Self-monitoring of blood glucose and treatment outcomes in type 2 diabetic patients

Agnieszka Bajkowska-Fiedziukiewicz[1,4], Katarzyna Cypryk[1,2], Tomasz Kozdraj[3], Anna Mikołajczyk-Swatko[4], Marcin Kosiński[2], Małgorzata Józefowska[4]

[1] Diabetes Clinic for Adults, Polish Mother's Memorial Hospital, Research Institute, Łódź, Poland
[2] Department of Diabetology and Metabolic Diseases, Medical University of Łódź, Polish Mother's Memorial Hospital, Research Institute, Łódź, Poland
[3] Chair of Social and Preventive Medicine, Department of Informatics and Medical Statistics, Medical University, Łódź, Poland
[4] Voivodeship Center of Diabetology and Metabolic Diseases, Łódź, Poland

Abstract: Objectives. The aim of the study was to evaluate an association between the frequency of blood glucose self-monitoring (SMBG) and glycemic control assessed by glycated hemoglobin (HbA_{1c}) levels. **Patients and methods.** A group of 600 type 2 diabetic patients aged 63.4 ±9 years (32 to 85 years) and with a mean diabetes duration of 11.4 ±7.7 years (min. 1 year, max. 38 years) were asked to perform weekly blood glucose self-monitoring with an 8-point glucose profile on a chosen day. They were also asked to declare their self-monitoring frequency. HbA_{1c} levels were measured in all the patients. **Results.** Most of the patients reported that they performed their SMBG 1–2 times a day (44.3%) or 1–2 times a week (31.8%). All of them measured their blood glucose after an overnight fast and after breakfast. Most patients performed their measurements also after lunch and dinner. Less than 50% of patients did their measurements at night-time. The mean HbA_{1c} level was 7.45 ±1.08%. Only 20% of patients achieved metabolic control of diabetes recommended by the Polish Diabetic Society (HbA_{1c} <6.5%). No severe hypoglycemia episodes were obsered. Glycated hemoglobin levels did not differ between the SMBG frequency groups. There was no correlation between HbA_{1c} levels and the frequency of self-monitoring in any group. **Conclusions.** There was no correlation between the frequency of SMBG and HbA_{1c}, which questions the need for multiple daily measurements of blood glucose in all type 2 diabetic patients.

Key words: self-monitoring of blood glucose, treatment outcomes, type 2 diabetes

INTRODUCTION

Diabetes is a chronic disease requiring continuous treatment and close cooperation between the physician and the patient; only on this condition can appropriate metabolic control be achieved. Large prospective clinical studies like Diabetes Control and Complications Trial (DCCT), United Kingdom Prospective Diabetes Study (UKPDS) and Kumamoto Study showed that proper glycemic control resulted in a substantial reduction of risk for chronic diabetes complications, both of micro- and macroangiopathic type [1-3].

Glycated hemoglobin (HbA_{1c}) is one of the parameters used to assess metabolic control in diabetes. It indicates a mean blood glucose concentration, showing both fasting and postprandial glycemia during the last 3 months. According to the Polish Diabetic Society (PTD), the target is to reach an HbA_{1c} value of ≤6.5% [4].

Personal involvement of the patient is an essential factor in the course of diabetes treatment. An indispensable component of the multifactorial diabetes treatment is self-monitoring. It is a set of decisions and actions taken by the patient which enable the disease control and proper modification of management depending on the varying conditions of everyday life. One of the most important stages of diabetes self-control is self-monitoring of blood glucose (SMBG) measured with a glucometer.

The European Association for the Study of Diabetes (EASD) recommends performing daily SMBG by patients treated with insulin. Such monitoring is also recommended for patients treated exclusively with diet or oral hypoglycemic medications. Although its frequency has not been determined, however, both fasting and postprandial levels should be measured with a frequency enabling to achieve the target glycemia [5]. According to PTD, patients treated with insulin should assess an overall glycemic profile at least once a week, and those treated with oral medications and diet at least once

Correspondence to:
Assoc. Professor Katarzyna Cypryk, MD, PhD, Klinika Diabetologii i Chorób Przemiany Materii, Uniwersytet Medyczny, Instytut Centrum Zdrowia Matki Polki, ul. Rzgowska 281/289, 93-338 Łódź, Poland, phone: +48-42-271-11-43, fax: +48-42-271-14-99, e-mail: kcypryk@mp.pl
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Table 1. Self-monitoring data in self-monitoring of blood glucose (SMBG) diaries of the studied group

Blood glucose in SMBG	N	Mean (mg/dl)	Minimum (mg/dl)	Maximum (mg/dl)	Standard deviation
Highest glucose level in the last week	600	187.9	91	388	43.0
Lowest glucose level in the last week	600	107.3	40	224	26.4
Fasting level	600	118.6	67	251	26.8
120 min after breakfast	600	162.0	34	315	41.0
Before lunch	394	132.7	40	228	27.9
120 min after lunch	586	180.7	88	355	39.6
Before dinner	375	133.5	50	212	25.2
120 min after dinner	574	167.0	90	411	36.1
At bedtime	380	147.4	39	280	27.6
At 3:00 AM	275	126.2	78	210	22.3

a month [6]. Self-monitoring at the beginning of pharmacological treatment, as well as during the change of medication and each relapse of the disease is of significance. It seems that glycemia measurements frequently made by the patient should lead to proper diabetes control, however, the studies assessing the influence of self-monitoring on the control of carbohydrate management in type 2 diabetes do not provide inconsistent results.

The objective of the study was to assess a relationship between the frequency of SMBG and HbA_{1c} values. The relation was assessed in type 2 diabetes patients to find out whether frequent SMBG allows to achieve lower glucose levels, thus enabling to achieve better treatment outcomes.

PATIENTS AND METHODS

The study involved 600 consecutive type 2 diabetes patients who were referred to the Voivodeship Diabetes Clinic in Łódź. The follow-up involved patients of both sexes, irrespective of age, education, diabetes duration and methods of treatment.

The mean age of the patients was 63.4 years (32–85 years, standard deviation [SD] = 9.0). The study group included 319 females aged 32–85 years (mean 64.9, SD = 8.8) and 281 males aged 35–83 years (mean 61.7, SD = 8.9). The mean diabetes duration in the study group was 11.4 years (SD = 7.7). The most frequent duration was 11–20 years. The patients were undergoing standard diabetes education provided by the clinic personnel.

A group of 397 (66.2%) patients was treated with insulin as monotherapy or in combination with oral medications; others were administered only oral medications.

The patients were requested to perform SMBG with their own glucometer. All patients were obliged to record maximum and minimum glucose levels during the last week and to perform an 8-point profile on a freely selected day. The profile included the following measurements: before breakfast, 2 hours after breakfast, before lunch, 2 hours after lunch, before dinner, 2 hours after dinner, at bedtime and at 3:00 AM. Each patient determined the frequency of their own SMBG,which served as the basis for division into the following groups:

A – minimum 5 measurements per day
B – 3–4 measurements per day
C – 1–2 measurements per day
D – 1–2 measurements per week
E – 1–2 measurements per month
F – no SMBG.

In all patients glycated hemoglobin was measured using the Bio-RAD Variant high-performance liquid chromatography (HPLC).

Statistical analysis

The calculations were made with STATISTICA 6.0 PL (Tulsa, OK, United States) software. We used the χ^2 test and analysis of variance (ANOVA). The value of $p<0.05$ was considered statistically significant.

RESULTS

All patients monitored blood glucose before and after breakfast, and almost all of them also after lunch and dinner. Night monitoring was performed by less than 50% of the patients. The details of SMBG in the whole study group are presented in Table 1.

The mean HbA_{1c} value in the whole studied group was 7.45% (SD = 1.08). Diabetes control recommended by PTD (HbA_{1c} ≤6.5%) was achieved only by 20% of the patients. No statistically significant difference in the mean HbA_{1c} value was observed between women (7.42%, SD = 1.08) and men

Table 2. Diabetes control parameters in sub-groups according to self-monitoring of blood glucose (SMBG) frequency

Group	A	B	C	D	E	F	p
SMBG frequency	5 and more times per day	3–4 times per day	1–2 times per day	1–2 times per week	1–2 times per month	No SMBG	
Proportion of patients (%)	0.8	18.2	44.3	31.8	3.2	1.7	–
Mean maximum blood glucose level (mg/dl)	205	185	188	190	168	195	>0.05
Mean minimum blood glucose level (mg/dl)	87	101	107	110	126	118	
Mean HbA_{1c} level (%)	7.54	7.25	7.50	7.52	7.39	7.54	

HbA_{1c} – glycated hemoglobin

(7.49%, SD = 1.09) (p >0.05). Patients treated with insulin had higher HbA_{1c} values (7.67%) than those on oral medication (7.02%) (p <0.05)

The mean values of maximum and minimum glucose and HbA_{1c} levels (Table 2) did not vary significantly in the individual groups. During the study, the patients did not report serious hypoglycemia, i.e. glycemia <40 mg/dl, neither did they require assistance.

The χ^2 test of independence did not show a statistically significant association between SMBG frequency and HbA_{1c} value in the individual groups. Similarly, the ANOVA did not show differences in HbA_{1c} values between the studied groups (p = 0.27; Fig. 1). The relation between HbA_{1c} values and SMBG frequency was also analyzed in 2 groups ie. that receiving insulin and that on oral hypoglycemic medication. All patients were on standard insulin therapy.

For the insulin group, χ^2 test of independence (HbA_{1c} values categorized by intervals) showed no statistically significant association between SMBG frequency and HbA_{1c} value (p = 0.63). ANOVA results, additionally obtained for 6 groups selected in respect of SMBG frequency, showed no differences in HbA_{1c} values in the insulin group (p = 0.16; Fig. 2).

Similarly, the oral medication group did not show statistically significant differences between HbA_{1c} values and SMBG frequency (χ^2 test of independence, p = 0.10; ANOVA, p = 0.15). The results are shown in Figure 3.

DISCUSSION

Self-monitoring of blood glucose is a recognized diabetes monitoring method. It is recommended for patients in order to achieve the desired glucose levels, prevent hypo- and hyperglycemic incidents, and thus to prevent acute and chronic diabetic complications. This method is definitely recommended for insulin patients and patients on alternative treatment.

It was demonstrated that self-monitoring in type 1 diabetes patients undergoing intensive insulin therapy is associated with improved glycemia, which enables to achieve lower HbA_{1c} values [7]. There is an ongoing discussion whether such self-monitoring is justified in type 2 diabetes, in patients treated with oral medications and diet. In our study, we did not find any association between SMBG frequency and diabetes control levels. Such a relation was found neither in insulin nor in oral medication patients. In 1997, Faas et al. [8] published a review of 77 studies concerning SMBG in type 2 diabetes patients performed between 1976 and 1996. Only 6 of them were randomized controlled trials (RCTs), and only one trial showed significant improvement in HbA_{1c} levels in type 2 diabetes patients performing SMBG (reduction

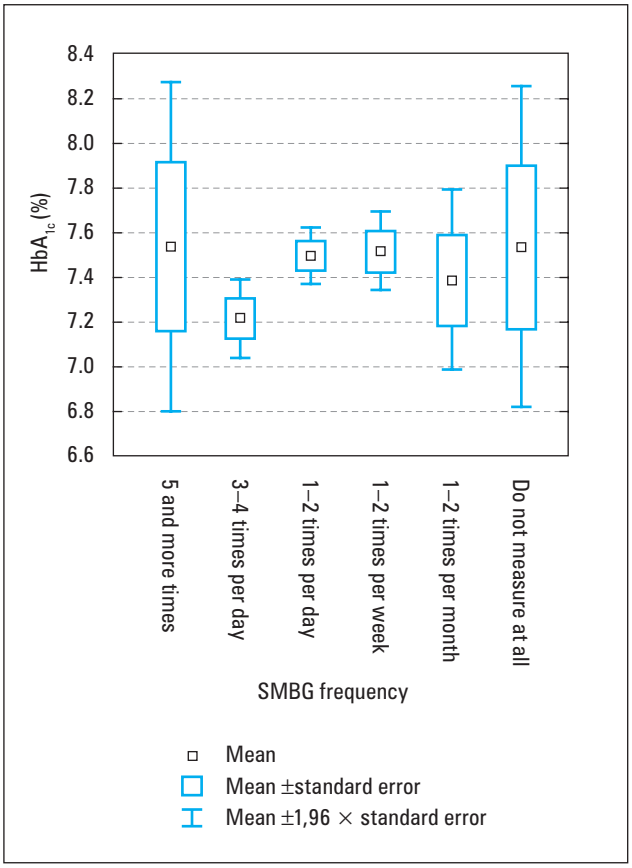

Fig. 1. Glycated hemoglobin (HbA_{1c}) values in sub-groups depending on self-monitoring of blood glucose (SMBG) frequency in the whole study group (n = 600)

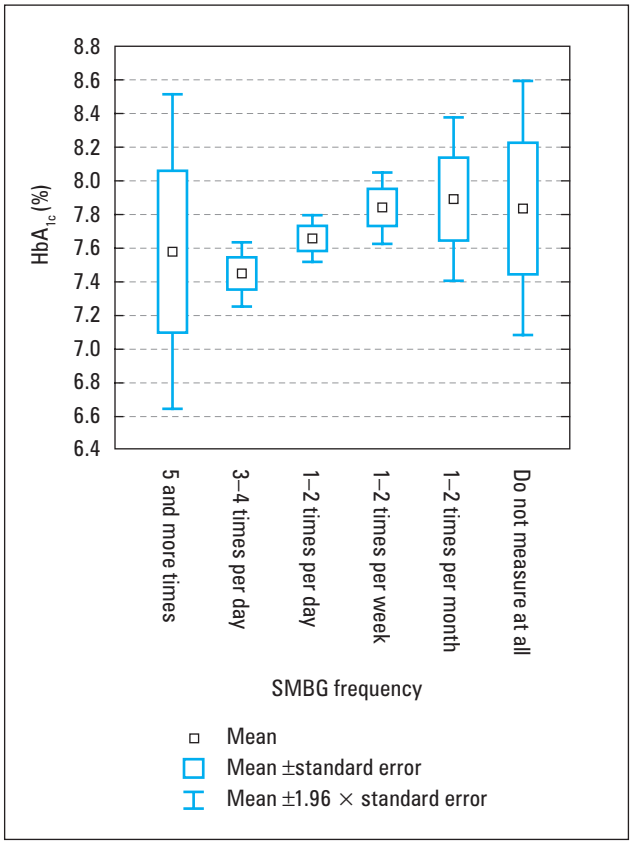

Fig. 2. Glycated hemoglobin (HbA_{1c}) values in sub-groups depending on self-monitoring of blood glucose (SMBG) frequency in the insulin group (n = 397)

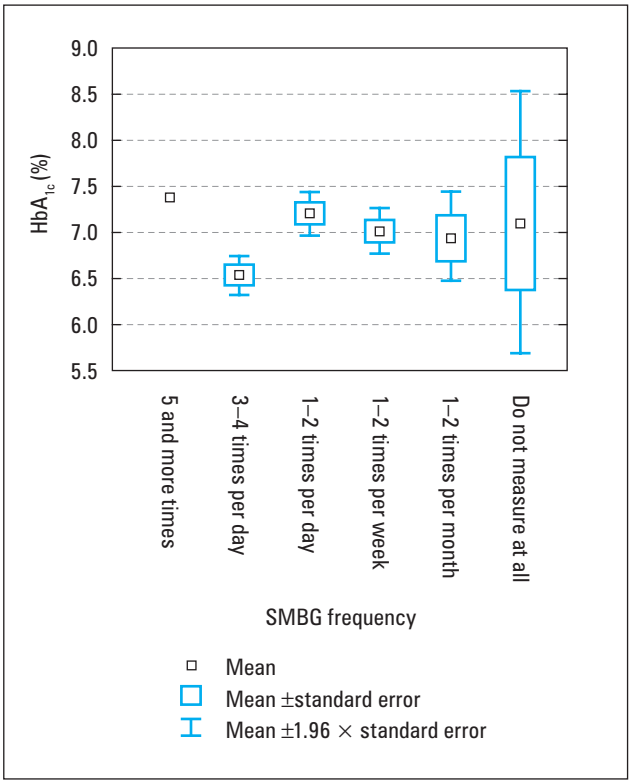

Fig. 3. Glycated hemoglobin (HbA_{1c}) values in sub-groups depending on self-monitoring of blood glucose (SMBG) frequency in the oral medication group (n = 203)

by 0.9%, p <0.05) [9]. Only 8 out of 18 studies published between 1990 and 1999 pertained to RCTs (including 6 published by Faas). A meta-analysis of 4 studies demonstrated that performing SMBG results in a slight and insignificant reduction in mean HbA_{1c} levels (by 0.6% at most). The results should, however, be interpreted carefully due to study design limitations of the trials included in the meta-analysis [10].

Results similar to our study have been shown in numerous other studies. A study carried out in England and involving 290 type 2 diabetes patients treated with insulin did not show an association between HbA_{1c} reduction and SMBG frequency [11]. Other centers did not show such a relation either, irrespective of the type of therapy in type 2 diabetes [12-14]. Recent DiGEM RCTs completed in 2007 and a study by Davidson carried out in 2005, likewise did not show significant differences in HbA_{1c} values between patients performing and not performing SMBG [15,16].

A study from Germany and Austria on type 2 diabetes patients treated with insulin showed a significant HbA_{1c} reduction (by 0.16%) in patients performing SMBG more frequently (average of 2.7 per day) in comparison with patients performing SMBG once a day. In patients treated with diet or oral medications who performed SMBG twice per day, HbA_{1c} values were significantly higher (increase by 0.14%, p <0.0001) than in patients performing SMBG once per day [17]. One of the large observational studies showed a relation between SMBG performed at home and significantly lower HbA_{1c} levels both in type 1 (n = 1159; SMBG 3 times per day; reduction in HbA_{1c} levels by 1%, p <0.001), and type 2 diabetes patients (n = 23,153; SMBG at least once per day; reduction in HbA_{1c} levels by 0.4–0.6%) [18]. For type 2 diabetes, the relation was found both in patients treated with insulin and those treated only with oral medications or diet. In patients who performed SMBG irrespective of frequency, HbA_{1c} levels were by 0.4% lower than in patients not performing SMBG (p <0.0001) and decreased with the increase in SMBG frequency. Also a large RCT carried out by Schwedes et al. [19], involving type 2 diabetes patients treated with oral medications or diet, showed a significantly higher reduction in HbA_{1c} values in patients performing SMBG than in patients not performing SMBG (1% vs. 0.6%, p <0.05). A similar relation was demonstrated in a study by Guerci et al. [20] (0.9% vs. 0.5%, p <0.05).

Based on results of the studies carried out to date, no clear-cut answer could be provided to the question as to whether intensive SMBG is justified in type 2 diabetes patients. However, there is a relatively small number of studies showing such an association, and the authors of those studies suggest to approach the results carefully, indicating study design limitations associated with heterogeneity of the studied

populations and undertaken interventions. Therefore, the following question shall be raised: how often and at what times of the day SMBG is to be performed to achieve a satisfactory level of metabolic control in type 2 diabetes?

The studies carried out to date do not provide unambiguous hints, although some reports suggest that in order to answer the aforementioned question it is essential to use SMBG results appropriately, both by the physician and the patient, which in this case requires appropriate education of the patient [21].

It is not, however, the fact of SMBG performance itself, but a correlation between the results obtained by the patient and health measures taken by him/her, which may lead to improvement of treatment efficacy. It was demonstrated in a randomized study by Moreland et al. [22] which answered the question whether SMBG education contributed to the improvement of glucose level and an increase in SMBG frequency. All 199 diabetic patients (type 1 – 35%, type 2 – 65%, HbA_{1c} ≥8.0%) were divided into 3 groups: patients receiving a glucometer and education, patients receiving a glucometer without education and a standard group without a glucometer and education. The highest reduction in HbA_{1c} values were observed in patients performing SMBG who received education (–0.13 ±1.28%), lower in patients performing SMBG without education (–0.04 ±1.31%). In patients not performing SMBG and not receiving education, an increase in glycated hemoglobin was observed (+0.04 ±–1.10%)

Education of patients should therefore constitute an integral part of diabetes treatment, because only competent use of information coming from current blood glucose allows optimization of frequency and costs of self-monitoring. A methodology of self-monitoring education remains an open question.

In conclusion, no relation between SMBG frequency and glycemic control level undermines the usefulness of repeated monitoring in all type 2 diabetes patients. It seems that performance of expensive SMBG must be combined with intensive education of patients.

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