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Original Article

The effect of simplified paired self-monitoring of blood glucose in patients with type 2 diabetes mellitus with persistent poor glycemic control

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Abstract: Aims: To investigate the effectiveness of paired self-monitoring of blood glucose (SMBG) in patients with persistent elevated hemoglobin A1C (A1C) under complex regimens. Methods: Patients with type 2 diabetes mellitus who had poor glycemic control with complex anti-hyperglycemic regimens were recruited for this study. During 3 months of intervention, at least 3 sets of paired SMBG (breakfast, lunch and dinner) in a week were proposed and scheduled consultations with a care team were arranged. After the program ended, a 9-month extension study was conducted to explore the A1C change. Results: The A1C level of the 33 patients enrolled was significantly improved as compared with that of the 30 controls 3 months after intervention (9.6 to 8.1%; $P < 0.001$). The improvement of glycemic control was maintained for 12 months. The A1C improvement was associated with a reduction of preprandial blood glucose (8.5 to 7.3 mmol/l; $P < 0.05$), post-prandial blood glucose excursion (2.9 to 2.0 mmol/l; $P < 0.05$), and SMBG frequency ($r = -0.38$; $P = 0.029$). Conclusions: A simplified paired SMBG accompanied by diet and physical activity recording may be helpful in patients with type 2 diabetes mellitus with persistent poor glycemic control.

Keywords: Paired SMBG, type 2 diabetes mellitus

Introduction

Self-monitoring of blood glucose (SMBG) has been long recognized as a key component of treatment regimens and an essential requirement in diabetes management. However, encouraging SMBG in patients with type 2 diabetes mellitus for better glycemic control has been questioned [1]. Recently, Farmer et al. [2] conducted a meta-analysis study, which was powered by acquiring individual patient data from randomized controlled studies, and found a subtle hemoglobin A1c (A1C) reduction (~0.25%) in patients with type 2 diabetes mellitus taking oral anti-diabetic drugs (OADs) after performing SMBG for 3 and 6 months. Similarly, Malanda et al. reported a 0.3% A1C reduction at 6 months after initializing SMBG in patients with type 2 diabetes mellitus taking OADs only [3]. The study further indicated that the benefits of A1C reduction diminished at 12 months, and no evidence that SMBG improves patients' satisfaction, well-being or quality of life was found [3]. Furthermore, the evidence of SMBG in patients with type 2 diabetes mellitus with insulin may also remain uncertain [1, 4, 5]. On the basis of the above results, the clinical value may be limited of advising SMBG as part of daily management for patients with type 2 diabetes mellitus, particularly in patients taking OADs only.

Despite the fact that these *"evidence-based"* reports may attenuate the value of SMBG for patients with type 2 diabetes mellitus [1-3], studies have discussed the limitations of these studies and suggested that SMBG data should be managed more comprehensively to achieve a glycemic benefit [6, 7]. In non-insulin-treated patients with type 2 diabetes mellitus, Polonsky et al. proposed that structured SMBG, a record of a 7-point SMBG profile associated with meal size and energy level on 3 consecutive days, could provide more clear information regarding

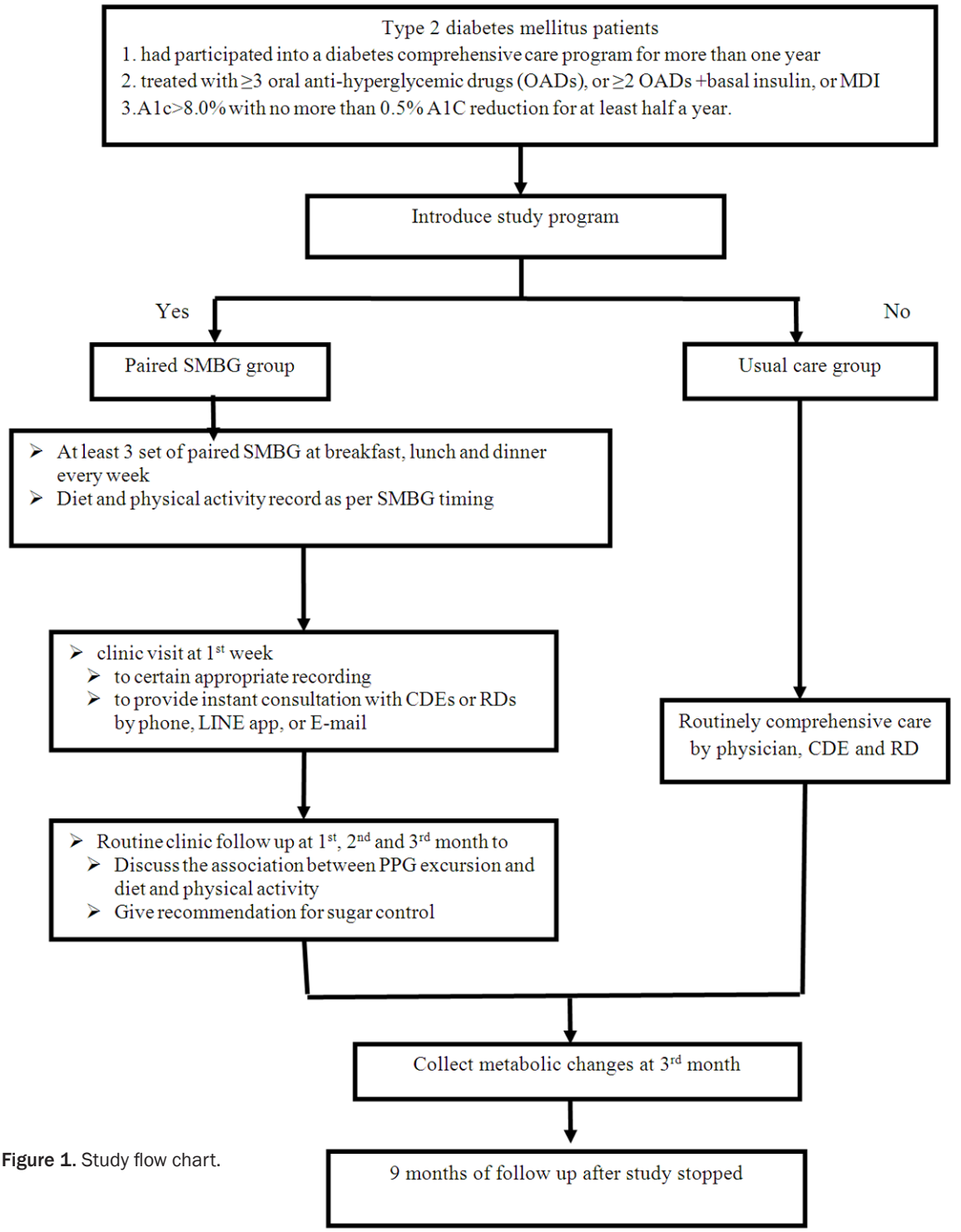

Figure 1. Study flow chart.

a patient's lifestyle to health practitioners and enable improvement of their glycemic control [8]. The study further demonstrated that this structured SMBG recording was helpful to patients with type 2 diabetes mellitus even though the SMBG frequency was lower as compared with the usual care group [8].

The significance of paired SMBG, a method of blood glucose testing before/after a specific event, in patients with type 2 diabetes mellitus who responded poorly to diabetes management and had persistent A1C elevation may need further clarification in the real world. Despite the value of SMBG in patients with type

2 diabetes mellitus being reinforced by some studies, some of the participants were being treated with diet and exercise alone or with one OAD only [8, 9]; thus, the significance of paired SMBG in glycemic control may be easily emphasized by prescribing other anti-hyperglycemic drugs. In addition, a frequency of SMBG of more than 6 times in one day may be too bothersome for most patients with type 2 diabetes mellitus [8, 9]. Furthermore, it has been suggested that a non-experimental study, instead of a randomized controlled study design, may also be of value in the assessment of the importance of SMBG and identify the groups in which SMBG would be of most benefit in diabetes [10, 11]. In light of these considerations, the present study aimed to evaluate the effect of a simplified paired SMBG, accompanied with diet and physical activity recording, together with a diabetes care program in patients with type 2 diabetes mellitus with persistent poor glycemic control in clinical practice.

Materials and methods

Subjects

To examine the value of SMBG, we focused on patients with type 2 diabetes mellitus with persistent poor glycemic control in a specialized diabetes care clinic [12-14]. Patients with type 2 diabetes mellitus with persistent poor glycemic control under complex regimens were defined as follows: 1. They had participated in a diabetes comprehensive care program for more than 1 year; 2. They were being treated with ≥ 3 OADs, or ≥ 2 OADs plus basal insulin, or with multiple daily insulin injections (MDI); and 3. They had persistent A1C > 8.0% with no more than a 0.5% A1C reduction for at least half a year. To be included in our study, patients' medical records were reviewed to have not performed SMBG or have monitored randomly. The patients were also able to read and write independently. The exclusion criteria were: (1) patients with T1DM; (2) hospitalization within the last 6 months prior to enrollment; (3) medical treatment that may cause fluctuation of glycemic control (e.g., steroid treatment, carcinogenic disease undergoing therapy); (4) pregnant patients or those who were breastfeeding; (5) patients with a psychological disorder or diabetic-related distress as assessed by the Chinese short-form problem areas in diabetes scale [15].

Study design

To disclose the efficacy of SMBG in the clinical practice, this study was designed as a *quasi-experimental* study. Patients who fulfilled the inclusion criteria were suggested to follow the study protocol by two primary investigators (Chia-Jung Chang and Szu-Hua Chen). The study flow chart is presented in **Figure 1**, the details being as follows: (1) Patients were asked to perform at least 3 sets of paired SMBG (i.e., one at breakfast, one at lunch and one at dinner, recorded before and 2 hours after each meal) in a week [16]; (2) Patients were taught to record their diet (e.g., by paper or photographs) and physical activity as per SMBG; (3) A clinic visit with the primary investigators was scheduled for the 1st week to review the integrity of the SMBG, diet and physical activity recording; (4) Other than the primary investigators, clinic visits at the 1st, 2nd and 3rd month with a certified diabetes educator (CDE), a registered dietician (RD) and a primary care physician were arranged to review the recordings and give recommendations regarding the associations between blood glucose and dietary intake/physical activity; (5) In addition to scheduled clinic visits, instant consultations were also provided via telephone, e-mail or smart phoneLINE app. Patients who were willing to participate in the program were provided with a OneTouch Ultraeasy (Johnson & Johnson) or an Accu-Chek Performa (Roche Diagnostics) glucose meter and 20 strips, which were sponsored by the Taiwan Association of Diabetes Educators. The data and frequency of SMBG were obtained from the paper recording and the data uploaded via OneTouch® Diabetes Management Software (Johnson & Johnson) or the Accu-Chek Smart Pix device (Roche Diagnostics). Patients who were not willing to enroll in the program were managed as usual (i.e., routine 3-month exams and clinic visits with a physician, CDE and RD). The primary outcome was a change in A1C from enrollment to 3 months. To reveal the effects of our study protocol, a 9-month extension observation study was conducted to explore the change in A1C after the program had stopped. This study was approved by the Institutional Review Board of Kaohsiung Medical University Hospital. Written inform consents were obtained from the participants.

Table 1. Baseline characteristics of the participants with type 2 diabetes mellitus

	Paired SMBG (*n* = 33)	Usual care (*n* = 30)	*P*
Age (yr)	52.8 ± 11.6	66.7 ± 10.3	< 0.0001
Gender (F/M)	12/21	11/19	0.98
Disease duration (yr)	11.2 ± 7.9	13.8 ± 8.6	0.213
BMI (kg/m^2)	26.8 ± 4.7	26.39 ± 3.6	0.632
Educationallevel			
< 9 years	11	24	< 0.0001
≥ 9 years	22	6	
Smoking (yes)	7	2	0.152
Alcohol (yes)	4	3	1.000
Exercise (yes)	18	15	0.803
A1C (%)	9.6 ± 1.1	9.0 ± 1.1	0.078
sBP (mmHg)	134.2 ± 19.7	134.2 ± 20.0	0.962
dBP (mmHg)	77.3 ± 10.6	73.5 ± 12.8	0.209
Cholesterol (mmol/L)	5.0 ± 1.3	5.0 ± 1.0	0.965
LDL-C (mmol/L)	2.8 ± 1.2	2.9 ± 0.9	0.845
Triglycerides (mmol/L)	1.4 ± 0.7	1.4 ± 0.5	0.953
Regimens (%)			
With insulin	54.5	60.0	0.800
≥ 3 OADs	45.5	40.0	

BMI: body mass index; A1C: hemoglobin A1c; sBP: systolic blood pressure; dBP: diastolic blood pressure; LDL-C: low density lipoprotein cholesterol; OAD: oral anti-diabetic drug.

Measurements

Basic physical information, including body height, body weight and blood pressure, was obtained before enrollment in the study. Blood samples were collected after at least 8-hour of overnight fasting. A biochemical automatic analyzer (Beckman-Coulter Inc. Fullerton, CA) was used to analyze blood samples and measure plasma glucose, total cholesterol, HDL-C, LDL-C and triglycerides. A1C was measured at baseline and then quarterlyin whole blood using ion exchange high-performance liquid chromatography (BIO-RAD®, VARIANTTM II Turbo, Hercules, CA). Our laboratory analyses were under internal and external quality control at the laboratory of the College of American Pathologists surveys.

Statistical analysis

Data analysis was carried out using SPSS (version 17.0). In the comparisons of baseline characteristics between groups, Mann-Whitney tests were used to compare continuous values and Chi-square tests were used to compare categorical parameters. To investigate the change of A1C during study period, Wilcoxon tests were used to investigate the before-after differences in each group. As regard to the comparisons of A1C change between groups, repeated measures ANOVA with adjustments of baseline significant factors (i.e. age and educational level) were performed. The Pearson correlation test was used to examine the relationship between frequency of SMBG and A1C change. The statistical power was calculated by G*power 3.1.9.2 software [17].

Results

A total of 63 patients fulfilled the inclusion criteria; however, 30 patients refused to participate in the program, and they were defined as the usual care group. The most common reason for refusal was that the study protocol was too bothersome and interfered with their daily activity. 33 patients, forming the intervention group, were enrolled into the program.

The basic characteristics of the subjects are presented in **Table 1**. There were no differences in the gender distribution, diabetes disease duration, body mass index and daily habits (i.e., the prevalence of smoking, alcohol drinking and exercise) between the study groups. However, as compared with the usual care group, the participants in the intervention group were younger and had a higher education level. The baseline blood pressure, total cholesterol, triglycerides, low-density-lipoprotein cholesterol and A1C levels did not differ between the study groups.

The change in glycemic control is presented in **Figure 2**. Patients who did not participate in the program did not show an improvement in A1C (from 9.0 ± 1.1% to 8.9 ± 1.2; *P* = 0.838) at 3 months and remained indolence to the end of the study (from 9.0 ± 1.1% to 8.6 ± 1.2%; *P* = 0.276). On the contrary, the intervention group demonstrated a significant A1C reduction from 9.6 ± 1.1% to 8.1 ± 1.2%; *P* < 0.001) at 3 months, and the improvement persisted for 12 months, from 9.6 ± 1.1% to 8.3 ± 1.4%; *P* =

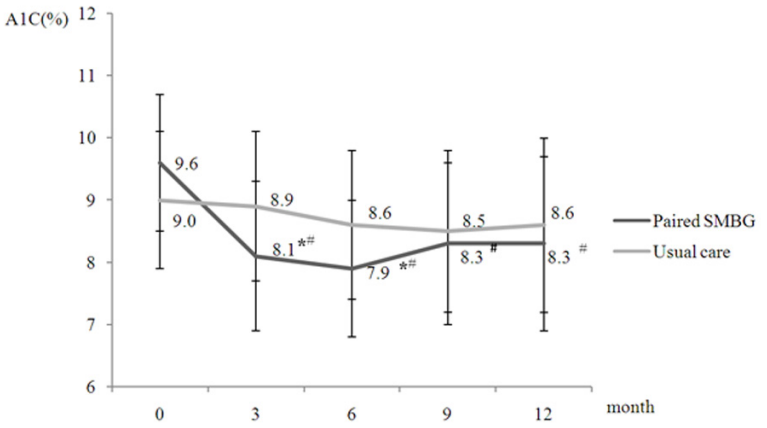

Figure 2. Changes in A1C in the paired SMBG group and the usual care group. *Significant as compared with the usual care group; #Significant as compared with baseline.

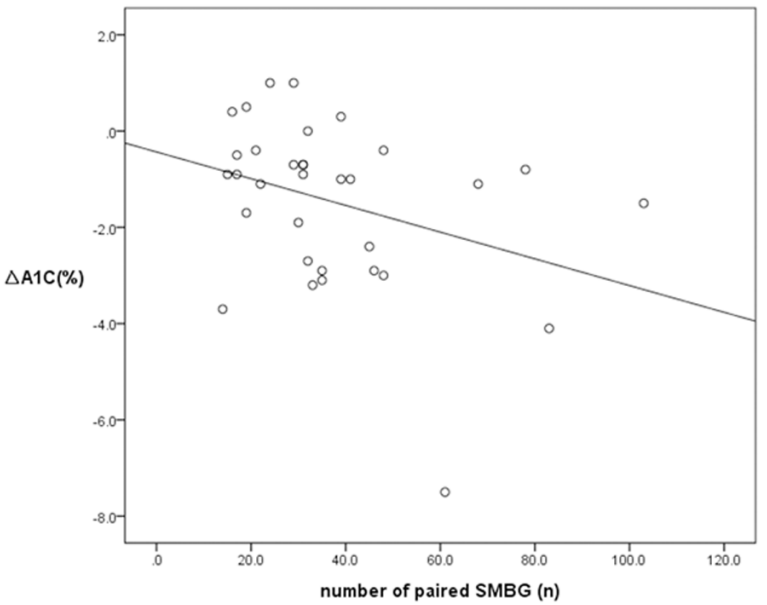

Figure 3. Correlation between number of paired SMBG and A1C reduction.

0.008). The improvement in A1C in the intervention group was resulted from a reduction in pre-prandial glucose (from 8.5 ± 2.4 to 7.3 ± 2.0 mmol/L; $P < 0.05$) and post-prandial glucose excursion (from 2.9 ± 2.4 to 2.0 ± 1.9 mmol/L; $P < 0.05$). In addition, the number of paired SMBG was significantly related to A1C reduction (**Figure 3**; r = -0.38; $P = 0.029$). As compared with the usual care group, the advantage of A1C control not only showed at the end of program ($P = 0.008$) but also remained for an additional 3 months after the program had stopped ($P = 0.018$); however, the difference in A1C diminished at subsequent follow-up (**Figure 2**).

Discussion

The major finding of the current study was that simplified paired SMBG associated with diet and physical recording could be useful in patients with type 2 diabetes mellitus with persistent poor glycemic control. In front of recently published meta-analysis studies [2-4], our results may be viewed as weak evidence; however, it should be noted that these *"evidence-based"* reports should be read carefully. These meta-analysis reports were underscored by including only randomized controlled trials, which are often viewed as a rigorous design to validate the efficacy of an intervention; however, it also could become a limitation in the issue of discussing SMBG value [10, 11]. Unlike a pharmacological study, which frequently is run as an unchanging intervention with an identical method across patients and settings, the frequency and timing of SMBG not only varies largely depending on the clinical scenario of a patient with diabetes mellitus but also differs from patient to patient in real world. In particular, in lacking consideration of the regimen/lifestyle changes arising from SMBG recording when reviewing potential studies in these reports, these SMBG meta-analysis studies may be prejudiced by simply an adopting a "yes vs. no" rationale. In addition, some flaws of the RCTs included in the meta-analysis reports may also attenuate the value of SMBG benefits (i.e., baseline A1C too low (~7.5%) to be benefited [18, 19]; only patients were randomized, not physicians [20]; an identical treatment algorithm in both arms of the study irrespective of the SMBG value [19, 21]). On the basis of the above-mentioned con-

founders, it is not surprising that the value of SMBG was concluded to be limited in these meta-analysis reports.

To increase the value of SMBG, it should be emphasized that these data should be tested in a meaningful fashion and fed back to patients properly; if not, the importance of these numerical data is minimal. In the study conducted by Kleefstra and colleague [19], the report clearly showed that there was only slight glycemic improvement if patients were not assisted by a health care provider with knowledge of how to reach good glucose control according to the SMBG recording. On the contrary, when the paired SMBG data and accompanying dietary and physical activity information were examined together by the patient and a diabetes management team, the patients with type 2 diabetes mellitus benefited in terms of an approximate 0.9%~1.6% improvement in A1C [8, 9]. Furthermore, self-confidence and autonomous motivation could also be provoked in diabetes self-management by performing meaningful SMBG [22]. In line with these reports [8, 9], our study supported that the keys to glycemic improvement were whether the SMBG data were recorded properly, discussed discreetly and responded to in a timely manner.

In the present study, there was no significance in medication changes between the paired-SMBG group as compared with the usual casual group (36.4% vs. 30.0%; P = 0.593). However, as compared with the usual care group, we found a significant improvement in post-prandial glucose excursions, which may accompany improvement in recognizing dietary carbohydrate after intervention (data not shown). Consequently, SMBG performed by paired-testing, rather than randomly, could play a key role in glycemic improvement. Furthermore, the improvement in A1C during the observation period in the intervention group implied that diabetes self-management could be established to a certain degree during a 3-month period of intervention. Generally, many patients often measure their glucose while fasting or during the pre-prandial period; however, lacking measurement of post-prandial glucose does not provide information regarding how the size or composition of a meal affects the glycemic response [6, 23]. This may be one of the reasons for which some studies did not observe an A1C improvement [19, 21]. By paired SMBG accompanied by a dietary record, it is possible to provide a concrete and observational approach for patients, who can discuss the substantial glucose excursions with healthcare providers and be motivated to make dietary adjustments, particularly in terms of carbohydrates. In association with previous reports [8, 9, 24], our results indicated that a clear record including paired SMBG and the associated diet should be promoted.

Despite our study proposing a simplified SMBG method, which asked participants to record pre-/post-prandial blood glucose at breakfast, lunch and dinner (at least 6 data out of 3 paired SMBG), as well as diet and physical activity during one week, nearly half (47.6%) of the candidates refused to participate. The low participation rate was consistent with previous study [25] and reflected the difficulties in promoting post-prandial blood glucose measurement in clinical practice, particularly in patients who are elderly and less educated. Our results also suggested that younger and more educated patients more readily realize why they should test, understand what the results mean, and make efforts towards diabetes self-management. Moreover, the consistent result of a positive association between paired SMBG frequency and A1C reduction [26] also suggested that better glycemic control could be achieved if more useful information is provided. Despite the improvement in A1C persisting to the end of study in the intervention group, our results showed that the advantage in A1C control between the study groups only persisted for 3 months after the study protocol ended, and then diminished. This may be a result of most patients not turning this structured SMBG recording into routine diabetes self-management in order to achieve better glycemic control. Nevertheless, our results also demonstrated that a strategy to endorse patients with type 2 diabetes mellitus performing a structured SMBG would be useful, particularly in elderly and less educated patients.

There are several limitations of our study. First, there may be concerns of our non-randomized study design which could unable to validate our proposed methods in these poor controlled diabetic patients; however, it should be noted that

our study may be more truthfully to realize the effect of paired SMBG in clinical practice [10, 11]. Furthermore, our result may shed light on the benefits of paired SMBG in these poor controlled patients with type 2 diabetes mellitus. Second, owing to the incomplete recordings (e.g. meal size, duration of physical activity) as per paired SMBG, we were unable to clarify which behaviors improved glycemic control; however, the lack report of diet/physical recordings were also shown in other SMBG studies [8, 9]. This may reflect the difficulties of having appropriate diet/physical recording for diabetic patients, particularly of appropriate diet recording. Despite this, we believe that our study clearly proved that paired SMBG assisted in diabetes management and improved glycemic control. Third, the influence of the Hawthorne Effect could not be ruled out during intervention, which may have biased our results; however, our extended study did not find a significant glycemic relapse, which may somewhat relieve this concern. Fourth, the small number of SMBG participants may limit the value of our study. At first, the sample size (n = 48) was estimated assuming a mean difference of 0.5% in A1C after the study, with a SD of 1.2% (two-sided, $\alpha = 0.05$, $\beta = 80\%$). Unfortunately, only 33/63 patients were enrolled in the study, which echoed the reality of under-utilization of post-prandial glucose monitoring in patients with type 2 diabetes mellitus [25]. In addition, our study focused on persistently poorly-controlled diabetic participants, which further limited the number of study participants. However, post-hoc analysis demonstrated a greater than 90% statistical power, which may alleviate some of the concerns regarding our study. Additionally, in contrast to a lack of A1C change in the usual care group, the successful A1C reduction in the paired SMBG group may strengthen the value of our study protocol. On the basis of the above, we believe that the present study could provide some additional information useful for current medicine.

In conclusion, by a simplified paired SMBG accompanied with diet and physical activity recording, patients with type 2 diabetes mellitus with persistent poor glycemic control could benefit in collaboration with a diabetes care team. A more informative plan to promote and maintain pair-testing SMBG in patients with type 2 diabetes mellitus is necessary, particularly in those who are older and less educated.

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Disclosure of conflict of interest

None.

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