Contents available at Sciverse ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

International Diabetes Federation

Frequency of blood glucose testing in well educated patients with diabetes mellitus type 1: How often is enough?

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ARTICLE INFO

Article history:
Received 19 December 2011
Received in revised form
1 November 2012
Accepted 17 December 2012
Published on line 29 May 2013

Keywords:
Diabetes type 1
Education
Self-monitored blood glucose

ABSTRACT

Aims: Self-monitored blood glucose (SMBG) and knowledge of insulin requirements are pivotal for good metabolic control in patients with diabetes mellitus type 1. However, the SMBG-frequency needed for optimal glycaemic control especially in well educated patients is unclear.

Methods: In patients with type 1 diabetes treated with flexible intensified insulin therapy, we evaluated HbA1c values and the directly preceding computerised SMBG-frequencies over a 12 months period. To estimate the association between HbA1c and SMBG-frequency, we fitted a piecewise linear spline model with a change in slope at 4 SMBGs per day which is the recommended minimal SMBG-frequency at our institution.

Results: A total of 150 patients were available for analysis, with a median baseline HbA1c of 7.1% (interquartile range 6.6, 7.8). In the multivariable analysis (adjusted for gender and psychological problems), each additional SMBG measurement was associated with an estimated difference in HbA1c of −0.19% (95% confidence interval (CI) −0.42, 0.05) for ≤4 SMBGs per day and of −0.02% (95% CI −0.10, 0.06) for >4 SMBGs per day.

Conclusions: Good diabetes control can be achieved in routine diabetes care with flexible intensified insulin therapy based on continuing patients' education and with a minimum of 4 SMBGs per day.

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1. Introduction

Intensified insulin therapy in patients with type 1 diabetes includes patients' education, multiple daily insulin injections (MDI) or the use of continuous subcutaneous insulin infusion (CSII) and self-monitored blood glucose (SMBG) measurements. Each measured blood glucose value offers the opportunity to adapt insulin treatment according to actual needs. In this regard, continuous glucose monitoring system (CGMS) augmented pump therapy could be the ultimate approach for excellent diabetes control while avoiding severe hypoglycaemia [1,2].

The most important factor, however, connecting CGMS and insulin pump or SMBG and insulin pen is patients' ability to understand their individual insulin or carbohydrate requirements and to act accordingly. Thus, the key element for patients' outcome is knowledge of personal glucose metabolism and insulin kinetics rather than the technical devices used to measure glucose or apply insulin. This has been described in various studies that showed substantial improvements in HbA1c and reduction in severe hypoglycaemia in

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Abbreviations: IQR, interquartile range; BMI, body mass index.
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http://dx.doi.org/10.1016/j.diabres.2012.12.024

response to a standardised education programme while using the same technical devices [3–7]. Conversely, well educated patients could achieve good metabolic control with a limited number of SMBGs per day. We recently published a quality of care analysis in well educated type 1 diabetic patients, where we found a median HbA1c of 7.1%, with two-thirds of the patients achieving values below 7.5% [8].

In view of the current opinion of some experts that CGMS augmented pump-therapy should represent the treatment of choice for patients with type 1 diabetes, the aim of the present study was to assess the association between HbA1c and the number of SMBGs per day in our type 1 diabetic patient population at the University Hospital in Basel, Switzerland, where nobody used CGMS.

2. Methods

2.1. Patients

In a retrospective cross-sectional study as of 2006, we previously analysed 232 consecutive patients followed in our outpatient clinic [8]. In this study, we focussed on the association between HbA1c and the number of SMBGs per day in the same cohort of patients approximately two years later for the period May 2007 to April 2008. Inclusion criteria in the present study were the availability of at least one HbA1c measurement and concomitant data set of directly preceding SMBG data that were transferred from patients' individual glucometers into the Diabass® Professional software (Konstanz, Germany). A total of 468 HbA1c values with directly preceding SMBG data from 150 patients were available for analysis; of the original cohort, 44 (19%) patients were lost to follow-up and 38 (16%) patients did not have sufficient data in the Diabass® system.

All patients were treated following the principles of flexible intensified insulin therapy (FIT), which is the standard of care for type 1 diabetic patients in our institution since 1990. A detailed description of FIT can be found elsewhere [7]. During the visits, patients were encouraged to review and analyse measured blood glucose values together with their treating physicians. We further encouraged patients to perform at least 4 SMBGs per day. During the visits, we transferred data from available glucometers into the Diabass® Professional software.

HbA1c values (DCA 2000+ Analyzer, Bayer Diagnostics Europe, Dublin, Ireland), with a reference range between 4.2% and 6.5% for healthy individuals, were available at the time of the visits; patients were usually seen 3–4 times a year.

For this study, we calculated the average number of SMBGs per day during the last month prior to HbA1c measurement.

One year after initial data collection (i.e. in 2007), all patients were contacted and asked about the frequency of severe hypoglycaemia in the last year and in the last 5 years. Because very few events were reported for the last year, we used data for the last 5 years for our analysis of hypoglycaemic events [8]. We defined severe hypoglycaemia as an event requiring assistance from another person to administer oral carbohydrates, glucagon, or other resuscitative actions.

Psychological problems was determined based on patients' chart records as of 2006, including depression, clinically relevant eating behaviour disorders, and alcohol or drug abuse.

2.2. Statistical analyses

We used marginal models for repeated measures to estimate the difference in HbA1c corresponding to a 1 measurement increase in the number of SMBGs per day. We modelled the difference in HbA1c using a piecewise linear spline with a change in slope at 4 SMBGs per day. Our choice of spline was based on the current standard of care recommendation at our institution for type 1 diabetic patients. We fit the above model for HbA1c in dependence of SMBG-frequency using generalised estimating equations (GEE) with an identity working correlation matrix [9].

In the multivariable analysis, we assessed the association between HbA1c and the number of SMBGs per day adjusted for potentially confounding determinants of HbA1c, namely gender and psychological problems.

To contrast monitoring systems with a recommended minimum SMBG-frequency of 3 and 4, we additionally fit an analogous model with a change in slope at 3 and graphically illustrated the two systems.

For each analysis, we report an estimate and, using robust standard errors, 95% confidence interval (CI) of the difference in HbA1c corresponding to a 1 measurement increase in the number of SMBGs per day. We used R version 2.15.1 (R Foundation of Statistical Computing, Vienna, Austria) and the R add-on package *gee* version 4.13-18 for our analyses; and for graphics, we used the R add-on package *ggplot2* version 0.9.2.1 [10].

3. Results

3.1. Patients' characteristics

Baseline characteristics assessed as of 2006 for included ($n = 150$) and excluded ($n = 82$) patients are shown in Table 1. Included patients had a median age of 46 years (interquartile range (IQR) 37, 58), 66 (44%) were female. Relative to excluded patients, included patients were less likely to suffer from psychological problems. The median most recent HbA1c value in included and excluded patients was 7.10 (IQR 6.60, 7.78) and 7.15% (IQR 6.60, 7.88), respectively.

3.2. HbA1c and SMBG-frequency

Mean HbA1c declined with an increasing number of SMBGs per day in our population of well educated type 1 diabetes patients (Fig. 1). This decline continued beyond 3 and up to at least 4 SMBGs per day before flattening, and the monitoring system with a recommended minimum SMBG-frequency of 4 (Fig. 1, right panel) apparently provided a more sensible fit to the data and non-parametric curve than the one with a recommended SMBG-frequency of 3 (Fig. 1, left panel).

The estimated differences in HbA1c corresponding to a 1 measurement increase in the number of SMBGs per day were

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