Structured self-monitoring of blood glucose reduces glycated hemoglobin in insulin-treated diabetes

Noriko Kato*, Jinyan Cui, Mitsutoshi Kato

ABSTRACT

The aim of the preset study was to investigate the effectiveness of structured self-monitoring of blood glucose (SMBG) in insufficiently controlled insulin-treated diabetes. A total of 86 insulin-treated patients were randomized to a routine testing group (RTG; $n = 43$) and a structured testing group (STG; $n = 43$). The STG used a chart to record seven-point blood glucose (BG) profile on three consecutive days per month. The primary end-point was the glycated hemoglobin (HbA1c) at 3 months and 6 months. There were no significant differences of HbA1c between the RTG and STG at 3 months. However, the STG had significantly improved HbA1c at 6-month follow-up compared with the RTG ($P = 0.002$). In the STG, HbA1c decreased by 0.5% from 7.9 (SD 0.5) to 7.4 (0.7)%, whereas it decreased by 0.1% in the RTG from 7.9 (0.5) to 7.8 (0.7)%. In the STG, 55% of the patients were willing to continue structured SMBG and they achieved a 0.7% decrease of HbA1c. The present findings suggest that structured SMBG significantly improves glycemic control. (J Diabetes Invest, doi: 10.1111/jdi.12072, 2013)

KEY WORDS: Glycemic control, Insulin-treated diabetes, Self-monitoring of blood glucose

INTRODUCTION

Self-monitoring of blood glucose (SMBG) is widely recommended as a component of diabetes management[1,2]. There is a general consensus that SMBG should be implemented by a more structured and standardized approach for patients with type 2 diabetes[3]. The International Diabetes Federation (IDF) provides several examples of focused SMBG regimens. One of which involves obtaining a seven-point blood glucose (BG) profile (before and 2-hour after each meal, and at bedtime) over three consecutive days (7-point 3-day testing)[4]. The recent Structured Testing Program Study showed that this structured seven-point 3-day testing regimen can significantly reduce glycated hemoglobin (HbA1c) when used by appropriately trained non-insulin-treated patients and their carers[5]. However, there has not been a study examining this SMBG regimen in insulin-treated patients. We considered that the seven-point 3-day structured SMBG regimen could achieve a better understanding of the BG profile by obtaining comprehensive BG data, and thus could lead to improved treatment.

The cost of SMBG is reimbursed for insulin-treated diabetes by the National Health Scheme in Japan. We investigated whether carrying out structured seven-point 3-day SMBG and charting the BG profile could improve glycemic control in insufficiently controlled insulin-treated patients without any additional cost.

Kato Clinic of Internal Medicine, Tokyo, Japan
*Corresponding author. Noriko Kato Tel.: +81-3-5668-2161 Fax: +81-3-5668-2162
E-mail address: norikoka@gol.com
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MATERIALS AND METHODS

Participants

The present study was a randomized controlled trial that compared the structured testing group (STG) with the routine testing group (RTG). The study duration was 3 months, with an additional 3 months of follow up. Patients visited Kato Clinic of Internal Medicine (Kato Clinic), which specializes in treating diabetes, for review once a month.

Inclusion criteria were: (i) insulin-treated diabetes registered at Kato Clinic; (ii) familiarity with SMBG, and (iii) HbA1c >6.9%.

The study was approved by the ethics committee of Nishi Tokyo Clinical Diabetes Study Group (approval number: 100223) and was carried out in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

During the first 3-month period, the STG carried out a seven-point 3-day structured SMBG before each visit to the clinic. The BG values were recorded with the Accu-Chek®360° View Blood Glucose Analysis System (360° View; Roche Diabetes Care, Roche Diagnostics GmbH, Mannheim, Germany), an easy-to-use graphing tool for seven-point 3-day testing (Figure S1).

During the next 3-month period, a subgroup of the STG continued the seven-point 3-day testing and recorded data with

360° View (STG1), whereas the other subgroup went back to routine testing and logbook recording (STG2).

As the control group, the RTG carried out routine SMBG and recorded data in a logbook throughout the 6-month period.

An introduction to the 360° View was provided for the STG. Patients visited the clinic monthly, and their therapy was adjusted based on the SMBG data.

SMBG strips were supplied within the reimbursable range.

End-Points and Statistics

The primary end-point was the change of HbA1c from baseline to 3-month and 6-month. HbA1c (%) was estimated as a National Glycohemoglobin Standardization Program (NGSP) value[6].

All results are shown as mean (standard deviation). Data were compared by Mann–Whitney *U*-test and Tukey test. A *P*-value of <0.05 was considered to be statistically significant.

RESULTS

A total of 100 out of 800 diabetic patients registered at Kato Clinic were recruited, and 86 patients (4 type 1 and 82 type 2 diabetes) were enrolled. Three patients dropped out and 83 patients completed the study (42 in the STG; 41 in the RTG). Additional 3-month follow-up data were available for these 83 patients. The STG patients either continued seven-point 3-day testing and recording data with the 360° View method (STG1, $n = 23$) or went back to routine testing (STG2, $n = 19$). Figure 1 shows a consort diagram of the participants.

Their demographic and disease characteristics at baseline are listed in Table 1. There were no significant differences between the two groups. All patients were treated with insulin and 56% injected insulin three or more times a day.

Changes of HbA1c

As shown in Figure 2 and Table 2, the change of HbA1c at 6-month was significantly larger in the STG than the RTG (–0.5% vs –0.1%, $P = 0.002$). No significant difference in the reduction of HbA1c was seen at 3-month.

Adherence to Structured SMBG

After 3-month, patients in the STG chose to either continue seven-point 3-day testing using the 360° View recording paper tool (STG1) or to resume their previous routine testing (STG2), recording data in a logbook. A total of 23 patients continued structured testing (STG1; 55%) and 19 patients discontinued it (STG2; 45%).

The STG1 showed further improvement of HbA1c from 8.0 (0.6) to 7.5 (0.5)% and 7.3 (0.6)% at baseline, 3-month and 6-month, respectively. The change of HbA1c was significantly larger than in the RTG, being –0.7% vs –0.1% ($P = 0.002$).

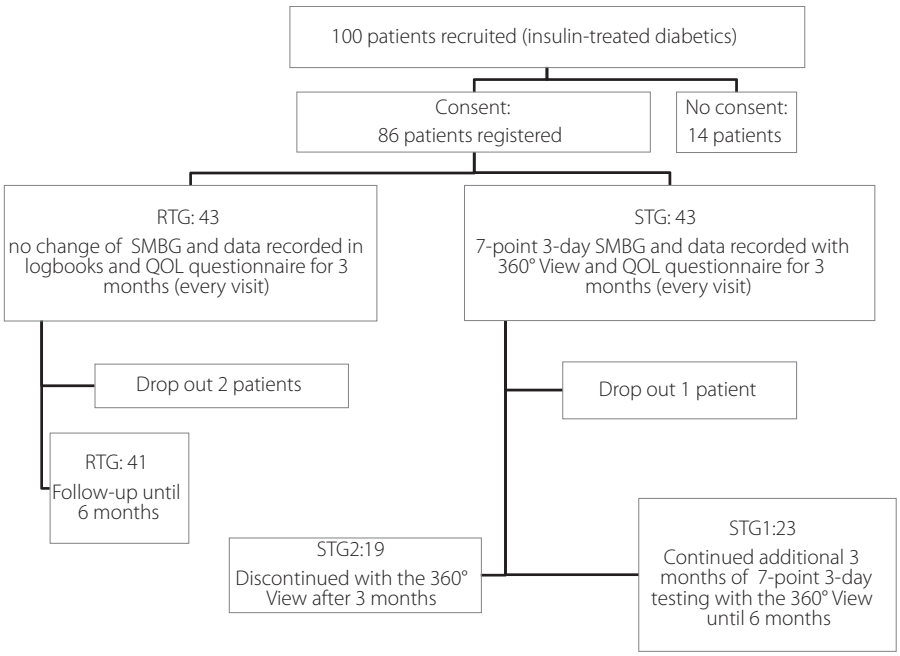

Figure 1 | Consort diagram of the patients. A total of 86 insulin-treated patients were randomized to the structured testing group (STG) or routine testing group (RTG), with two and one drop-outs during the 3-month study, respectively. A total of 41 patients in the RTG and 42 in the STG completed the 3-month study and follow-up until 6 months. In the STG, 19 returned to routine self-monitoring of blood glucose (SMBG) and 23 continued structured testing with the Accu-Chek®360° View Blood Glucose Analysis System during follow up until 6 months. QOL, quality of life; STG1, a subgroup of the STG that continued the seven-point 3-day testing and recorded data with the Accu-Chek®360° View Blood Glucose Analysis System; STG2, a subgroup that went back to routine testing and logbook recording.

Table 1 | Baseline characteristics of patients in each group

Mean (SD)	Routine testing group	Structured testing group	Total	*P*-value
n	41	42	83	–
Sex (% Male)	54	55	54	0.921
Diabetes type (% type 1)	2	7	5	0.320
Age (years)	61.0 (13.2)	58.9 (11.5)	60.0 (12.3)	0.305
Weight (kg)	69.2 (14.9)	67.5 (16.9)	68.3 (15.9)	0.392
BMI (kg/m^2)	27.0 (4.9)	26.3 (4.5)	26.6 (4.7)	0.377
Duration of diabetes (years)	14.9 (8.2)	14.8 (8.0)	14.8 (8.1)	0.953
HbA1c (% NGSP)	7.9 (0.5)	7.9 (0.5)	7.9 (0.5)	0.808
SMBG Duration (years)	6.9 (3.6)	6.0 (3.3)	6.4 (3.4)	0.278
Insulin units per day	30.5 (13.3)	32.1 (12.6)	31.3 (12.9)	0.547
SBP (mmHg)	125 (10)	124 (13)	125 (11)	0.880
DBP (mmHg)	65 (7)	65 (7)	65 (7)	1.000

BMI, body mass index; DBP, diastolic blood pressure; HbA1c, glycated hemoglobin; NGSP, National Glycohemoglobin Standardization Program; SBP, systolic blood pressure; SD, standard deviation; SMBG, self-monitoring of blood glucose.

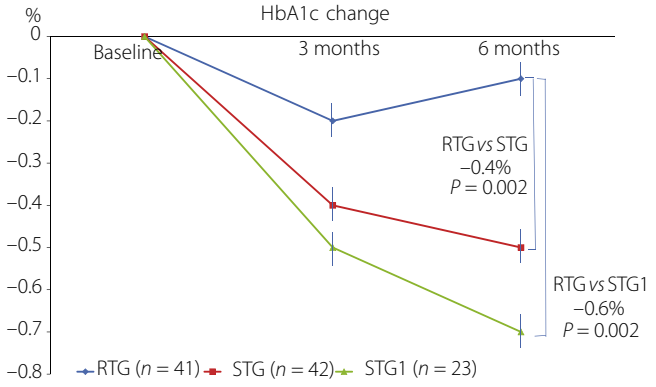

Figure 2 | Changes of glycated hemoglobin HbA1c over time. The structured testing group (STG) showed improved glycemic control compared with the routine testing group (RTG), with the difference of HbA1c being 0.4%. A subgroup of the STG that continued the seven-point 3-day testing and recorded data with the Accu-Chek®360° View Blood Glucose Analysis System (STG1) continued structured testing until 6 months and improved further, with the difference of HbA1c being 0.6%. Both differences were statistically significant.

Change of Treatment

By 3-month, α-glucosidase inhibitors α-GI was added-on to significantly more patients in the STG vs patients in the RTG (7 vs 1). The STG tested both preprandial and postprandial BG, whereas many patients in the RTG mainly monitored fasting BG. We saw increased prescription of other oral agents in the STG, but the differences between the two groups were not as significant as α-GI. We made fine adjustments of insulin treatments quite often for both groups, but the dosage changes between the two groups were not significantly different.

Table 2 | Change of glycated hemoglobin at 3 months and 6 months

Mean (SD)	Baseline HbA1c (%)	Change of HbA1c (%) from baseline at 3 months	Change of HbA1c (%) from baseline at 6 months
RTG (*n* = 41)	7.9 (0.5)	−0.2 (0.7)	−0.1 (0.7)
STG (*n* = 42)	7.9 (0.5)	−0.4 (0.6)	−0.5 (0.7)
STG1 (*n* = 23)	8.0 (0.6)	−0.5 (0.7)	−0.7 (0.6)
STG2 (*n* = 19)	7.8 (0.4)	−0.3 (0.5)	−0.3 (0.7)
P-value (RTG vs STG) Mann–Whitney test	0.898	0.158	0.002
P-value (RTG vs STG1) Tukey test	0.615	0.141	0.002
P-value (RTG vs STG2) Tukey test	0.797	0.780	0.559

HbA1c, glycated hemoglobin; RTG, routine testing group; SD, standard deviation; STG, structured testing group.

We concluded that the seven-point 3-day testing with the use of 360° View can help to improve glycemic control in insufficiently controlled insulin-treated patients.

DISCUSSION

The present study suggested that the structured testing and visualized blood glucose profile showed a comprehensive blood glucose profile in an easily understood format, which helped with the optimization of treatment and motivation of patients. This method is also practically implementable, shown by the high adherence rate.

The insulin-treated patients in the present study had an average 15-year history of diabetes, 56% injected insulin three times or more a day, and more than half of them also had hypertension and/or dyslipidemia. They found difficulties in reaching the HbA1c target (<6.9%), despite treatment with insulin and carrying out routine SMBG.

In order to reach the target HbA1c value (<6.9%), not only fasting, but also postprandial hyperglycemia, should be addressed[7]. The 2011 Guideline for Management of Post Meal Glucose in Diabetes suggested that SMBG should be considered, because it is currently the most practical method for monitoring glycemia after meals[8]. However, many patients only test their fasting blood glucose level, which provides little indication about their postprandial blood glucose profile or hypoglycemia.

We clearly observed that patients in the STG had increased awareness about the relationship between blood glucose level and diet. It allowed patients to recognize postprandial hyperglycemia and made it more likely for them to agree to add-on α-GI, which contributed to the reduction of post-meal blood glucose (post-dinner −46 mg/dL 3-month after α-GI was added, $P = 0.052$).

Currently, there is no published guideline for SMBG in Japan. It is up to the healthcare providers to suggest the timing and frequency of testing, whereas patients choose how to carry it out and record the data. We believe that the reason that STG improved HbA1c was multidimensional. It is important for healthcare providers and patients to share SMBG data, and collaborate in the treatment of diabetes.

The structured testing SMBG method used in the present study is effective (HbA1c), and can be implemented (adherence) in insulin-treated patients.

A limitation of the present study was the small number of patients and they were from one clinic. We wish to have this structured testing carried out in other clinics with more patients in a future study.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Figure S1 | Blood glucose pattern recorded with Accu-Chek®360° View Blood Glucose Analysis System sheet and continuous glucose monitoring.