Available online at www.sciencedirect.com
ScienceDirect
Diabetes Research and Clinical Practice 75 (2007) 30–34
DIABETES RESEARCH AND CLINICAL PRACTICE
www.elsevier.com/locate/diabres

Efficacy of continuous glucose monitoring system (CGMS) to detect postprandial hyperglycemia and unrecognized hypoglycemia in type 1 diabetic patients

Frederico F.R. Maia [a,*], Levimar R. Araújo [a,b]

[a] *Department of Physiology, Faculdade de Ciências Médicas de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil*
[b] *Department of Endocrinology and Metabolism, Hospital Universitário São José, Faculdade de Ciências Médicas de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil*

Received 9 September 2005; accepted 12 May 2006
Available online 27 June 2006

Abstract

Background: To evaluate the efficacy of continuous glucose monitoring system (CGMS) to detect postprandial hyperglycemia and unrecognized hypoglycemia in type 1 diabetes mellitus (DM1) patients.
Methods: We studied 46 patients (43.4%M/56.6%F), average age of 25.9 ± 12.8 years, submitted to 72 h CGMS. It were analyzed: capillary glycemia (CG) and CGMS sensor's value, glycemic excursions, postprandial hyperglycemia, asymptomatic hypoglycemia and therapeutic management after CGMS. Correlation coefficient during hypo and hyperglycemia and sensitivity/specificity were determined.
Results: The mean capillary glucose values were 191.8 ± 46.2 mg/dl versus 190.9 ± 42.1 mg/dl by CGMS sensor, with no statistical difference by *T*-test ($T = -0.6$; $p = 0.79$). The CGMS was significantly more efficient in detection of glycemic excursion than CG ($p = 0.001$). The postprandial hyperglycemia was identified in 76.9% of diabetic patients and asymptomatic hypoglycemia was detected in 58.2% of these patients. The correlation coefficient presented no significance ($p = 0.16$) during hypoglycemia versus during hyperglycemia ($p = 0.002$). The CGMS sensor presented low sensitivity (79.1%) to detect hypoglycemia versus hyperglycemia (96.8%).
Conclusions: The CGMS showed to be a good method to identify postprandial hyperglycemia, to improve therapeutics management and confirmed the low sensitivity of CGMS to detect unrecognized hypoglycemia in DM1 patients.

Keywords: Continuous glucose monitoring system; Unrecognized hypoglycemia; Postprandial hyperglycemia; Diabetes mellitus type 1

1. Introduction

The major inconvenience of self-monitoring of blood glucose (SMBG) in clinical practice is due to the fact that blood glucose is only intermittently measured by fingerstick capillary glycemia (CG) from which only a partial and, therefore, incomplete picture of blood glucose fluctuations can be made [1,2]. Because of many factors, including pain and inconvenience, many patients with diabetes do not accept frequent fingersticks for SMBG [3], including just 10% of the patients submitted to eight point fingerstick by 3 days during continuous glucose monitoring system (CGMS) complete this recommendation.

* Corresponding author. Tel.: +55 31 3296 3345; fax: +55 31 3283 9772.
E-mail addresses: fredfrm@hotmail.com, frederico@diabetes.med.br (Frederico F.R. Maia).

0168-8227/$ – see front matter
doi:10.1016/j.diabres.2006.05.009

The Diabetes Control and Complications Trial (DCCT) established that intensive and multidisciplinary treatment of type 1 diabetes mellitus (DM1) improved metabolic control and reduces the complications of disease [4]. Psychological aspects and patient's acceptance of DM1 may exercise some influence in their glycemic control [5].

Despite an excellent A1c levels and target preprandial glucose levels, type 1 diabetic patients often experience asymptomatic hypoglycemia and postprandial hyperglycemia that are not evident with routine monitoring [6,7]. In addition, families frequently do not measure blood glucose levels during the night and 55% of severe hypoglycemic events in the DCCT occurred during sleep [8]. Several studies demonstrated the utility of the continuous glucose monitoring system to improve metabolic control, to detect more glycemic excursions (hypo and hyperglycemia) and to detect more postprandial hyperglycemia than SMBG [7,9–13]. The efficacy of CGMS in detecting hypoglycemia is not well established in medical literature [7,14–16].

This study aimed to determine the accuracy of CGMS and the efficacy of this method to detect unrecognized hypoglycemia and postprandial hyperglycemia in DM1 patients. The complications of CGMS in this population are still discussed.

2. Subjects and methods

2.1. Patients

This retrospective study assessed 46 DM1 patients (25.9 ± 12.8 years), duration of DM1: 1.0–20.0 years, mean duration of 12.5 ± 9.3 years, submitted to 72 h CGMS (Medtronic; Northridge, CA). Each patient had a mean A1c level $> 7.0\%$ (range: 7.0–10.5%) for 1 month before participating in the study. All participants were on intensive insulin treatment with 25% receiving continuous subcutaneous insulin infusion (insulin pump therapy) and 75% receiving multiple daily injections (MDIs). There were 56.6% of females and 43.4% of males.

2.2. Glucose sensor

The MiniMed Meditronic (Northridge, CA) CGMS, the first model approved by FDA (food and drug administration, EUA) was used for subcutaneous glucose monitoring. The glucose is measured by an electrochemical assay of glucose-oxidize detecting values range from 40 to 400 mg/dl. The system consists of a subcutaneous sensor connected by a cable to a pager-sized glucose monitor. Glucose readings are acquired by the monitor every 10 s and an average glucose value is stored in the monitor memory once every 5 min (up to 288 measurements per day and 864 in all exam). Each glucose sensor provides glucose information for up to 72 h. After the initial 60 min, the electrical current in nanoampere is converted in glucose value after the information of this is measured in the monitor. The stored values in the monitor are downloaded by the MiniMed Com-Station and presented in graphical and statistical form via a computer program and the sensor is eliminated.

2.3. Procedure

All patients were submitted to basic orientations of CGMS function and the register of all events in ''patient diary'', by one person (F.F.R.M). During the CGMS, all participants had to perform at least four capillary glycemic tests per day and enter these values into the CGMS monitor to obtain correlation coefficients between the SMBG and the CGMS values. All SMBG tests were performed using the digital glucometer (Accu-Chek Active; Roche Diagnosis). The first capillary glycemia entered in the monitor were realized after 60 min of CGMS. Families were asked not to change their dietary practices during the study.

It were analyzed: mean CG and mean CGMS sensor's glycemic value; glycemic excursions; postprandial hyperglycemia (NR < 140 mg/dl); unrecognized hypoglycemia; complications (trauma, local infection, disconnection); dropped the method; therapeutic management after CGMS. Correlation coefficient during hypo, hyper and normoglycemia and sensitivity/specificity were determined. Mean absolute differences (MAD's) were assessed and a Clark error grid was constructed.

The glycemic excursions were based on patient's information and correlated by CGMS register. Hypo and hyperglycemia were defined as blood glucose < 70 mg/dl and >180 mg/dl, respectively. The duration of hypo, hyper and normoglycemia were registered in hours/percent for comparison effect. The postprandial hyperglycemia was considered when blood glucose values were over than 140 mg/dl 2 h after lunch. The hypoglycemic crises were registered by glycemia < 70 mg/dl and unrecognized hypoglycemia when no clinical symptoms were presented. The choice of blood glucose < 70 mg/dl as a cut-off for hypoglycemia was based on the fact that poorly controlled DM1 patients often experimented clinical manifestations of hypoglycemia under this level according to medical literature and previous studies with CGMS [7,17,18]. There was no consensus in literature about this value for hypoglycemia during CGMS analysis (50–70 mg/dl) [6,7,17–20].

The accuracy of CGMS sensor was based on comparison of capillary glycemic values and sensor's values by the *T*-test during hypo, normo and hyperglycemia, with p value < 0.05. The sensitivity and specificity of sensor's value for hypo, hyper and normoglycemia were determined by statistical analysis.

The complications during the CGMS were based in medical observation and patient's information. It were analyzed the complications during the sensor implantation (bleeding and pain) and during the exam (trauma, local infection,