DIABETES CLINICAL SUMMARIES

CGM WELL CONTROLLED (2009): BENEFIT OF CGM IN WELL CONTROLLED TYPE 1 DIABETES

STUDY RATIONAL

- In the randomised JDRF-trial in patients with type 1 diabetes and baseline HbA1c level ≥7.0%, CGM was associated with improved glycaemic control (HbA1c reduction of 0.34%).[1]
- JDRF conducted this separate, concurrent randomised trial to evaluate the efficacy and safety of CGM in adults and children with type 1 diabetes who already had successfully achieved glycaemic control (HbA1c levels <7.0%) with intensive insulin therapy.

OBJECTIVES

- To evaluate the clinical effectiveness of CGM in reducing hypoglycaemia in subjects with Type 1 diabetes who already achieved glycaemic control, as compared to SMBG alone.

DESIGN AND METHODS

- This study was a randomised controlled trial comparing CGM (CGM group) and SMBG alone (SMBG group) over 6 months.
- Subjects eligibility criteria: Type 1 diabetes for ≥1 year; aged ≥8 years; on either MDI therapy or CSII therapy; HbA1c level <7.0%.
- A run-in phase was conducted for all subjects with a blinded CGM to assess baseline glucose levels.
- Subjects randomised to the CGM group were instructed to use CGM on a daily basis and to perform a blood glucose measurement before making a management decision. Subjects randomised to the SMBG group were instructed to perform ≥4 SMBG measurements per day.
- Visits were conducted at 1 week, and 1, 2, 3, 4.5 and 6 months with one scheduled phone contact between each visit (Figure 1).
- Glucose levels were measured in the SMBG group at 3 and 6 months using a blinded CGM.
- HbA1c levels were measured at baseline, 3 and 6 months.
- Episodes of severe hypoglycaemia (defined as an event requiring third-party assistance) and of hyperglycaemia resulting in ketoacidosis were also documented.
- Analyses were performed to assess consistency of the treatment effect in subgroups based on age (8 –14, 15–24, and ≥25 years).
- The primary endpoint was the change in the time spent in hypoglycaemia (<70 mg/dL) from baseline to 6 months. The secondary endpoints were the change in HbA1c levels and the rate of severe hypoglycaemia from baseline to 6 months.

KEYPOINTS

- 7.8 times bigger reduction in time spent in hypoglycaemia (<70 mg/dL) in the CGM group
- 46.8% less hypoglycaemic events (<54 mg(dL) in the CGM group
- No increase of HbA1c

DESIGN AT A GLANCE

- Randomised Controlled Trial
- CGM vs SMBG alone
- 6 Months duration
- 129 subjects (aged 8 to 69) with HbA1c <7%

ENDPOINTS

- Time spent in hypoglycaemia <70 mg/dL
- Severe hypoglycaemia
- HbA1c levels

REFERENCE

The Effect of Continuous Glucose Monitoring in Well-Controlled Type 1 Diabetes. Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study Group. Diabetes Care 2009;32:1378–1383

FROM THE AUTHORS

"Based on the weight of evidence, CGM is beneficial for adults and children with type 1 diabetes who already have achieved excellent control with home glucose monitoring"

Medtronic
Further, Together

FIGURE 1: Study Design

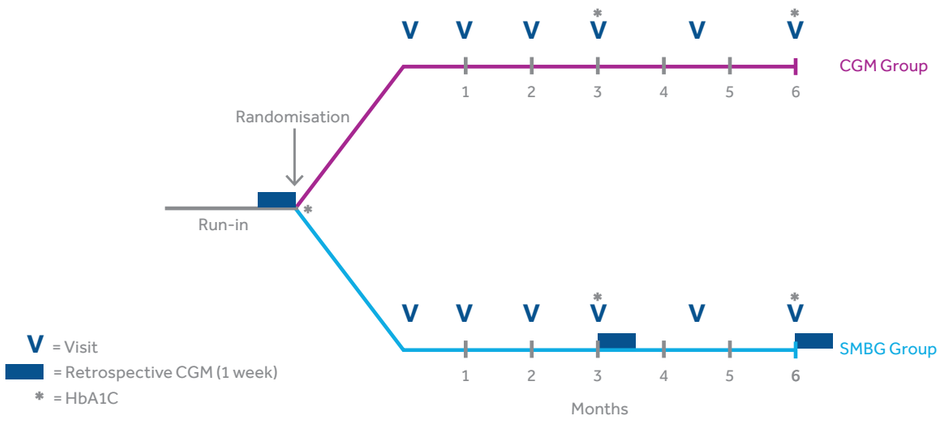
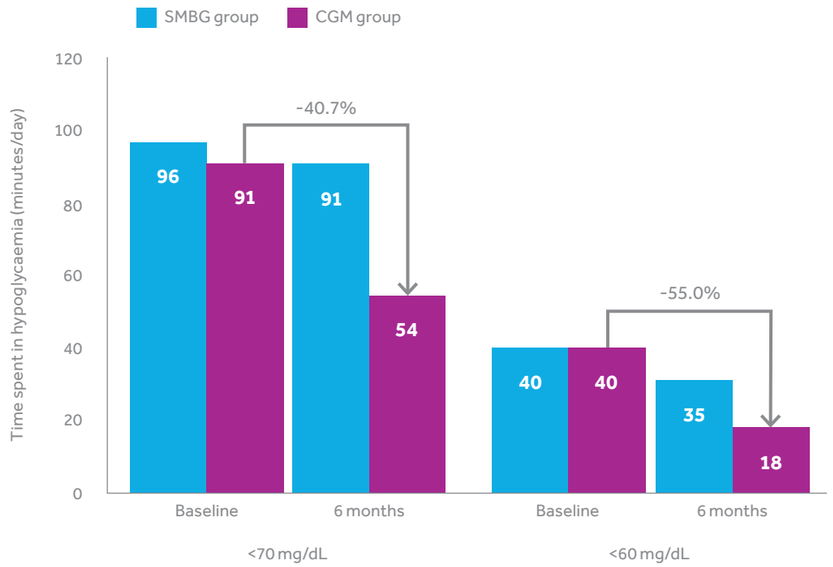


FIGURE 2: Time spent in hypoglycaemia



RESULTS

- A total of 129 children and adults (aged 8 to 69) were randomised to the CGM group (67 subjects) or to the SMBG group (62 subjects).
- Frequency of sensor use in the CGM group remained high for the entire study duration independently from the age group. Median CGM use was:
  - 6.8 days/week in subjects ≥25 years old
  - 6.2 days/week in the 15 to 24 year olds
  - 6.4 days/week in the 8 to 14 year olds

Hypoglycaemia

- The median time per day spent <70 mg/dL was reduced by 40.7% in the CGM group (91 vs 54 minutes from baseline to 6 months) as compared to a 5.2% reduction in the SMBG group (96 vs 91 minutes from baseline to 6 months). This represents a 7.8 fold bigger reduction with CGM compared to SMBG alone.
- The Area Under the Curve (AUC) <70 mg/dL was reduced by 59.4% in the CGM group (0.64 to 0.26 from baseline to 6 months) as compared to 18.3% reduction in the SMBG group (0.60 to 0.49 from baseline to 6 months).
- The hypoglycaemic event rate (≥ 20 minutes with blood glucose level <54mg/dL) was 46.8% lower in the CGM compared to the SMBG group (0.25 vs 0.47 events per day, respectively).

Severe hypoglycaemia

- There was no significant difference in the severe hypoglycaemia event rates between the CGM group and the SMBG group (27.1 vs 33.1 events per 100 subject-years, respectively).

HbA1c

- There was no significant difference in the change in HbA1c levels between the CGM group (6.4 to 6.4% from baseline to 6 months) and the SMBG group (6.5 to 6.8% from baseline to 6 months).
- More subjects in the CGM group had an HbA1c reduction ≥ 0.3% (31% vs 5%)
- Less subjects in the CGM group had an HbA1c increase ≥ 0.3% (28% vs 52%)
- More subjects in the CGM group retained an HbA1c level <7.0% (88% vs 63%)

CONCLUSIONS

- The use of CGM in addition to SMBG was associated with a significant reduction of hypoglycaemia in both children and adults with Type 1 diabetes who already achieved glycaemic control (HbA1c <7.0%).
- No increase was observed in HbA1c levels with the use of CGM.
- No increase was observed in severe hypoglycaemia with the use of CGM.

Additional References

1. Continuous glucose monitoring and intensive treatment of type 1 diabetes. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring study group. N Engl J Med 2008; 359:1464-76.