Sustained Benefit of Continuous Glucose Monitoring on HbA1c, Glucose Profiles, and Hypoglycemia in Adults with Type 1 Diabetes

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group

Key Points

Why is this study important?
• This study demonstrates the benefits of CGM over a extended period of time.
• It describes the 12 follow-up data of adults (≥25 years) who were randomized to use CGM, (6-month study1 plus 6-month study follow-up2).

Study Highlights
• This 6-month extension study2 followed adults (≥25 years) with type 1 diabetes and with baseline A1c levels of ≥7.0%, and those with baseline A1c <7.0%, randomized to CGM.
• Mean change in A1c from baseline to 12 months was statistically significant in subjects with a baseline A1c of ≥7.0%.
• A1c remained stable at 6.4% in subjects who started the study with a baseline A1c <7.0%, with no severe hypoglycemic events during the 6-month study extension.
• Severe hypoglycemia was experienced by 8 subjects during the first 6 months and 3 subjects in the second 6 months. N=83
• Time per day with glucose levels in the range of 71-180 mg/dL increased significantly from baseline to 12 months in both groups of adults using CGM.

Patient Benefits
• The adults who continued to use CGM on a daily basis had sustained benefits of improved glucose control. The benefits persisted despite less intensive follow-up, designed to approximately typical clinical practice.
• Body weight, daily insulin dose, and frequency of daily SMBG did not change during the study.

Authors Conclusions
• Most adults continued to use CGM on a daily or near-daily basis and had sustained benefits of improved glucose control. These benefits continued despite less intensive study follow-up.
• An important observation was the low rate of severe hypoglycemic events during the 6-month study extension. The total absence of severe hypoglycemia while maintaining a mean A1c of 6.4% in subjects with a baseline A1c of <7.0% was striking.
• It is possible that in the previous 6-months of study; subjects’ learning to set appropriate low alarms, glucose targets, and titrating basal and bolus insulin doses, is responsible for the decline in severe hypoglycemic events in the second 6 months of study.
• The findings demonstrate that the benefits of CGM can be sustained for at least 12 months in motivated adults practicing intensive diabetes management. CGM provides the ability to achieve target A1c levels more safely than previously reported.


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Purpose
• To evaluate long-term effects of continuous glucose monitoring (CGM) in intensively-treated adults with type 1 diabetes (T1D).

Methods
• This paper describes the 6-month extension of adult (≥25 yrs) subjects with type 1 diabetes and with baseline A1c levels <7.0%, and those with baseline A1c levels ≥7.0%, that were randomized to CGM in the initial 6-months of study.¹
• Review of initial 6-month study methods:¹
  • Randomized, parallel group, multicenter, efficacy and safety study
  • Two separate study cohorts who differ based on study entry A1c levels:
    Main study cohort included T1DM with baseline A1c of 7.0% to 10.0% (referred to as ≥ 7.0%)
    Exploratory Pilot cohort included T1DM with baseline A1c of <7.0%
  • Participants in both cohorts fell into three age groups: 8-14 years old, 15-24 years old, and ≥25 years old
  • This paper reports on the ≥25 years old age group
• Insulin pumps were used by 90% (n=75) of the subjects and multiple daily injections (MDI) by 10% (n=8).
• The study protocol has been described in a previous publication.¹

Results
• Median CGM use was 7.0 days/week in month 6 and 6.8 days/week during month 12.
• Use of CGM in the twelfth month did not vary with baseline A1c (P=0.38).
• Subjects with a baseline A1c of ≥ 7.0% (n=49):
  o Mean change in A1c from baseline to 12 months was -0.4 ± 0.6% (P<0.001).
  o The incidence of severe hypoglycemia fell from 20.5 events/100 person-years in the first 6 months to 12.1 in the second 6 months.
• Subjects with a baseline A1c of < 7.0% (n=34):
  o A1c remained within the target range over the entire 12 months of the study. A1c values were 6.4% at baseline, 6.3% at 6 months, and 6.4% at 12 months
  o The rate of severe hypoglycemia fell from 23.6 events/100 person-years to 0 events during the second 6 months.
• A severe hypoglycemic event was experienced by 8 subjects in the first 6 months, and in 3 during the second 6 months. N=83
• The rate of severe hypoglycemia fell from 21.8 events/100 person-years during the first 6 months, to 7.1 events/100 person-years during the second 6 months (P=0.18), and was not associated with baseline A1c.
• The median amount of time/day with glucose in the range of 71-180 mg/dL increased significantly from baseline to 12 months, (P=0.02); reflecting a decrease in both hypo- and hyperglycemia.
• Variability assessed with the standard deviation of glucose values (P=0.02) and mean amplitude of glycemic excursions (MAGE) (P=0.03) were reduced with CGM use from baseline to 12 months.