

Compliance to self-monitoring of blood glucose among patients with type 2 diabetes mellitus and its influential factors: a real-world cross-sectional study based on the Tencent TDF-I blood glucose monitoring platform

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Background: To investigate the compliance to self-monitoring of blood glucose (SMBG) among patients with type 2 diabetes mellitus (T2DM) and its influential factors.

Methods: The real-world SMBG use over 90 days among 415 T2DM patients were recorded by using a blood glucose monitoring platform (TDF-I, Tencent, China). Clinical features including age, sex, duration of diabetes, insulin treatment or not, and use of oral antidiabetic drugs were collected. Poor compliance was defined as the average frequency of weekly SMBG use over 90 days was below the criteria established by the physicians, and otherwise the patients were regarded as with good compliance. Factors affecting the SMBG compliance were analyzed by using independent sample *t*-test, Mann-Whitney U test, and multivariate logistic regression analysis.

Results: Only 57.6% of patients in the study cohort had good compliance to SMBG. Multivariate logistic regression models showed that only the duration of T2DM and the use of oral antidiabetic agents were independently associated with SMBG compliance; more specifically, patients with longer course of disease had poorer SMBG compliance, and those had used oral antidiabetic agents had poorer SMBG compliance.

Conclusions: SMBG compliance in T2DM patients needs to be further improved. For patients with a longer course of disease and/or under oral antidiabetic medication, interventions such as patient education should be adopted to increase the SMBG compliance.

Keywords: Type 2 diabetes mellitus (T2DM); self-monitoring of blood glucose (SMBG); compliance; cross-sectional study; real world study

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Introduction

In recent years, the prevalence of type 2 diabetes mellitus (T2DM) has been rising with the change of lifestyle, living environment, and accelerated aging process (1,2). According

to the International Diabetes Federation (IDF), the global diabetes prevalence estimate was 8.8% in 2015, and the number of people with diabetes reached 415 million people. In the high-income countries, T2DM accounts for about

87–91% of all diagnosed cases of diabetes. Diabetes kills over 5 million people every year, and most of them died of diabetic complications (3). Some studies including the UK Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT) have confirmed that good blood sugar control could effectively reduce the risk of diabetic complications (4,5). Thus, blood glucose monitoring has become essential for evaluating diabetic patients, developing a reasonable hypoglycemic regimen, reflecting the effectiveness of hypoglycemic treatment, and guiding treatment adjustment. Self-monitoring of blood glucose (SMBG) has been recommended for all diabetic patients in guidelines released by IDF, American Diabetes Association (ADA), and many other organizations (6,7).

Studies have revealed that SMBG can significantly improve metabolic control in T2DM patients and may reduce diabetes-related endpoint events (6,8). However, the SMBG implementation is far from satisfactory worldwide. For instance, the International Diabetes Management Practices Study (IDMPS) found that the rate of SMBG use was only 29.7%, 35.7%, and 38.5% among T2DM patients in Asia, Eastern Europe, and Latin America (9). Patients' SMBG compliance is an important factor in determining the performance of SMBG. Thus, it is particularly important to identify the patients' SMBG compliance and its influential factors. Although a number of previous studies have surveyed the patients' SMBG compliance and analyzed the potential factors that might affect SMBG compliance, these studies were mainly based on questionnaires and the results were often affected by a variety of human factors such as memory and emotion and thus could not reflect the real-world SMBG compliance (10-12).

In our current study, the real-world SMBG use among T2DM patients was automatically recorded in a real-time manner by using a blood glucose monitoring platform (TDF-I, Tencent, China), and SMBG compliance and its influential factors were analyzed accordingly (Figure 1).

Methods

Subjects

In this prospective study, 120 endocrinologists or general physicians who were involved in diabetes management were recruited via DXY.cn (website: www.dxy.cn/bbs/topic/31756300) from May to December 2015, and via these doctors 500 adults (≥ 18 years of age) patients with T2DM were randomly selected. After the enrollment



Figure 1 TDF-1 Smart Glucose Meter. Medical-level precision of BG measurement, beyond the criteria of ISO or GB/T, High calculating speed, much faster than traditional BG meter, Online professional guidance by diabetes HCP, Cloud service for BG data uploading and reserving, and Real-time Wechat notification to tell you the measurement of your family member.

of these patients, a uniform questionnaire was used to record the patients' clinical features including gender, age, body mass index (BMI), income, educational background, hypertension, and histories of cardiovascular and cerebrovascular diseases.

The inclusion criteria of T2DM patients were based on the diagnostic criteria of T2DM in the *Chinese Guidelines on the Management of Type 2 Diabetes Mellitus* (2013 edition), i.e., fasting plasma glucose (FPG) ≥ 7.0 mmol/L or 2 h postprandial plasma glucose (2hPPG) ≥ 11.0 mmol/L. The exclusion criteria for this study were: (I) younger than 18 years of age; (II) unconscious or unable to learn how to use the blood glucose meter; (III) accompanied by other major diseases such as malignancies, end-stage liver disease, or kidney disease; and (IV) with an expected survival of less than 90 days. This study strictly followed the *Declaration of Helsinki* on medical protocol and ethics, and all patients signed the informed consents.

Blood glucose monitoring method and definition of SMBG compliance

The blood glucose monitoring conditions within 90 days after patient enrollment were recorded. The blood glucose meters used by all patients was TDF-I intelligent blood glucose meter (Tencent, China), and the test strips were

based on glucose oxidase technique, with double electrodes to ensure measurement accuracy. The device has passed the ISO2013 quality system certification. Unlike the conventional portable glucose meters, the TDF-I intelligent blood glucose meter has built-in MTK6571 dual core CPU and 512Mb+4G memory, with own GSM SIM card for network connection, which allows the synchronization of blood glucose monitoring data to patient management platform.

Patients' SMBG frequency was determined by the physicians based on the guidelines for blood glucose monitoring [e.g., *Chinese Guidelines on Clinical Application of Blood Glucose Monitoring* (2015 edition)] (13) and on individual patient's blood glucose level, blood glucose variability, history of medical visits, history of medication, and course of disease. Poor compliance was defined as the average weekly SMBG frequency over 90 days was below the criteria established by the physicians, and otherwise the patients were regarded as with good compliance.

Statistical analysis

Kolmogorov-Smirnov method was used to assess whether the continuous variables were normally distributed. The differences in the continuous variables between two groups were analyzed using independent *t*-test or Mann-Whitney U test. Categorical data were compared using chi-square test; for categorical variables with a hierarchical structure, rank transformation was performed firstly before Mann-Whitney U test. Multivariate logistic regression analysis was performed to analyze the effect of each potential variable on patients' SMBG compliance. All the statistical processing was completed in SPSS 22.0 software and GraphPad Prism 6.0 software. A P value of <0.05 was considered statistically significant.

Results

Clinical features and SMBG compliance of the patients

Totally 415 T2DM patients entered the final analysis. The clinical features of these subjects are summarized in *Table 1*. It was found that 236 T2DM patients (57.6%) had good T2DM compliance.

Factors affecting SMBG compliance of patients

To identify the factors affecting SMBG compliance of

Table 1 Clinical features and SMBG compliance of the patients

Features	Results (n=415)
Age (years)	55 [47–61]
Gender (male/female)	238/177
Course of disease (years)	5 [3–11]
Body mass index (kg/m ²)	25.2 (23.0–27.3)
Education background (higher education/ non-higher education/unknown)	172/238/5
Employment (management/general staff/ retired or unemployed/unknown)	64/150/199/2
Annual income (above 100,000/50,000– 100,000/below 50,000/unknown)	109/113/185/8
Physical activity (active/inactive/unknown)	251/163/1
Smoking (yes/no/unknown)	89/322/4
Alcohol use (yes/no/unknown)	188/222/5
Hypertension (yes/no)	78/337
History of cardio-cerebrovascular disease (yes/no)	25/390
Insulin treatment (yes/no/unknown)	174/239/2
Use of oral hypoglycemic agents (yes/no/unknown)	221/192/2
SMBG compliance (good/poor)	239/176

SMBG, self-monitoring of blood glucose.

patients, we compared the clinical features of patients with good SMBG compliance and those with poor SMBG compliance. As shown in *Table 2*, age, sex, BMI, history of hypertension, history of cardiovascular disease, education background, income status, employment, and insulin treatment were not associated with SMBG compliance ($P>0.05$). Only the duration of diabetes mellitus and use of oral hypoglycemic agents were correlated with patients' SMBG compliance ($P<0.01$).

Multivariate logistic regression analysis was further applied to assess the effects of the duration of diabetes mellitus and use of oral hypoglycemic agents on SMBG compliance among the enrolled T2DM patients. It was found that both two factors were independently correlated with the patients' SMBG compliance (*Table 3*). Longer duration of diabetes was associated with poorer SMBG compliance among the T2DM patients (for each 1-year extension, OR =0.96; 95% CI: 0.92–1.00); besides, patients who had used oral hypoglycemic agents had poorer SMBG

Table 2 Factors affecting SMBG compliance of patients

Factors	Good SMBG compliance	Poor SMBG compliance	P value
Sample size	239	176	–
Age (years)	55 [46–61]	56 [48–61]	0.26
Gender (male/female)	144/95	94/82	0.16
Course of disease (years)	4 [2–11]	6 [3–12]	<0.01
Body mass index (kg/m ²)	25.3 (22.9–27.0)	25.2 (23.4–27.4)	0.37
Education background (higher education/non-higher education/unknown)	106/130/3	66/108/2	0.136
Employment (management/general staff/retired or unemployed/unknown)	42/84/113/0	22/66/86/2	0.20
Annual income (above 100,000/50,000–100,000/below 50,000/unknown)	62/64/108/5	47/49/77/3	0.98
Physical activity (active/inactive/unknown)	143/96/0	108/68/0	0.75
Smoking (yes/no/unknown)	55/182/2	33/140/2	0.64
Alcohol use (yes/no/unknown)	109/128/2	79/94/3	0.72
Hypertension (yes/no)	41/198	37/139	0.32
History of cardio-cerebrovascular disease (yes/no)	14/225	11/165	0.87
Insulin treatment (yes/no/unknown)	96/142/1	78/97/1	0.67
Use of oral hypoglycemic agents (yes/no/unknown)	70/168/0	151/24/1	<0.01

SMBG, self-monitoring of blood glucose.

Table 3 Multivariate logistic regression analysis of factors affecting the patients' SMBG compliance

Factors	OR (95% CI)	P value
Use of hypoglycemic agents		
No	1 (reference)	–
Yes	16.16 (9.54–27.36)	<0.01
Course of disease (per 1-year extension)	1.05 (1.05–1.09)	0.02

SMBG, self-monitoring of blood glucose

compliance too (OR =16.16; 95% CI: 9.54–27.36).

Discussion

In our current study, the real-world SMBG use among T2DM patients was recorded by using a blood glucose monitoring platform (TDF-I, Tencent, China), it was found that only 57.6% of patients had good SMBG compliance. Multivariate logistic regression models showed that only the duration of T2DM and the use of oral antidiabetic agents were independently associated with SMBG compliance; more specifically, patients with longer course of disease

had poorer SMBG compliance, and those had used oral antidiabetic agents had poorer SMBG compliance.

Data from 67 major centers in the United States indicated that, regardless of patient age or treatment, a higher frequency of SMBG use was associated with lower glycated hemoglobin (HbA1c) value (14). Thus, it is particularly important to identify the factors that affect patients' SMBG compliance. However, most previous studies (10–12,15–18) on SMBG compliance were questionnaire-based, which could not perfectly reflect the real-world situations. In our current study, the monitoring platform could record and store the patients' SMBG use in

a real-time manner and thus restore the real-world SMBG situations; furthermore, it can avoid impacts of subjective interference factors such as memory, personal emotion, and concealment, which are common in questionnaire-based surveys. We found that 57.6% of T2DM patients had good SMBG compliance. While the definition of SMBG compliance may differ among studies, the poor SMBG compliance among T2DM patients in our study was consistent with the findings of many other studies (16,18,19). Thus, there is still a long way to go to further improve the patients' compliance to SMBG.

We also found that SMBG compliance was associated with duration of diabetes and use of oral antidiabetic drugs: patients with longer course of diabetes had poorer SMBG compliance, besides, patients who had used oral antidiabetic drugs had poorer SMBG compliance too. The poor compliance in patients with long course of disease may be explained by the fact that patients tend to have negative attitude towards the disease along with the prolongation of the course of disease. Abubakari *et al.* concluded that patients' negative perceptions of disease and confidence in disease control were important predictors of diabetes self-management (15). The poor compliance among patients under oral antidiabetic medication may be related to unrealistic SMBG recommendations proposed by clinicians under different treatment protocols. According to Metcalfe *et al.*, there appeared to be relatively large under-dispensing of SMBG in patients requiring insulin and a high over-dispensing in those using oral drug alone (20).

In addition, in our current study we also found that T2DM patients' SMBG compliance was not correlated with age, gender, BMI, high education level, income, employment, physical activity, smoking, alcohol use, history of hypertension, history of cardio-cerebrovascular disease, and insulin treatment. However, some questionnaire-based studies had conflicting findings. Li *et al.* found that higher income was independently correlated with better SMBG compliance (18). Charity *et al.* found that payment for glucose meter was associated with the poor compliance to SMBG program (19), while O'Neil *et al.* concluded economic hardship was not an associated factor of SMBG in diabetic patients (17). It is speculated that these controversies might be caused by both the research design (questionnaire-based or real-world recording) and the definition of SMBG compliance.

However, our study had some limitations. Considering the operational feasibility, we only collected the information on SMBG use over 90 days after enrollment but did not

collect blood glucose-related data such as postprandial blood glucose, glycosylated hemoglobin, and hypoglycemia. In our future studies we will further collect these information and optimize data analysis. Furthermore, by using the blood glucose monitoring platform (TDF-I, Tencent, China), we will further realize mobile health care to remind patients of SMBG use and medication in real time, so as to evaluate the effectiveness of mobile platforms in increasing SMBG compliance and integrated diabetes management.

In summary, we for the first time used an intelligent blood glucose meter to record the SMBG use in T2DM patients and reflected the real-world SMBG implementation in a real-time manner; furthermore, we accurately analyzed the influential factors of SMBG compliance. It was found that only 57.6% of T2DM patients had good SMBG compliance; more specifically, patients with longer duration of diabetes had poorer SMBG compliance, besides, patients who had used oral antidiabetic drugs had poorer SMBG compliance too. Thus, for patients with a longer course of disease and/or under oral antidiabetic medication, interventions such as patient education should be adopted to increase the SMBG compliance.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This study strictly followed the *Declaration of Helsinki* on medical protocol and ethics, and all patients signed the informed consents.

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