

# DIABETES CLINICAL SUMMARIES



## CGM META-ANALYSIS (2011): BENEFIT OF CGM VS SMBG

### STUDY RATIONAL

- Continuous Glucose Monitoring (CGM) uses a small glucose sensing electrode inserted in the subcutaneous tissue to monitor the glucose concentration of interstitial fluid in people with diabetes.
- Real time CGM provides information on direction, magnitude, frequency, and duration of glycaemic oscillations continuously in order to help patients and their health care providers better control their diabetes.
- A meta-analysis combining 'individual patient' data from several recent clinical studies was performed to assess the performance of CGM.

### OBJECTIVES

- This meta-analysis aimed to evaluate the clinical effectiveness of real time Continuous Glucose Monitoring (CGM) compared to Self-Monitoring of Blood Glucose (SMBG) alone in type 1 diabetes.

### DESIGN AND METHODS

Studies addressing all the following criteria were considered for inclusion in the meta-analysis:

- Randomised Controlled Trial (RCT) comparing CGM and SMBG alone and having the same insulin delivery mode in both arms (MDI or CSII)
- Evaluating glycaemic control and hypoglycaemia
- Type 1 diabetes population
- ≥2 months treatment duration
- Published up to June 2010

The eligibility of each study was assessed by independent reviewers.

The following individual subject data were requested to the publication authors: age, duration of diabetes, treatment allocation (CGM or SMBG only), sensor usage (days per week), HbA1c levels at baseline and study completion, number and corresponding Area Under the Curve (AUC) of hypoglycaemic events at baseline and study completion.

Hypoglycaemic events were measured with retrospective (blinded) CGM for 6-day periods at baseline and study completion and were defined as glucose value <3.9 mmol/L (70 mg/dL).

The primary endpoints were the change in HbA1c levels and in hypoglycaemia AUC from baseline to study completion.

### KEYPOINTS

- 0.3% reduction in HbA1c
- Larger HbA1c reduction with increased CGM usage
- 0.23% reduction in hypoglycaemia exposure

### STUDY TYPE

- Meta-analysis of 6 RCTs
- CGM vs SMBG alone
- Between 3 and 6 months duration
- 953 subjects with Type 1 diabetes

### ENDPOINTS

- Change in HbA1c levels
- Change in hypoglycaemia AUC

### REFERENCE

Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomized controlled trials using individual patient data.

Pickup JC et al. BMJ 2011;343:d3805. doi: 10.1136/bmj.d3805.

## RESULTS

A number of 6 clinical studies corresponding to the inclusion criteria were included in the meta-analysis. All studies were RCTs with a parallel design, published between 2006 and 2009 and lasting between 3 to 6 months. The insulin delivery mode was Continuous Subcutaneous Insulin Infusion (CSII) in 3 studies and either CSII or Multiple Daily Injection (MDI) in the 3 others.

Data from 892 subjects (449 allocated to CGM and 443 allocated to SMBG only) were available for the primary analysis.

### HbA1c levels

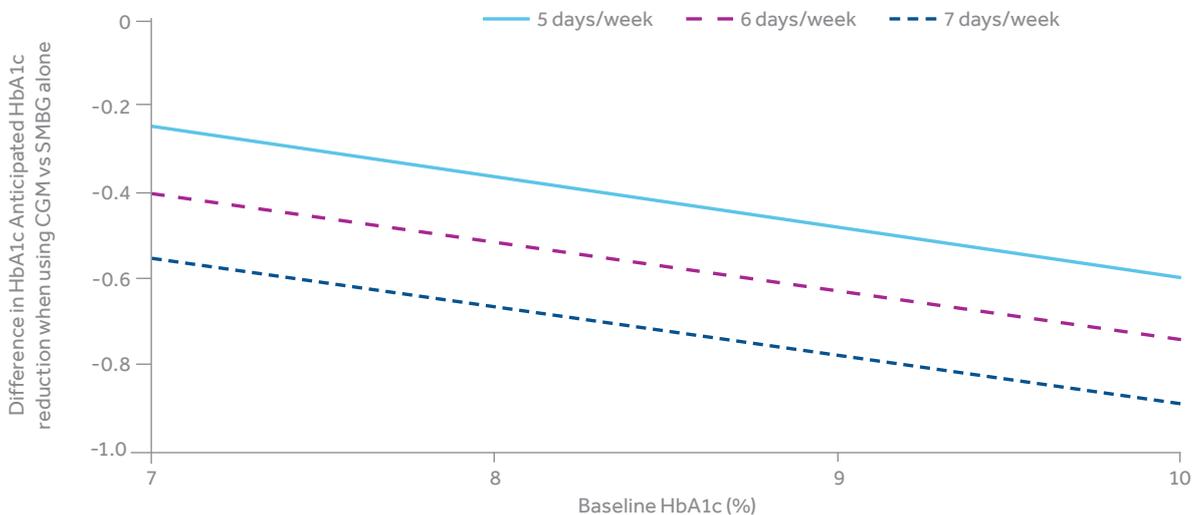
There was an overall reduction in HbA1c of 0.3% for subjects using CGM compared to the ones using SMBG only. Larger reductions were observed for subjects using CGM with the greatest frequency and with higher baseline HbA1c. Subject's age was found to have a comparatively smaller effect.

The anticipated HbA1c reduction can be estimated through a model (Figure1).

- Every one day increase of CGM usage per week increased the effect of CGM vs SMBG by 0.15%.
- Every 1% increase in baseline HbA1c increased the effect of CGM vs SMBG by 0.126%.
- Every 1 year increase in subject age increased the effect of CGM vs SMBG by 0.002%.

As an example, a 40 years' old subject using the CGM continuously and with 8% HbA1c and can expect an HbA1c reduction of 0.65%. With a 10% HbA1c level, the reduction increases to 0.9%.

**FIGURE 1: Anticipated HbA1c reduction when using CGM vs SMBG alone**



### Hypoglycaemia

At baseline, the median AUC in hypoglycaemia was 0.17. An AUC reduction of 23% (0.276) was observed with CGM compared to SMBG only.

## CONCLUSIONS

- The use of Continuous Glucose Monitoring (CGM) in addition to SMBG was associated with a significant reduction of HbA1c levels.
- Larger reductions were observed in subjects using CGM with greatest frequency and having higher HbA1c level at baseline.
- The HbA1c reduction can be anticipated through a model.
- The use of Continuous Glucose Monitoring (CGM) was also associated with a reduction of hypoglycaemia exposure.