INTRODUCTION

The main issues preventing a satisfactory control over glycaemia in the patients with type 1 Diabetes Mellitus are the uncontrolled variations like hypo- and hyperglycaemia. The usual mean of assessing the glycaemic control is by the glycaemic profiles, either at home or in the hospitals, which offer the physicians a limited number of measurements per day. The limitations are less of financial nature than the patients’ unwillingness to accept an increase in the blood sampling and overworking of the medical staff. Under the given circumstances, the usual seven measurements of the glycaemic profiles offer a sketchy image at best, of the daily glycaemic variations. The continuous glucose monitoring (CGM) eliminates the drawbacks of the glycaemic profiles. By measuring the glucose levels 288 times over 24 hours and with a duration of 72 hours per monitoring, the CGM can do 864 glucose measurements. The data collected can be downloaded on a computer and further analysed. The classic method relies on the patients’ self-awareness and their ability to identify the symptoms of hypo- and hyperglycaemia. The CGM avoids the human factor by providing the ability of independently identifying the extreme glycaemic values by warning the user of the situation. Although the CGM is currently used mostly in clinical research and/or under strict medical supervision, the method is valuable enough to be used on a wide scale in the therapy of type 1 Diabetes Mellitus.

PURPOSE

The purpose of this study is to comparatively assess the possibility of identifying the extreme values of glycaemia by the patient himself through the classic method (accomplishing a glycaemic profile) and through the use of the continuous monitoring method.

METHODS

A total of 33 patients with type 1 Diabetes from the Cluj-Napoca Diabetes Nutrition and Metabolic Disease Centre and the Regina Maria medical centre were included in the study, who were treated during 2006 and 2012. The patients were divided into two groups, 15 patients receiving CGM, while 18 others followed the classical method of glycaemic profiles. The study included adult patients of age 18 to 70, without significant associated pathology that would impair their self-care ability, all from urban area, who had previously been instructed in regard to the requirements of the self-monitoring and life style required of a person with type 1 Diabetes. The patients with incomplete records regarding their diabetes treatment, the patients with severe monitoring errors, from rural area and with very high glycated haemoglobin (HbA1c) levels (above 8%), the under aged were excluded from the study. Hypoglycaemia was defined
as any glycaemic value below 70 mg/dl while hyperglycaemia was defined as any glycaemia above 180 mg/dl. The above limits were also used to set the CGM sound warning limits.

The patients from the CGM group were instructed regarding the use of the monitor and did two blood tests daily for the monitor’s calibration. Each patient received a monitor for 72 hours for their personal use outside the hospital. During the 72 hours, they were responsible for the entire maintenance of the monitor while a telephone help line was available. The CGM was set up and removed by a doctor in the hospital and the collected data were downloaded and processed with the software provided by the manufacturer. The patients from the self-monitoring group were asked to undergo a glycemic profile with glycaemia being measured seven times a day (at 7,10,13,16,19,22 and 3 o’clock). The time of the first measurement was between 7 and 8 o’clock and the time of the following measurements were adjusted in order to observe the 3 hour interval.

### RESULTS

<table>
<thead>
<tr>
<th>No.</th>
<th>CGM</th>
<th>Glucose self monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Man-hours</td>
<td>1080 (45 days)</td>
<td>432 (18 days)</td>
</tr>
<tr>
<td>Measured glycaemic values</td>
<td>13050 (12960 CGM values + 90 blood test values)</td>
<td>126</td>
</tr>
<tr>
<td>No. of detected hypoglycaemia</td>
<td>9 (32 different values during 9 separate occasions)</td>
<td>1</td>
</tr>
<tr>
<td>Total hypoglycaemia duration</td>
<td>Approx.: 2.6 hours</td>
<td>Impossible to determine</td>
</tr>
<tr>
<td>No. of detected hyperglycaemia</td>
<td>87 (2648 values in 87 separate events)</td>
<td>21</td>
</tr>
<tr>
<td>Total hyperglycaemia duration</td>
<td>220, 6 hours</td>
<td>Impossible to determine</td>
</tr>
</tbody>
</table>

33 patients with type 1 diabetes were included in the study. The patients were divided into two groups, 15 patients receiving CGM, while 18 others followed the classical method of glycemic profiles. The monitoring duration for the CGM group was of 1080 hours (45 days), while for the control group it was of 432 hours (18 days). The total number of measured glycaemic values was different for the two groups. The CGM group had 13050 glycaemic measurements (12960 by CGM and 90 by blood glucose test). The control group had a total of 126 glycaemic measurements. The CGM revealed a total of 9 hypoglycaemia (32 distinct values below 70 mg/dl in 9 different events), while the control group had only one hypoglycaemia detected. The overall duration of the recorded hypoglycaemia was of 2.6 hours in the CGM group and was impossible to measure in the control group. A total of 87 different instances of hyperglycaemia were recorded for the CGM group, with a total duration of 220.6 hours. For the control group, a total of 21 hyperglycaemia were found, but the total duration was impossible to assess.

### DISCUSSIONS

The results prove the advantages of the CGM. Over the duration of the study, the CGM group had 103.6 more glycaemic measurements than the control group. The increased number of measurements allowed for an early warning of the onset of hypoglycaemia. For the duration of the hypoglycaemia, the patients could periodically evaluate the efficacy of their measures to correct the low blood sugar levels. The higher number of detected hypoglycaemia also confirms the method efficacy. In regard to hyperglycaemia, the CGM proved useful both by warning the patients of going over the target glycaemic values and by informing the patients of the severity of the hyperglycaemia. From a medical point of view, the CGM proved useful both in identifying a greater number of extreme glycaemic values and providing an instrument of assessing their extent and by offering the ability to identify glycaemic variations patterns.

### CONCLUSIONS

The CGM can help the patients with type 1 diabetes to identify the presence of hypoglycaemia, offering them the necessary feed-back for the evaluation of the efficacy of the corrective measures and the severity of the hypoglycaemia. The CGM can warn the wearer of exceeding the target glycaemic values and facilitate the timely response to correct the glycaemic increase and to prevent a recurrence of such an event. From a medical point of view, the analysis of the collected data can help to identify patterns of glycaemic variations and can help to take the right decision in correcting the treatment flaws and preventing future hypo- and hyperglycaemia.

### BIBLIOGRAPHY