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Original article

Multicentre, randomised, controlled study of the impact of continuous sub-cutaneous glucose monitoring (GlucoDay®) on glycaemic control in type 1 and type 2 diabetes patients

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Abstract

Aim. – This randomised study was designed to investigate the impact of continuous glucose monitoring (CGM) for 48 h on glycaemic control with a 3-month follow-up in patients with type 1 (T1D) or type 2 (T2D) diabetes.

Methods. – A total of 48 patients with poor glycaemic control (HbA1c: 8–10.5%) underwent CGM for 48 h using the GlucoDay® system (A. Menarini Diagnostics), after which they were randomly assigned to treatment adjustments based on either their CGM profile (CGM group) or their usual self-monitoring of blood glucose (SMBG group). HbA1c measurement and 48-h CGM were repeated 3 months later.

Results. – Altogether, 34 patients with either T1D (n = 9) or T2D (n = 25) completed the study; seven patients chose to leave the study, and seven patients in the CGM group were excluded because their baseline CGM graphs were not interpretable. HbA1c levels decreased significantly in the CGM group (n = 14, –0.63 ± 0.27%; P = 0.023), but not in the controls (n = 20, –0.28 ± 0.21%; P = 0.30). In T2D patients, the improvement associated with CGM vs SMBG was due to HbA1c decreases (mean: –0.63 ± 0.34%; P = 0.05 vs –0.31 ± 0.29%; P = 0.18, respectively). However, HbA1c did not change significantly with CGM in T1D patients. Comparisons of CGM data at baseline and after 3 months showed no significant changes in glucose control, glucose variability or hypoglycaemia. No major adverse events related to the GlucoDay® system were reported.

Conclusion. – This is the first randomised study showing that CGM improves glycaemic control in patients with T2D.

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Keywords: Continuous glucose monitoring; GlucoDay®; Type 1 diabetes; Type 2 diabetes; Randomised controlled trial

Résumé

Impact de la mesure continue du glucose sous-cutané (système GlucoDay®) sur le contrôle glycémique des diabétiques de types 1 et 2 : étude multicentrique, randomisée et contrôlée.

Objectif. – déterminer dans une étude randomisée l’impact d’un enregistrement continu du glucose sous-cutané pendant 48 heures sur le contrôle glycémique trois mois plus tard chez des patients présentant un diabète de type 1 (DT1) ou de type 2 (DT2).

Méthodes. – Quarante-huit patients avec un mauvais équilibre glycémique (HbA1c : 8–10,5 %) ont bénéficié d’un enregistrement continu du glucose sous-cutané pendant 48 heures avec le système GlucoDay® (A. Menarini Diagnostics) et ont été randomisés en deux groupes : ajustement de traitement en fonction de l’autosurveillance glycémique capillaire (groupe ASG) ou du profil d’enregistrement continu du glucose sous-cutané (groupe CGM). Le dosage d’HbA1c et le port du GlucoDay® ont été renouvelés trois mois plus tard.

Résultats. – Trente-quatre patients avec un DT1 (n = 9) ou un DT2 (n = 25) ont participé à la totalité de l’étude, sept patients l’ont arrêtée et sept patients dans le groupe CGM ont dû être exclus en raison d’un enregistrement initial non interprétable. Le niveau d’HbA1c a diminué significativement dans le groupe CGM (n = 14, –0,63 ± 0,27 %, P = 0,023) mais non dans le groupe ASG (n = 20, –0,28 ± 0,21 %, P = 0,30). L’amélioration dans le groupe CGM (en moyenne : –0,63 ± 0,34 %, P = 0,05 versus –0,31 ± 0,29 % dans le groupe ASG, P = 0,18) était due à une diminution d’HbA1c chez les patients DT2, l’HbA1c ne différant pas significativement chez les patients DT1. La comparaison des données,

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d’enregistrement continu du glucose sous-cutané initiales, et à trois mois n’a pas montré de différence pour le contrôle glycémique, la variabilité glycémique ou les hypoglycémies. Aucun effet indésirable en relation avec le système GlucoDay® n’a été décrit.

**Conclusion.** – Il s’agit de la première étude randomisée montrant que l’enregistrement continu du glucose sous-cutané permet l’amélioration de l’équilibre glycémique chez des DT2.

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**Mots clés :** Enregistrement continu du glucose ; GlucoDay® ; Diabète de type 1 ; Diabète de type 2 ; Étude randomisée

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1. **Introduction**

Tight glycemic control is crucial in the prevention of microangiopathic complications in patients with type 1 (T1D) [1] or type 2 (T2D) [2] diabetes. Oral antidiabetic and insulin regimens need to be tailored to the HbA1c and glucose levels in the individual patient [3]. However, as glucose levels vary widely throughout the 24 h cycle, multiple assays are needed to accurately assess glycemic control. Self-monitoring of blood glucose (SMBG)—which involves several measurements of blood glucose taken during the course of the day by the patient himself, followed by the appropriate treatment adjustments—improves glycemic control in type 1 diabetics [4] and may also benefit patients with type 2 diabetes [5–7]. However, as SMBG requires several finger pricks each day, its efficacy is limited by the number of tests per day that the patient is either willing or able to perform. Moreover, SMBG provides information at only a few time points throughout the day and no information at all during sleep [8]. Studies have shown that increasing the number of daily SMBG tests improves metabolic control in patients with T1D or pharmacologically treated type 2 (T2D) diabetes [9]. This finding raises the possibility that continuous glucose monitoring (CGM) could lead to further improvement in metabolic control.

Several devices for CGM have been developed in recent years. These minimally invasive devices measure glucose levels in interstitial fluid. The GlucoDay® (A. Menarini Diagnostics, Florence, Italy) device comprises a microdialysis sensor that is implanted subcutaneously and connected to an external portable unit. The system measures glucose, using the glucose-oxidase method, every second, computes the mean over each 3 min interval and stores the resultant values [10]. The system is meant to be used for 2 days at a time. Other devices include the CGMS® and Guardian RT® (Medtronic MiniMed, Northridge, CA), the STS® (DexCom, San Diego, CA) and the FreeStyle Navigator® (Abbott Diabetes Care, Alameda, CA), in which a needle-type sensor generates a signal that is proportional in intensity to glucose variations in the subcutaneous interstitial fluid [11,12]. These devices are designed to be used for at least three consecutive days.

CGM devices have proved capable of detecting subclinical hypoglycaemic episodes and unsuspected glucose excursions [13,14]. However, few randomised controlled studies have evaluated their impact on glycemic control and, in any case, were confined to patients with T1D [14–21]. Several studies showed improvement in HbA1c levels with CGMS® in paediatric patients [15,18, 19] and with Guardian RT® used continuously for 3 months [16]. However, the only data available for patients with T2D come from a recent study by Allen et al. showing that counselling based on CGM feedback improved physical activity and HbA1c levels [22].

The objective of the present study was to evaluate the impact of CGM on glycemic control using the GlucoDay® system for 48 h in adults with T1D and those with insulin-requiring or non-insulin-requiring T2D. Our hypothesis was that CGM could significantly improve Hba1c levels compared with SMBG, and that these improvements would be smaller in patients with T2D compared with T1D.

2. **Methods**

2.1. **Patients**

We preselected 56 adults with either T1D or T2D, of whom 48 were included in our multicentre, prospective, randomised controlled trial (Fig. 1). Recruitment took place in the diabetology departments of five university hospitals—in Bondy, Lyon, Marseille, Paris and Reims— in France. Inclusion criteria were:

- patients with T1D, aged 18–70 years, treated with continuous insulin infusion or at least three insulin injections per day, and performing SMBG at least three times a day, or patients with T2D, 40–70 years of age, treated with oral antidiabetic agents with or without one insulin injection per day at a stable dosage over the past 3 months, and performing SMBG at least four times a week;
- Hba1c = 8.0–10.5%;
- routine follow-up (two to four visits) at the study centre for at least 1 year;
- no previous experience with CGM.

Exclusion criteria were pregnancy, acute disease with subsequent poor glycemic control, proliferative retinopathy and renal failure, defined as a creatinine clearance below 30 mL/min. The study was approved by the local ethics committee (Aulnay-sous-Bois), and written informed consent was obtained from all patients before inclusion in the study.

2.2. **The GlucoDay® system**

This microdialysis system has been described elsewhere [10]. In brief, mean interstitial glucose values in subcutaneous interstitial fluid over 3 min periods are determined using the glucose-oxidase method to test the dialysate. The values are stored in the device, downloaded to a computer and presented as a graph. The device has proved reliable [10,12,23,24]
even after meals [25] and during hypoglycaemic episodes [26]. GlucoDay® tolerability is considered satisfactory [10,23–26], and the system is more accurate than CGMS® in patients with T1D [27].

2.3. Study protocol

On the first study day, a fasting blood sample was drawn for a baseline HbA1c assay using high-performance liquid chromatography (HPLC), and the GlucoDay® device implanted. Over the next 48 h, patients continued to carry out their usual daily activities, SMBG, diet, physical exercise, and insulin and/or oral antidiabetic therapy. The patients then returned to hospital to have their GlucoDay® system removed. They also completed a questionnaire on any discomfort and pain they may have experienced during the 48 h monitoring period.

Patients were then randomly allocated to either the CGM group, where the CGM data were made known to both the physician and patient, or the control group, where the CGM data were not disclosed to either the physician or patient. A randomisation scheme was centrally generated, by computer, for each study hospital and according to diabetes type (1 or 2), using a 1:1 ratio. Each patient was then evaluated by a physician who made recommendations for diet, physical activity, and drug dosages and dosing times, according to his own experience and the routine protocols used at his hospital. These recommendations were based on the CGM data in the CGM group, and on the SMBG data in the controls. CGM profiles, such as the effects of diet and physical activity on glycaemic control, were also used as a patient-education tool in the CGM group.

After 3 months, the study patients returned to hospital for blood sample collection and GlucoDay® reimplantation. Their HbaA1c levels were determined centrally as before. Two days later (after GlucoDay® removal), each patient was evaluated by a physician, and completed a questionnaire on the tolerability and acceptability of the device.

2.4. Outcome measures

The primary outcome measure was the change in HbA1c levels after 3 months compared with baseline. The secondary outcome measures were evaluated by comparing the 48 h CGM data at baseline with those obtained after 3 months. These measures included:

- glucose control (mean interstitial glucose values, minimum–maximum glucose values, and proportion of time spent at less than 70 mg/dL, 70–150 mg/dL and more than 150 mg/dL);
- glucose variability (standard deviation [SD] of the mean glucose value; mean amplitude of glucose excursions [MAGE] computed as the arithmetic mean of the differences between consecutive peaks and nadirs, with measurement of the peak-
Table 1
Study patients’ characteristics according to type of diabetes as determined by random allocation.

<table>
<thead>
<tr>
<th></th>
<th>Type 2 diabetes</th>
<th></th>
<th>Type 1 diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total (n = 25)</td>
<td>CGM group (n = 11)</td>
<td>Control group (n = 14)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>9.13 ± 0.22</td>
<td>9.22 ± 0.30</td>
<td>9.07 ± 0.16</td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.2 ± 5.2</td>
<td>57.2 ± 4.4</td>
<td>57.3 ± 5.9</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>11.6 ± 9.0</td>
<td>10.5 ± 8.0</td>
<td>12.6 ± 9.9</td>
</tr>
<tr>
<td>Gender ratio (male/female)</td>
<td>17/8</td>
<td>8/3</td>
<td>9/5</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28.7 ± 5.1</td>
<td>30.0 ± 5.2</td>
<td>27.7 ± 5.1</td>
</tr>
<tr>
<td>Insulin regimen (SCI/CSII)</td>
<td>9/0</td>
<td>3/0</td>
<td>6/0</td>
</tr>
<tr>
<td>Oral antidiabetic agents with no insulin treatment (%)</td>
<td>16 (64)</td>
<td>8 (73)</td>
<td>8 (57)</td>
</tr>
<tr>
<td>Retinopathy (%)</td>
<td>5 (20)</td>
<td>2 (18)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Nephropathy (%)</td>
<td>4 (17)</td>
<td>0</td>
<td>4 (28)</td>
</tr>
<tr>
<td>Neuropathy (%)</td>
<td>2 (8)</td>
<td>0</td>
<td>2 (14)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type 2 diabetes</td>
<td></td>
<td>Type 1 diabetes</td>
</tr>
<tr>
<td></td>
<td>Total (n = 9)</td>
<td>CGM group (n = 3)</td>
<td>Control group (n = 6)</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>9.02 ± 0.30</td>
<td>9.00 ± 0.67</td>
<td>9.03 ± 0.12</td>
</tr>
<tr>
<td>Age (years)</td>
<td>50.4 ± 15.2</td>
<td>47.3 ± 7.1</td>
<td>52.0 ± 12.7</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>20.3 ± 6.9</td>
<td>15.0 ± 5.7</td>
<td>21.1 ± 9.9</td>
</tr>
<tr>
<td>Gender ratio (male/female)</td>
<td>4/5</td>
<td>2/1</td>
<td>2/4</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24.0 ± 4.5</td>
<td>24.0 ± 7.8</td>
<td>24.0 ± 2.8</td>
</tr>
<tr>
<td>Insulin regimen (SCI/CSII)</td>
<td>7/2</td>
<td>3/0</td>
<td>4/2</td>
</tr>
<tr>
<td>Oral antidiabetic agents with no insulin treatment (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Retinopathy (%)</td>
<td>2 (22)</td>
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<td>2 (33)</td>
</tr>
<tr>
<td>Nephropathy (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neuropathy (%)</td>
<td>2 (33)</td>
<td>0</td>
<td>2 (33)</td>
</tr>
</tbody>
</table>

Data are expressed as means ± SD or n (%) of patients. SCI: subcutaneous injection(s); CSII: continuous subcutaneous insulin infusion (no statistically significant differences were found at baseline between the two treatment groups).

3. Results

3.1. Patients

A total of 34 patients completed the study (Fig. 1), including nine patients with T1D and 25 with T2D. Seven (25%) patients in the CGM group failed to receive their allocated intervention because their sensor data were either inadequate or not sufficiently reliable. Table 1 shows the study patients’ main characteristics.

3.2. Primary endpoint

HbA1c levels decreased significantly in the CGM group (from 9.17 ± 0.99 at baseline to 8.56 ± 0.97 after 3 months, P = 0.023), but not in the control group (from 9.03 ± 0.53 to 8.75 ± 1.26, P = 0.30). HbA1c decrease in the CGM group was due to a significant decrease in patients with T2D (from 9.22 ± 0.99 to 8.59 ± 1.04, P = 0.05), whereas no significant decrease was seen in the controls with T2D (from 9.07 ± 0.60 to 8.76 ± 1.43, P = 0.18). In the T1D patients, no significant HbA1c decrease occurred in either group (CGM group: from 9.00 ± 1.15 to 8.47 ± 0.83, P = 0.25; controls: from 8.93 ± 0.38 to 8.72 ± 0.89, P = 0.42). The main results are shown on Fig. 2.

3.3. Changes in 48 h CGM data over 3 months

The CGM data were examined in 19 of the 25 T2D patients (Table 2). In the remaining six patients, paired graphs could not be compared because data were not obtained throughout the 48 h period at either baseline (two control patients) or 3 months (two control patients and two CGM patients). No significant differences were found in glucose control, glucose variability or hypoglycaemia criteria between the controls and CGM group at either baseline or after 3 months. Also, no changes in these criteria between baseline and 3 months were significantly different between these two patient groups (Table 2).

3.4. Device safety and acceptability

The only adverse events related to the device over the 68 CGM periods were four (5.8%) cases of uncomplicated implantation-site skin reactions, which required no specific treatment.

The tolerability questionnaires completed by the patients were assessed using a questionnaire with four response options for each item (no problems, mild problems, moderate problems and severe problems). Among the 25 patients, six (24%) reported no problems with the sensor implantation (bilateral first-category risk). One (4%) patient reported mild problems, four (16%) reported moderate problems, and one (4%) patient reported severe problems. A total of 34 patients completed the study (Fig. 1), including nine patients with T1D and 25 with T2D. Seven (25%) patients in the CGM group failed to receive their allocated intervention because their sensor data were either inadequate or not sufficiently reliable. Table 1 shows the study patients’ main characteristics.

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Glucose variability

Hypoglycaemia

Data are expressed as means ± SD.

Table 2
Changes during 48 h continuous glucose monitoring (CGM) between baseline and the 3-month evaluation in type 2 diabetic patients.

<table>
<thead>
<tr>
<th>Glucose control</th>
<th>Group</th>
<th>Baseline</th>
<th>After 3 months</th>
<th>P&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean glucose value (mg/dL)</td>
<td>Control&lt;sup&gt;b&lt;/sup&gt;</td>
<td>164 ± 42</td>
<td>146 ± 36</td>
<td>0.129</td>
</tr>
<tr>
<td></td>
<td>CGM&lt;sup&gt;c&lt;/sup&gt;</td>
<td>185 ± 42</td>
<td>168 ± 55</td>
<td>0.572</td>
</tr>
<tr>
<td>Time spent at &lt; 70 mg/dL (%)</td>
<td>Control</td>
<td>5 ± 8</td>
<td>7 ± 9</td>
<td>0.510</td>
</tr>
<tr>
<td></td>
<td>CGM</td>
<td>7 ± 15</td>
<td>3 ± 4</td>
<td>0.533</td>
</tr>
<tr>
<td>Time spent at 70–150 mg/dL (%)</td>
<td>Control</td>
<td>39 ± 21</td>
<td>53 ± 21</td>
<td>0.071</td>
</tr>
<tr>
<td></td>
<td>CGM</td>
<td>26 ± 25</td>
<td>39 ± 25</td>
<td>0.462</td>
</tr>
<tr>
<td>Time spent at &gt; 150 mg/dL (%)</td>
<td>Control</td>
<td>56 ± 29</td>
<td>39 ± 24</td>
<td>0.065</td>
</tr>
<tr>
<td></td>
<td>CGM</td>
<td>66 ± 33</td>
<td>58 ± 27</td>
<td>0.675</td>
</tr>
<tr>
<td>Maximum glucose value (mg/dL)</td>
<td>Control</td>
<td>341 ± 90</td>
<td>342 ± 88</td>
<td>0.978</td>
</tr>
<tr>
<td></td>
<td>CGM</td>
<td>380 ± 110</td>
<td>376 ± 132</td>
<td>0.887</td>
</tr>
<tr>
<td>Minimum glucose value (mg/dL)</td>
<td>Control</td>
<td>58 ± 30</td>
<td>57 ± 24</td>
<td>0.847</td>
</tr>
<tr>
<td></td>
<td>CGM</td>
<td>79 ± 39</td>
<td>63 ± 16</td>
<td>0.410</td>
</tr>
</tbody>
</table>

Glucose variability

| Standard deviation of mean glucose value (mg/dL)      | Control   | 50 ± 12  | 52 ± 21       | 0.743         |
|                                                      | CGM       | 50 ± 60  | 55 ± 14       | 0.274         |
| Amplitude of glucose excursions (mg/dL)              | Control   | 96 ± 23  | 94 ± 34       | 0.905         |
|                                                      | CGM       | 84 ± 21  | 87 ± 27       | 0.843         |
| M index                                              | Control   | 45 ± 30  | 40 ± 29       | 0.647         |
|                                                      | CGM       | 60 ± 32  | 50 ± 44       | 0.680         |
| Number of hypoglycaemic excursions                   | Control   | 0.33 ± 0.65| 0.58 ± 1.08   | 0.491         |
|                                                      | CGM       | 0.14 ± 0.38| 0 ± 0          | 0.356         |
| Number of hyperglycaemic excursions                  | Control   | 4.5 ± 1.6| 4.1 ± 1.8     | 0.447         |
|                                                      | CGM       | 4.0 ± 1.7| 3.4 ± 1.3     | 0.578         |

Hypoglycaemia

| Time spent with hypoglycaemia (min)                  | Control   | 11 ± 25  | 18 ± 37       | 0.628         |
|                                                      | CGM       | 3 ± 7    | 1 ± 3         | 0.609         |
| Low blood glucose index (LBGI)                       | Control   | 1.04 ± 1.60| 1.34 ± 1.51   | 0.651         |
|                                                      | CGM       | 0.31 ± 0.61| 1.58 ± 3.04   | 0.379         |

Data are expressed as means ± SD.
<sup>a</sup> Statistical analysis between criteria at baseline and at 3 months.
<sup>b</sup> n = 12.
<sup>c</sup> n = 7.

ties in 25 (36.7%), 16 (23.5%), 20 (29.4%) and seven (10.3%) patients, respectively.

4. Discussion

This was the first multicentre, randomised, controlled trial of the GlucoDay<sup>®</sup> device in patients with T1D and T2D. CGM use was associated with improved glycaemic control in insulin-requiring and non-insulin-requiring patients with T2D. The GlucoDay<sup>®</sup> system caused little or no discomfort in users. Earlier randomised studies of unique or sequential CGM in patients with T1D showed improvement in HbA<sub>1c</sub> levels in paediatric patients [15,18,19], but not in adults [14,20,21], which is in keeping with our findings. Use of CGM over longer periods of time may be necessary in T1D patients to reduce HbA<sub>1c</sub> levels through gradual adjustments by patients in insulin regimens, diet and lifestyle [16]. Real-time CGM that provides the current interstitial glucose level, with alarms for hyper- and hypoglycaemia, are probably more useful for patients with T1D, who experience higher rates of hypoglycaemia than do T2D patients [31,32].

Contrary to our study hypothesis, CGM improved glycaemic control in T2D patients, but not in those with T1D. However, as the day-to-day information on diabetes self-management was not recorded in the study, the relationship between GlucoDay<sup>®</sup> monitoring and improved glycaemic control cannot be analyzed. The T2D patients in the present study had poor glycaemic control despite treatment with several oral antidiabetic agents that were combined, in two thirds of patients, with a daily insulin injection, and CGM may have helped physicians to determine their optimal insulin regimen. CGM was associated with the use of larger amounts of antidiabetic medications in women with gestational diabetes compared with SMBG [33]. CGM may also help to determine when insulin therapy should be initiated or when to adjust the insulin regimen, most notably by providing information on postprandial glucose excursions [34]. Basal insulin may fail to ensure blood glucose control throughout the day as a result of a shorter effect duration than expected and/or failure to control postprandial excursions [35]. In the latter cases, improved glycaemic control may be obtained by adding a short-acting insulin injection before the meal associated with the largest postprandial glucose excursion [34].

Although many patients are unable to correctly interpret their HbA<sub>1c</sub> levels, most diabetic patients have sufficient knowledge of their disease to be warned by high blood glucose levels [36]. This means that the HbA<sub>1c</sub> improvements may have been greater...
with a decrease in HbA1c [22]. Activity led to an increase in physical activity over 8 weeks along thus, CGM used to educate patients on the benefits of physical activity day and night that may help patients to better understand their disease, the effects of diet and physical activity, and the need to adjust insulin regimens or to intensify the overall treatment. The present study had a number of limitations. First, 37% (20/54) of the randomised patients failed to complete the study, leaving the number of patients in the CGM group smaller than the number in the control group. Also, the lack of a statistically significant effect in our T1D patients may have been due to inadequate power, as the total number of T1D patients was small. In conclusion, the present study offers the first evidence that CGM improves glycaemic control in patients with T2D. One likely explanation of this beneficial effect is the improved assessment of glucose excursions with CGM compared with SMBG, leading to improved dietary and pharmacological interventions. The GlucoDay® device was well tolerated, easy to use and well accepted by all patients despite the large size of the portable component. The routine use of CGM in patients with uncontrolled T2D deserves consideration, and further studies involving larger numbers of patients are necessary to determine whether the repeated use of CGM will further improve glycaemic control.

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References


Fig. 2. Changes in HbA1c in type 1 (upper) and type 2 (lower) diabetic patients in the control (dotted line) and continuous glucose monitoring (CGM) (solid line) groups. *P < 0.05 for type 2 diabetes patients in the CGM group between baseline and 3 months.


