.)[2]

- *CGM users experienced a more stable glucose profile, which is a protective factor against hypoglycaemia.[3]*

No improvement in glycaemic variability in SMBG group.

Dexcom CGM Use Reduced Glycaemic Variability After 22 Weeks of Use



HIGHLIGHTS

- 72% reduction in average number of hypoglycaemic events
- Decreased average number of night-time hypo events by more than half
- Reduced risk of severe hypo
- Reduced hypo-related distress
- Reduced glycaemic variability; more stable glucose profile
- Improved time within range

Improved Glucose Control, Fewer Lows

The use of CGM demonstrated that reduction of hypoglycaemia is not a limiting factor in achieving better glucose control.

For more information on Dexcom Continuous Glucose Monitoring, please contact us on **1300 851 056** or at **diabetes@amsl.com.au**

amsldiabetes.com.au

References: **1.** Heinemann L, Freckmann G, Faber-Heinemann G, Stefania Guerra S, Ehrmann D, Waldenmaier D, Hermanns N. Benefits of continuous glucose monitoring use in adults with type 1 diabetes and impaired hypoglycaemia awareness and/or severe hypoglycaemia treated with multiple daily insulin injections: Results of the multi-centre, randomised controlled HypoDE study. Lancet. In press. **2.** Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. Diabetes Care. 2017;40(12):1631-1640. **3.** Abraira C, Henderson WG, Colwell JA, et al. Response to Intensive Therapy Steps and to Glipizide Dose in Combination With Insulin in Type 2 Diabetes: VA feasibility study on glycemic control and complications (VA CSDM). Diabetes Care. 1998;21(4):574-579, as cited in Heinemann L, et al., 2018. **4.** Šoupal J, Petruželková L, Flekač M et al. Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study. Diabetes Technology & Therapeutics. 2016;18(9):532-538.

ARTG 169241. PR-100-240 August 2018