

No Effect of Periodic Continuous Glucose Monitoring on Hemoglobin A1c in Poorly Regulated Type 1 Patients

Henrik U. Andersen, M.D., D.MSc., Majbritt Kjellmann, R.N., Minna Wittrup, M.D., PhD,
and Thomas P. Almdal, M.D., D.MSc.

The purpose of this study was to assess whether the use of periodic continuous glucose monitoring (CGM) lowers hemoglobin A1c (HbA1c) in poorly controlled type 1 diabetes patients.

In a non-randomized study, patients with HbA1c >74 mmol/mol in three consecutive measurements were offered CGM for 6 days, then seen by a diabetologist and a diabetes nurse at start and again after 6 months. After 3 months, the patients were seen by a diabetes nurse and further offered to mail results of self-monitored blood glucose values (SMBG) for advice at 1.5 and 4.5 months. Patients who refused or were not offered CGM served as controls.

Primary end point: HbA1c at 6 months. Secondary end point: Patient satisfaction evaluated by a semi-structured questionnaire.¹

Forty-three (20 males/23 females) entered with only 35 completing the study. Thirteen patients had no diabetes complications, while 30 had either retinopathy or multiple complications. The median age was 49 (23–80) years and duration of diabetes was 18 (4–45) years. Intermittent CGM did not lower HbA1c (**Table 1**). Total insulin dose was 52 (12–120) IU at the start, and 54 (16–122) IU at 6 months (not significant). Seventy percent gained knowledge on their diabetes by using CGM. Seventy-five percent used the CGM frequently during the trial, but only 15% made many adjustments of insulin doses.

Table 1.
Results of HbA1c at Start and After Intervention with Periodic Continuous Glucose Monitoring in Poorly Regulated Type 1 Diabetes Patients^a

	Start	Month 6
Intervention group HbA1c (mmol/mol)	78 (67–109)	77 (51–98)
Control group HbA1c (mmol/mol)	82 (58–169)	80 (48–121)

^aResults are shown as median (range). Intervention group ($n = 35$) and control group ($n = 258$), not significant.

A recent meta-analysis reports an overall mean difference in HbA1c for personal CGM versus SMBG of -0.30%.² The effect of personal CGM requires that it is used often: for every 1 day increase of sensor use per week, the effect of CGM on HbA1c is increased by 0.15%.² It is a general perception that periodic CGM may help identify problems not identified by SMBG, e.g., nocturnal hypoglycemia and dawn phenomenon. Whether it affects HbA1c is unclear. In adults, only one randomized study comparing periodic CGM to SMBG has been reported, and no difference in HbA1c

Author Affiliation: Steno Diabetes Center, Gentofte, Denmark

Abbreviation: (CGM) continuous glucose monitoring, (HbA1c) hemoglobin A1c, (IU) international unit, (SMBG) self-monitored blood glucose values

Keywords: patient satisfaction, periodic CGM, poor regulation, type 1 diabetes

Corresponding Author: Henrik Ullits Andersen, M.D., D.MSc., Steno Diabetes Center, Niels Steensensvej 2, DK- 2820, Gentofte, Denmark, email address hua@steno.dk

was found 3 months after an intervention based on blinded CGM for 3 days. In children and adolescents, smaller non-randomized studies suggest that unblinded periodic CGM results in a 0.2–0.4% decrease in HbA1c.^{3,4} The SWITCH study is a randomized, controlled, crossover study, with a 4-month washout period to evaluate if adding CGM to experienced pump patients with suboptimal metabolic control provides additional therapeutic benefit. Subjects were randomized to sensor on or sensor off arms for 6 months.⁵ In the intervention period, HbA1c was decreased 0.43% compared with patients not using CGM. Withdrawal of the sensor resulted in glycemic control reverting towards baseline levels during the washout period. Thus, our data and the available literature suggests that CGM is primarily useful as a tool for making real-time correction of diabetes treatment and that limited individual learning in relation to diabetes treatment can be gained from periodic use of CGM. In the present study, patient satisfaction with CGM was high. A recent meta-analysis also reports that users felt confident about the device and gave positive reviews.⁶

Conclusion

An intensive program based on periodic CGM did not reduce HbA1c in poorly regulated type 1 diabetes patients

Disclosure:

All authors are employees of Steno Diabetes Center A/S, which is a research hospital working in the Danish National Health Service and owned by Novo Nordisk A/S. All authors own shares in Novo Nordisk A/S.

References:

1. Secher AL, Madsen AB, Ringholm L, Barfred C, Stage E, Andersen HU, Damm, Matheisen ER. Patient satisfaction and barriers to initiating real-time continuous glucose monitoring in early pregnancy in women with diabetes. *Diabet Med*. 2012; 29(2):272–7. doi: 10.1111/j.1464–5491.2011.03426.x.
2. Pickup JC, Freeman SC, Sutton AJ. 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. *BMJ*. 2011; 343:d3805. doi: 10.1136/bmj.d3805.
3. Ludvigson J, Hanas R. Continuous subcutaneous glucose monitoring improved metabolic control in pediatric patients with type 1 diabetes: a controlled crossover study. *Pediatrics*. 2003;111(5 Pt 1):933–8.
4. Chase HP, Roberts MD, Wightman C, Klingensmith G, Gark SK, Van Wyhe M, Desai S, Harper W, Lopatin M, Batkowiak M, Tamada J, Eastman RC. Use of the GlucoWatch biographer in children with type 1 diabetes. *Pediatrics*. 2003;111(4 pt 1):790–4.
5. Battelino T, Conget I, Olsen B, Schütz-Fuhrmann I, Hommel E, Hoogma R, Schierloh U, Sulli N, Bolinder J, the SWITCH study Group. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomized controlled trial. *Diabetologia*. 2012;55(12):3155–62. doi: 10.1007/s00125-012-2708-9. Epub 2012 Sep 11.
6. Gandhi GY, Kovalaske M, Kudva Y, Walsh K, Elamin MB, Beers M, Coyle C, Goalen M, Murad MS, Erwin PJ, Corpus J, Montori VM, Murad MH. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. *J Diabetes Sci Technol*. 2011;5(4):952–65.