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Self-monitoring of blood glucose in tablet-treated type 2 diabetic patients (ZODIAC-17)

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ABSTRACT

Background: Whether self-monitoring of blood glucose (SMBG) improves glycaemic control in patients with type 2 diabetes mellitus (T2DM) not using insulin is questionable. Our aim was to investigate the effects of SMBG in patients with T2DM who were in persistent moderate glycaemic control whilst not using insulin.

Methods: Patients were eligible when between 18 and 70 years of age, with an HbA1c between 7 and 8.5%, using one or two oral blood glucose lowering agents.

Forty-one of the anticipated 52 patients were randomly assigned to receive either SMBG added to usual care, or to continue with usual care for one year. A fasting glucose value and three postprandial glucose values were measured twice weekly (including a Saturday or a Sunday). The primary efficacy parameter was HbA1c. Furthermore, health-related quality of life and treatment satisfaction were assessed using the Short-form 36 Health Survey Questionnaire (SF-36), the Type 2 Diabetes Symptom Checklist (DSC-r), the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the WHO-Wellbeing Index (WHO-5).

Results: Change in HbA1c between groups was -0.05% (95% CI: -0.51, 0.41; p=0.507). Also, there were no significant changes between groups on the DTSQ, DSC type 2, WHO-5 or SF-36, except for the SF-36 dimension 'health change' which was lower in the SBMG group (mean difference: -12 (95% CI: -20.9, -3.1).

Conclusion: On top of the absence of a clinical benefit, tablet-treated T2DM patients experienced some worsening of their health perception. We therefore argue that the use of SMBG in this patient group is questionable, and its unlimited use and promotion should be reconsidered.

KEYWORDS

Blood glucose self-monitoring, diabetes mellitus type 2, haemoglobin A1c, glycosylated, quality of life

INTRODUCTION

Self-monitoring of blood glucose (SMBG) is an important tool in the management of diabetes mellitus in patients using insulin. For patients with type 1 diabetes mellitus, it is almost impossible to achieve good glycaemic control without SMBG.[1] In patients with type 2 diabetes mellitus (T2DM) using insulin SMBG can also help to improve glycaemic control.[2,3]

However, there still is much debate about the use and effectiveness of SMBG in non-insulin-treated T2DM.[4] A Cochrane review published in 2005 concluded that SMBG might be effective in improving glycaemic control in patients with T2DM who are not using insulin, translating into a possible benefit in haemoglobin A1c (HbA1c) of approximately 0.39%.[4,5] However, only two of the six studies included in this systematic review were rated as being of good methodological quality.[6,7] These two studies did not show a beneficial effect of SMBG on glycaemic control.

Our aim was to investigate the effects of SMBG on glycaemic control, quality of life and treatment satisfaction in patients with T2DM not using insulin, who are in persistent moderate glycaemic control. To answer our research question we designed a randomised controlled trial to compare SMBG use with usual care.

MATERIALS AND METHODS

Participants

In 1998, the Zwolle Outpatient Diabetes project Integrating Available Care (ZODIAC) Study was initiated in the Zwolle region (the Netherlands), as part of a shared care diabetes project.[8] Patients included in this shared care project were eligible for the present study if they met the following criteria: T2DM, 18 to 70 years of age, HbA1c 7 to 8.5% at previous annual check-up, use of one or two different oral blood glucose-lowering agents (moreover, when two oral blood glucose-lowering drugs were taken, they should not both be used at maximum dosage), oral blood glucose-lowering agents had not been changed during the past three months, no use of insulin, no use of devices for SMBG at the start of the study or in the preceding six months, and sufficient knowledge of the Dutch language to understand the requirements for the study. Patients meeting the eligibility criteria were asked to participate and were included in the study after written informed consent, whenever the HbA1c value during the current annual check-up was between 7 to 8.5% as well.

Intervention

Patients in the intervention group (SMBG group) were instructed to measure their blood glucose values four times a day (one fasting glucose concentration and three post-meal glucose concentrations (1.5 hours after the meal), twice weekly, on one weekday and one day in the weekend for a period of one year. Patients were requested to record these glucose values in a study diary. Patients in the SMBG group were all provided with a single glucose monitor (Accu-check Aviva, Roche Diagnostics Corp., Indianapolis, IN). No further education except how to handle the device was given, in order to ensure that besides the intervention, there were no education differences with the control group. Patients were taught, and could also see in their diary, which glucose values were considered normal or acceptable (fasting 4 to 8 mmol/l and postprandial 4 to 10 mmol/l), and which were abnormal. In case of blood glucose values below 3.5 mmol/l or above 20 mmol/l, patients were instructed to evaluate their self-monitoring and to perform an extra measurement. If this subsequent value was again above 20 mmol/l, the patient was requested to contact the study nurse (during office hours) or the general practitioner (outside office hours). When the value was again below 3.5 mmol/l, the patient would follow the instructions in case of hypoglycaemia.

Patients in the control group continued with usual care from their own healthcare provider. No other instructions were given, except for the explicit request not to use any form of SMBG during the study.

All patients continued to receive care from their own healthcare provider every three months during the study. Healthcare providers were asked not to make changes in glucose-lowering agents during the study period. Every three months the HbA1c was measured. If it exceeded 8.5%, glucose-lowering therapy was intensified, according to the Dutch guidelines at the time of the study. First, when possible, metformin was started or increased to the maximum (tolerated) dose. Second, when possible, a sulphonylurea derivate was started or increased to the maximum (tolerated) dose. When a patient was already being treated with a thiazolidinedione, the dose was increased to the maximum (tolerated) dose. If two maximally dosed oral blood glucose-lowering agents were not sufficient to lower HbA1c below 8.5%, insulin therapy was initiated.

Measurements

HbA1c levels were measured every three months. Furthermore, data collected at baseline and after 12 months included: diabetes duration, smoking with number of cigarettes, alcohol with number of units of alcohol, macrovascular complications (yes or no and date), medication, length (no shoes), weight (no shoes or coat), blood pressure, serum creatinine, lipid profile (non-fasting) with total cholesterol, high-density lipoproteins (HDL), low-density lipoproteins (LDL), triglycerides, total cholesterol/HDL and urinary albumin/creatinine ratio. All laboratory tests were performed in local hospital laboratories, where staff was unaware of treatment allocation.

In addition, at baseline, and after six and 12 months, patients were asked to fill in a questionnaire containing the Dutch versions of the Short-Form 36 Health Survey Questionnaire (SF-36),[9-11] the WHO five-item Wellbeing Index (WHO-5),[12,13] the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the Diabetes Symptoms Checklist.[14] The SF-36 and WHO test scores range from 0 to 100, with 100 representing the best possible well-being.[14] The DTSQ score can -range from 0 (very dissatisfied) to 36 (very satisfied). The two additional items measuring perceived frequency of hypoglycaemia and hyperglycaemia are scored from 0 (none of the time) to 6 (most of the time). To measure the presence and the perceived burden of diabetes-related symptoms, the revised version of the type 2 Diabetes Symptom Checklist (DSC-r) was used.[15] Scores on the eight scales can range from 0 to 5, with higher scores indicating more troublesome symptoms.

Outcome

Our pre-specified primary endpoint was HbA1c difference between groups. Our secondary endpoints were differences

between groups in HRQoL measures, diabetes-related complaints, treatment satisfaction, cumulative incidence of (necessity to start) insulin therapy, bodyweight and body mass index (BMI). For the primary endpoint, separate analyses were performed for patients who were compliant to the intervention (at least 80% of requested glucose measurements).

Randomisation

Randomisation was done using an independent third party. After inclusion and informed consent at the first visit, the study nurse or the investigator made a telephone call to a third party, who had numbers ranging from 1 to 60 in non-transparent envelopes, and was asked to draw an envelope. When an uneven number was drawn, the patient was allocated to the intervention group who had to perform SMBG (SMBG group). With an even number, the patient was allocated to continued usual care (no monitoring; control group).

Statistical analysis

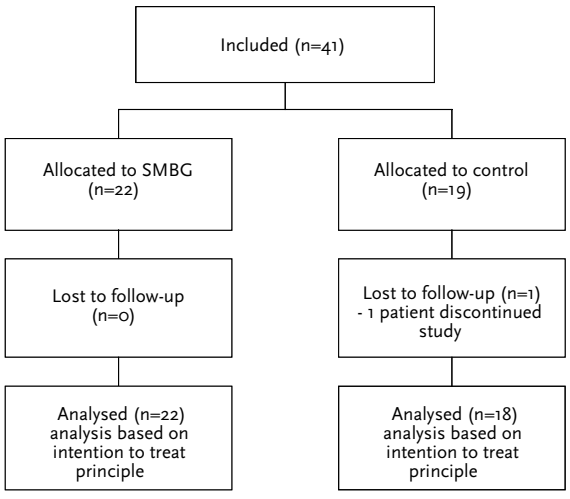
Mean HbA1c of patients with HbA1c 7 to 8.5% in our shared care diabetes project not using SMBG was 7.45 (standard deviation (SD) 0.38). Powered to detect a 0.39% absolute reduction in HbA1c in a one-year follow-up of patients performing SMBG as compared with control patients, with a power 95%, alpha 0.05 two-tailed, the total sample size of the study should be 52. To take dropout into account, the aim was to include 60 patients.

To evaluate differences in target variables over time and between the groups, we used the repeated measures of the general linear model (GLM) with the Greenhouse-Geiser test to compensate for lack of sphericity. Concerning HbA1c, in case of missing values, these values were imputed by the Expectation Maximisation (EM) algorithm using the available HbA1c values. The baseline value was set as covariate. SPSS software, version 14.0, was used for all the analyses.

RESULTS

Patients were recruited from March 2006 until October 2007. A total of 41 patients were included in the study and randomised *(figure 1)* of which one patient in the control group refused to continue the study and withdrew consent. Of the 22 patients in the SMBG group, 17 (77%) performed at least 80% of the requested glucose registrations. Two patients performed half of the expected registrations, and from three patients no SMBG results at all were available; one of these patients did not perform SMBG at all, and gave as a reason that he could not find the time to do it, the second patient did not perform SMBG because he judged SMBG too difficult to perform. The third patient did not return his diary during his last visit and despite phone calls, letters and house visits, no contact could be established afterwards.

Figure 1. *Patient disposition*



Patient baseline characteristics are presented in *table 1*. Median HbA1c levels were 7.5 and 7.6% in the SMBG and control group, respectively. BMI and diabetes duration were different between groups. HbA1c levels at different time points in the study in both groups are presented in *table 2*. After 12 months, HbA1c dropped 0.1% in both groups with no significant difference between the SMBG and control group (-0.05% (95% CI: -0.51, 0.41; p=0.51)). When performing this analysis in the subgroup of compliant

Table 1. *Baseline characteristics*

	SMBG (n=22)	Control (n=18)
Gender (male)	12 (55)	13 (72)
Age (years)	59.5±8.0	58.7±7.8
Diabetes duration (year) *	5.0 (4.0, 7.0)	8.0 (3.8, 11.3)
Body mass index (kg/m²)	32.7±5.8	29.0±4.6
Systolic blood pressure (mm Hg)	151±21	147±18
Serum creatinine (µmol/l)	93±20	94±22
Cockcroft (ml/min) * †	91 (78, 121)	96 (72, 110)
Albumin creatinine ratio *	1.50 (0.58, 3.75)	1.0 (0.63, 3.20)
HbA_{1c} (%)*	7.5 (7.1, 7.9)	7.6 (7.3, 8.1)
HDL (mmol/l)	1.32±0.34	1.17±0.27
LDL (mmol/l)	2.35±0.71	2.48±1.05
Use of 2 oral blood glucose-lowering agents	12 (55)	12 (67)
Macrovascular complication	6 (27)	2 (11)

Data are mean ± SD or n (% of known data) unless otherwise indicated. * Data are median (P_{25},P_{75}); † estimated creatinine clearance; SMBG = self-monitoring of blood glucose; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table 2. *HbA1c per treatment group*

	Baseline	3 months	6 months	9 months	12 months	Change within groups *	Change between groups (95%CI)†
SMBG	7.6±0.5	7.5±0.6	7.4±0.7	7.5±0.8	7.5±0.8	-0.1±0.9	-0.05 (-0.51, 0.41)
Control	7.7±0.4	7.6±0.6	7.7±0.6	7.6±0.6	7.5±0.5	-0.1±0.8	‡

Data are mean ± SD within groups unless otherwise indicated. *from baseline to 12 months; † mean difference between groups with 95% CI; ‡ p=0.51; SMBG = self-monitoring of blood glucose.

patients, the between-group difference was -0.04% (95% CI: -0.52, 0.45; p=0.70). In a post-hoc analysis, adding BMI and diabetes duration as covariates (intention-to-treat analysis) did not change the results (-0.07% (95%CI: -0.56, 0.43; p=0.67)). Three patients in the intervention group progressed to insulin therapy *vs* none in the control group (p=0.10). No effects on BMI and weight were seen (data not shown).

Data concerning HRQoL outcome are presented in *table 3*. Scores on the subscales of the SF-36 mostly show a small and non-significant worsening in the SMBG group compared with the control group, except for the dimension 'health change'. After 12 months the score on this subscale was 12.0 (95% CI: -20.9, -3.1) points lower in the SMBG group compared with control (p<0.01). The dimension 'health change' consists of one item (with five possible answers) in the questionnaire: 'Compared with one year ago, how would you rate your health in general now?'. Concerning the WHO-5 questionnaire, the DTSQ and the DSC-r, no significant differences were found. Also, no significant differences were found for the separate eight scales of the DSC-r (data not shown).

DISCUSSION

SMBG did not improve glycaemic control in patients with moderately controlled type 2 diabetes treated with oral glucose-lowering agents in this study. Furthermore, SMBG did not have any positive effect on HRQoL, well-being, treatment satisfaction or diabetic symptoms. On the contrary, patients performing SMBG reported a decline in their health in general during the one-year study, compared with the control group.

After the two studies of high methodological quality, which were included in the Cochrane review from 2005 and did not find an effect of SMBG on glycaemic control, three other large randomised controlled trials of high methodological quality have been published (*table 4*).[6,7,16-19] In general, the results of our study are in line with these trials. One publication reported a positive effect of SMBG on HbA1c of 0.24% (95% CI: 0.03, 0.45).[18] This concerned a 27-week study in 610 patients, in which patients in the SMBG group were requested to perform SMBG five times a day (before each meal, two hours after the main meal and before bedtime), two days a week (one working and one non-working day); on top of that once a month postprandial measurements were taken after each meal. Unfortunately, this study did not measure HRQoL or treatment satisfaction. The two other studies did not find an effect of SMBG on HbA1c.[16,17] Farmer *et al.* compared a control group with less intensive and more intensive SMBG.[16] Differences in HbA1c compared with the control group were -0.14% (95% CI: -0.35, 0.07) and -0.17% (95% CI: -0.37, 0.03), for the less intensive and more intensive

Table 3. *Health-related quality of life scores (SF-36), wellbeing (WHO-5), diabetes treatment satisfaction (DTSQ) and diabetes symptoms (DSC-r) per treatment group*

	SMBG		Control		
Questionnaire	Baseline mean ± SD	1 year mean ±SD	Baseline mean ±SD	1 year mean ±SD	Change between groups (95%CI)
SF-36 physical component score	42.2±10.4	44.3±9.8	48.5±10.6	47.9±7.9	-0.0 (-5.2, 5.1)
SF-36 mental component score	55.5±7.4	53.1±9.5	50.6±10.6	51.6±7.7	-1.4 (-6.6, 3.7)
WHO-5 total score	68.0±20.7	74.4±14.5	71.0±17.9	76.3±11.4	-0.6 (-8.2, 7.0)
DTSQ total score	29.3±4.8	32.1±3.8	30.7±4.2	30.7±4.0	1.2 (-1.6, 4.1)
DTSQ hypo*	1.0 (0.0, 2.5)	1.0 (0.0, 2.0)	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)	0.3 (-0.5, 1.1)
DTSQ hyper	2.2±1.6	2.3±1.9	2.6±1.7	1.9±1.9	0.5 (-0.8, 1.8)
DSC-r total score*	0.5 (0.2, 1.0)	0.4 (0.3, 1.1)	0.7 (0.4, 1.0)	0.9 (0.3, 1.4)	-0.1 (-0.5, 0.3)

Data are mean ± SD or mean change (95% CI) unless otherwise indicated. Data are median (P_{25},P_{75}); SMBG = self-monitoring of blood glucose.

Table 4. *Randomised controlled trials of SMBG of high methodological quality in patients with type 2 diabetes not using insulin: effects on HbA1c*

Study	Treatment arm		
First author	**Intervention**	**Control**	**Intervention vs. control**
Allen	12.4→10.4	11.7→9.7	~0.0 (p>0.95)
Davidson	8.5→7.7	8.4→7.8	-0.2 (95% CI: -1.1, 0.6)
Farmer*	1) 7.41→7.28 2) 7.53→7.36	7.49→7.49	1) -0.14 (95% CI: -0.35, 0.07) 2) -0.17 (95% CI: -0.37, 0.03)
O'Kane	8.8→6.9	8.6→6.9	-0.07 (95% CI: -0.38, 0.25)
Barnett	8.12→6.95	8.12→7.20	-0.24 (95% CI: -0.45, -0.03)

***Group 1 received less intensive SMBG and group 2 more intensive self-monitoring of blood glucose (SMBG).**

SMBG groups, respectively.[16] Furthermore, the health utility score as measured with the EuroQoL (EQ-5D) questionnaire was lower in the more intensive intervention group compared with the control group.[16] In the study by O'Kane *et al*. the effect on HbA1c of SMBG compared with control was -0.07% (95% CI: -0.38, 0.25), and they reported a significantly worse outcome on the depression scale of the well-being questionnaire in the SMBG group compared to the control group.[17]

The one-year follow-up study of Farmer *et al*. had two different intervention groups (n=453).[16] Patients in the less intensive intervention group (performing SMBG three times a day (one fasting and two pre- or postprandial values), two days a week) were instructed to strive for preprandial glucose concentrations of 4 to 6 mmol/l and postprandial concentrations of 6 to 8 mmol/l. No further information about how to interpret glucose values was given to subjects. In addition to the care as given in the 'less intensive group', the more intensive group received training and support in timing, interpretation and using results, also to enhance motivation and maintain adherence to diet, physical activity and drug regimens. The more intensive group was also encouraged to experiment with SMBG to explore the effects of specific activities. The study by O'Kane *et al*. also had a one-year duration, and included 184 patients with new onset diabetes.[17] Patients in the SMBG group were requested to measure four fasting and four postprandial values per week and received advice on interpretation and appropriate (lifestyle) responses to high and low readings.

An important limitation of our study is the sample size. We needed 52 and aimed at 60 patients, but were only able to include 41 patients due to a variety of reasons. In 2007, out of the 10,403 patients between 18 and 70 years of age in the ZODIAC project, 74% had an HbA1c below 7% during their annual check-up and were therefore not eligible for inclusion.[8] Furthermore, many of the patients with higher HbA1c levels were not persistently in the HbA1c range of 7 to 8.5%, or were on a maximum dosage of oral blood glucose-lowering agents, or already performed SMBG. Regarding our results, the 95% confidence interval is wider than the relevant difference of 0.39% our study was powered on, i.e. -0.51 to 0.41, which means that this magnitude of benefit cannot be excluded in the patients performing SMBG, but also not in the control group.

SMBG can be performed in different frequencies and at many different moments during the day. SMBG can be performed with or without exact knowledge about the interpretation and use of glucose values. We instructed patients to perform one fasting glucose measurement and three glucose measurements 90 minutes post-meal twice a week. We gave information about which values were acceptable or unacceptable, but not about how to reach good control. Patients were not assisted more often by a healthcare provider with knowledge and advice about how to achieve glucose values in the target range. So, the SMBG performed in our study is more a structured form of self-measurement than self-regulation, which is more often done and easier to do in cooperation with patients on insulin.

What can be regarded as a strong point of our study is that we used a form of SMBG which, in our opinion, reflects what happens in daily practice. Furthermore, by using this study design, we were able to rule out the effects of education on HbA1c. The difference in intervention between the groups in our study is the performance of SMBG itself and not some other form of education, which in itself is reported to improve HbA1c by 0.32%.[21]

In conclusion, tablet-treated T2DM patients, rating their health over a one-year period, experienced a worsening on the dimension 'health change' of the SF-36 when performing SMBG. Failing to find a clinical benefit, we conclude that there appears to be no evidence for a positive impact of SMBG on HRQoL or treatment satisfaction in T2DM patients treated with oral glucose-lowering agents, although we cannot completely rule this out based on this study. We therefore argue that the use of SMBG in this patient group is questionable, and its use should be reconsidered.

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