

Effectiveness for self-monitoring of blood sugar on blood glucose control in Turkish patients with type 2 diabetes mellitus

Davut Baltacı¹, Ali Kutlucan², Serkan Ozturk³, Ayhan Saritas⁴, Ahmet Celer¹, Gokhan Celbek², Harun Deler¹, Yusuf Aydin², Handan Ankarali⁵

¹Department of Family Medicine, ²Department of Internal Medicine; School of Medicine, Duzce University, ³Department of Cardiology, School of Medicine, Izzet Baysal University, Bolu, ⁴Department of Emergency Medicine, ⁵Department of Biostatistics; School of Medicine, Duzce University, Duzce; Turkey

ABSTRACT

Aim Diabetes mellitus (DM) is a chronic disease requiring continuous monitoring and treatment. Self-monitoring of blood glucose (SMBG) is frequently recommended. The purpose of the study was to evaluate effectiveness of SMBG on metabolic control in Turkish patients with type 2 DM.

Methods The cross-sectional study enrolled type 2 diabetic patients without insulin regimen. The participants were assigned to three groups according to status of SMBG: group 1- regular, group 2 - irregular and group 3 - never SMBG implementation.

Results A total of 349 patients were enrolled. There was no significant difference in mean fasting and post-prandial blood glucose, lipid profile values between the groups. The number of patients with high education level in group 1 was higher than groups 2 and 3 ($p = 0.001$). HbA1c level was higher in groups 2 and 3 than group 1, but not significantly ($p = 0.285$). Mean spot urinary albumin-creatinine ratio (ACR) in group 1 is significantly lower than in groups 2 and 3 ($p = 0.008$ and $p = 0.044$, respectively), but no significant difference was observed between group 2 and 3 ($p = 0.473$).

Conclusion The study indicated that regular use of SMBG was not superior to irregular/never use of SMBG on glycemic control, but it seemed to be good intervention for prevention of diabetic nephropathy. We suggestively offered that SMBG should be recommended for patients with a high education level to meet the goal of its use, and it should be incorporated into self-management with effective educational intervention.

Key words: HbA1c, Diabetes Mellitus, Albumin-creatinine ratio, Glycemic control

Corresponding author:

Davut Baltacı
Department of Family Medicine,
Faculty of Medicine, Duzce University,
Duzce, Turkey
Phone: +90 380 5421390-5820
Fax: +90380-5421390-1387
E-mail: davutbaltaci@hotmail.com

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INTRODUCTION

Diabetes mellitus (DM) is a relatively common disease with major public health implications and remains a major problem with increasing rate in the world (1). The prevalence, incidence, mortality, morbidity, cost to society, and the effectiveness of treatment and prevention are discussed. Primary preventable measures involving weight management, exercise, and glycemic control can reduce microvascular complications in diabetic patients (2,3). Diabetes mellitus is a chronic disease requiring complex treatment modality and close follow-up along with close cooperation between the physician and the patients (1). It causes a lot of complications such as renal, cardiac and neurological. In management of diabetes mellitus, preventing the development of a complication is the main goal (4). The most acceptable and reliable method for diabetes mellitus is strict blood sugar control (5). There is strong evidence that intensive glycemic control effectively reduces diabetic complications. To achieve it, many methods and diabetes care were developed (6). Self-monitoring of blood sugar (SMBG) is one of the widely recommended methods, because SMBG is considered as one of the cornerstones in management of diabetes mellitus (7). This method is definitely recommended for insulin patients and patients on alternative treatment (8). 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 HbA1c values (9). There is an ongoing discussion whether such self-monitoring is justified in type 2 DM (T2DM), in patients treated with oral medications and diet (10). In recent studies, it was suggested that SMBG was not cost-effective and most patients had not preferred using glucometers due to its difficulties in usefulness and complications (11).

Although SMBG with glucometers is widely used by diabetic patients, the efficacy of SMBG in T2DM is still questionable. Near-normal blood glucose control with self-monitoring is more difficult to achieve in some patients with diabetes mellitus (12). Achievement of near-normal blood glucose control by using glucometer is based on patient's education level, awareness and perception about their disease and their attitudes towards SMBG with glucometers. Moreover, educating patients on diabetes care is necessary (13, 14).

Socio-economical level can also impact SMBG (15). Patients should be aware of the purpose and guidelines of glucometer use to achieve goals of SMBG (16). In literature, there are several reports regarding SMBG and its effectiveness, but it is still controversial. To best knowledge, there are a few studies on effectiveness of SMBG on glycaemic control in Turkish diabetic patients (17,18).

In this study, we aimed to evaluate effectiveness of SMBG on metabolic control among Turkish diabetic patients.

PATIENTS AND METHODS

Study design and patient enrollment

Patients with type 2 DM admitted to the outpatient clinic for diabetes care were enrolled. The cross-sectional and descriptive study was conducted by endocrinology division of Internal Medicine Department and Department of Family Medicine, Duzce University, Turkey, between June and December 2011. The patients with duration of DM for more than 1 year and those treated with only oral anti-diabetic agents (OAD) were included. The patients with diabetes mellitus type 1 and those with DM type 2 under insulin treatment were excluded. The patients were assigned into three groups according to the status of SMBG. Group 1 included the patients who had regularly used SMBG for at least 6 months; group 2 included the patients had irregularly used SMBG for at least 6 months; group 3 included the patients who had never used SMBG.

Data collection

Socio-demographic data of patients including age, gender, education level (illiterate, literate, primary-secondary school, high school and university), duration of diabetes mellitus, comorbid disease, occupation, smoking situation (current, former and never) were recorded. Status of SMBG was obtained and evaluated with frequency of daily, weekly and monthly blood glucose measurement via glucometer. Frequency of SMBG was recorded as never, once a month, twice a month, once a week, twice a week, three or more times a week, once a day, twice a day and three or more times a day. Anthropometric measurements such as weight, height were measured as consistent with international guidelines (19).

Biochemical and urinary parameters including light density lipoprotein cholesterol (LDL-cho), high density lipoprotein cholesterol (HDL-cho), triglycerides (TG), total cholesterol (T-cho), creatinine, fasting blood glucose, post-prandial glucose, HbA1c were measured. Urinary albumin creatinine ratio was checked. Body mass index (BMI) was calculated with formulation of weight (kg)/height (m)².

All patients were informed about the study and informed consent was obtained. The Ethics Committee of Duzce University School of Medicine approved the study (Ethic No: 2010/75).

Data analysis

In the study, the patients were assigned to three groups according the American Diabetes Association (ADA) criteria for SMBG (20,21). Regular SMBG was defined as at least one measurement a day for blood glucose level at home. Irregular SMBG was defined as one measurement a month or at most two measurements a week at home for SMBG. Never SMBG was defined as never measurement or a measurement a year at home for blood glucose level.

PASW version 18.0 was used for statistical analysis. Countable or scale variables were stated as mean ± standard deviation. Categorical variables were characterized as count and percent frequencies. The relationships between scale variables and SMBG groups were evaluated by using one way ANOVA and between categorical variables and SMBG groups were evaluated by using Chi-Square test. Kolmogorov-Smirnov test was used for normality test about scale variables. After biochemical and urinary parameters which had no normal distribution were transformed on logarithmic scale, covariance analysis was used for relation between SMBG, socio-demographic characters, clinical variables and biochemical and urinary parameters. Mean ± SE standard was used for logarithmically transformed and adjusted variables. Mean ± SD was used for non-adjusted variables. P value of 0.05 was used for significance.

RESULTS

A total number of 349 T2DM patients without insulin treatment was consequently enrolled within 6-month period of the study. The patients were assigned to three groups. Group 1 included 111

diabetic patients who had regularly practiced SMBG at home with a glucometer, group 2 included 133 diabetic patients who had irregularly practiced SMBG, and group 3 included 105 diabetic patients who had never practiced SMBG.

Male to female ratio was 144/205 (41.3 % vs. 58.7 %). Mean age was 54.2 ± 9.7 years. Duration of diabetes mellitus was 6.5 ± 4.9 years (2-20 years). Mean fasting and post-prandial blood glucose levels were 158.8 ± 59.5 and 246.1 ± 144.3 mg/dL. Mean HbA1c level was 7.6 ± 1.7 %, and 39.3 % of the patients had HbA1c level over 7.5 % (n = 137). Mean spot urinary ACR was found to be 50.3 ± 181.9 mg/g and 24.1 % had albuminuria (micro and macro albuminuria). Majority of participants were at the level of primary and secondary school (n = 186, 53.3 %). The ratio of current smokers was 16.9 % among all. Majority had hypertension (n = 250, 71.6 %). One of the complications such as dislipidemia, diabetic neuropathy, diabetic nephropathy, stroke and coronary artery diseases were observed in 60.5 % of patients (n = 211) (Table 1).

The ratio of females in groups 3 and 2 was higher than in group 1, but not statistically significant (64.2 %, 56.9 % and 53.6 %, respectively; p = 0.129). Statistically significant difference was

Table 1. Basic socio-demographic and clinical features of patients

Features	N (%) of patients	Variable	N (%) of patients
Gender	Male 144 (41.3)	Hypertension (+)	250 (71.6)
	Female 205 (58.7)	Complications (+)	211 (60.5)
Education	Illiterate 46 (13.2)	Variables	
	Literate 45 (12.9)	Mean ± SD	
	Primary-secondary 186 (53.3)	Age (years)	54.2 ± 9.7
Smoking	High school 43 (12.3)	Hba1c (%)	7.6 ± 1.7
	University 29 (8.3)	ACR (mg/d)	50.3 ± 181.9
	Never 243 (69.7)	BMI (kg/m2)	31.5 ± 5.6
HbA1c (%)	Current 59 (16.9)	Waist/Hip Ratio	0.94 ± 0.12
	Former 47 (13.5)	Duration of DM (Years)	6.5 ± 4.9
	< 6.5 93 (26.6)	FBG (mg/dL)	158.8 ± 59.5
ACR	6.5-7.5 119 (34.1)	PBG (mg/dL)	246.1 ± 144.3
	≥ 7.5 137 (39.3)	LDL-cho (mg/dL)	114.9 ± 33.4
	< 30 mg/g 265 (75.9)	HDL-cho (mg/dL)	45.8 ± 11.2
	30-300 mg/g 74 (21.2)	TG (mg/dL)	183.3 ± 137.2
	≥ 300 mg/g 10 (2.9)	Total-cho (mg/dL)	199.7 ± 102.2

SD, standard deviation; ACR, albumin-creatinine ratio; HbA1c, glycohemoglobin; BMI, body mass index; FBG, fasting blood glucose; PBG, post-prandial glucose; LDL-cho, light density lipoprotein cholesterol; HDL-cho, high density lipoprotein cholesterol; TG, triglycerides

Table 2. Comparisons of socio-demographic features of patients according to group distribution

Sociodemographic Features (n = 349)	Number (%) of patients			P
	Group 1 (n = 111)	Group 2 (n = 133)	Group 3 (n = 105)	
Gender				
Male	51 (45.9)	56 (42.1)	37 (35.2)	0.270
Female	60 (54.1)	77 (57.9)	68 (64.8)	
Education				
Illiterate	9 (8.1)	16 (12.0)	21 (20.0)	0.020
Literate	14 (12.6)	13 (9.8)	18 (17.1)	
Primary-secondary school	57 (51.4)	74 (55.6)	55 (52.4)	
High school	18 (16.2)	21 (15.8)	7 (6.7)	
University	13 (11.7)	9 (6.8)	4 (3.8)	
Hypertension (+)	74 (66.7)	98 (73.7)	78 (74.3)	0.228
Complication (+)	59 (53.2)	87 (65.4)	65 (61.9)	0.188
Smoking				
Non-smokers	66 (59.5)	93 (69.9)	84 (80.0)	0.001
Current smokers	28 (25.2)	15 (11.3)	16 (15.2)	
Former smokers	17 (15.3)	25 (18.8)	5 (4.8)	

observed in education level of patients between groups. The ratio of patients with high education level (high school and university) in group 1 was higher than groups 2 and 3 (27.9 %, 24.6 % and 10.5 %, respectively; $p = 0.001$). It was observed that complications were more seen in group 3 than groups 1 and 2, but not statistically significant (77.2 %, 68.1 % and 69.1 %, respectively; $p = 0.188$). The ratio of current smokers was significantly higher than in groups 2 and 3 (24.5 % vs. 12.1 % and 14.6 %; $p = 0.001$) (Table 2).

FBG, PBG, HDL-*chol*, Total-*Chol*, HbA1c and spot urinary ACR were not normally distributed, so they were transferred into logarithmic scale. Adjusted-transformed logarithmic scale values were compared. Mean age, duration of disease and body mass index of patients in groups were observed similar ($p > 0.05$). There was no significant difference in mean FBG, PBG, LDL-*chol*, HDL-*chol*, TG and Total-*chol* levels between groups. HbA1c level was lower in group 1 than in group 2 and 3, but not statistically significant (1.9 ± 0.02 %, 2.0 ± 0.02 and 2.0 ± 0.03 , respectively, $p = 0.285$). When spot urinary albumin creatinine ratio was compared among groups, statistical significance was observed. Mean ACR in group 1 was significantly lower than in group 2 and group 3 ($p = 0.008$ and $p = 0.044$, respectively), but no significant difference was observed between group 2 and group 3 ($p = 0.473$) (Table 3).

The ratio of patients whose HbA1c < 6.5 was similar in the groups, but slightly higher in group 1 (34.5%, 22.6 % and 25.7 %, respectively; $p = 0.601$). The ratio of the patients with normoalbuminuria (urinary albumin/ creatinine less than 30.0 mg/d) was observed as higher in group 1 than groups 2 and 3, but not significantly (80.9 % vs. 79.3 % and 74.8 %, respectively, $p = 0.551$) (Table 4).

minuria (urinary albumin/ creatinine less than 30.0 mg/d) was observed as higher in group 1 than groups 2 and 3, but not significantly (80.9 % vs. 79.3 % and 74.8 %, respectively, $p = 0.551$) (Table 4).

Table 3. Comparisons of metabolic and glycemic indexes of patients according to group distribution

Variables (n = 349)	Number (%) of patients			P
	Group 1 Mean \pm SD/ SE	Group 2 Mean \pm SD/ SE	Group 3 Mean \pm SD/ SE	
Age (years)	54.2 \pm 9.6	53.9 \pm 9.3	53.3 \pm 10.5	$p > 0.05$
Duration of DM (years)	6.6 \pm 5.1	6.5 \pm 4.8	6.1 \pm 4.7	$p > 0.05$
BMI (kg/m²)	31.1 \pm 4.9	313.3 \pm 5.7	32.1 \pm 6.1	$p > 0.05$
FBG (mg/dL)				
Unadjusted	155.1 \pm 48.5	163.8 \pm 64.3	160.4 \pm 66.4	$p > 0.05$
Adjusted	4.9 \pm 0.04	5.0 \pm 0.04	4.9 \pm 0.04	
PBG (mg/dL)				
Unadjusted	226.7 \pm 86.8	268.7 \pm 211.5	241.1 \pm 103.6	$p > 0.05$
Adjusted	5.3 \pm 0.05	5.4 \pm 0.05	5.4 \pm 0.06	
LDL-<i>chol</i> (mg/dL)	109.3 \pm 35.3	114.1 \pm 34.9	114.9 \pm 31.5	$p > 0.05$
HDL-<i>chol</i> (mg/dL)				
Unadjusted	47.1 \pm 12.7	44.6 \pm 10.1	45.6 \pm 11.4	$p > 0.05$
Adjusted	3.8 \pm 0.03	3.6 \pm 0.03	3.8 \pm 0.03	
TG (mg/dL)				
Unadjusted	187.6 \pm 147.8	172.2 \pm 105.9	195.2 \pm 154.3	$p > 0.05$
Adjusted	5.1 \pm 0.1	5.0 \pm 0.1	5.0 \pm 0.1	
T-<i>chol</i> (mg/dL)	197.3 \pm 41.6	211.8 \pm 176.4	194.2 \pm 43.1	$p > 0.05$
HbA1c (%)				
Unadjusted	7.4 \pm 1.5	7.8 \pm 1.7	7.7 \pm 1.9	$p > 0.05$
Adjusted	1.9 \pm 0.02	2.0 \pm 0.02	2.0 \pm 0.03	
SBP (mm-Hg)	135.6 \pm 23.3	134.7 \pm 24.1	137.2 \pm 22.5	$p > 0.05$
DBP (mm-Hg)	86.3 \pm 14.7	85.6 \pm 13.9	86.4 \pm 15.1	$p > 0.05$
ACR (mg/g)				
Unadjusted	42.9 \pm 148.6	47.1 \pm 104.4	62.2 \pm 265.9	0.028
Adjusted	1.8 \pm 0.2	2.5 \pm 0.2	2.3 \pm 0.3	

SD, standard deviation; ACR, albumin-creatinine ratio; HbA1c, glycohemoglobin; BMI, body mass index; FBG, fasting blood glucose; PBG, post-prandial glucose; LDL-*chol*, light density lipoprotein cholesterol; HDL-*chol*, high density lipoprotein cholesterol; TG, triglycerides; SBP, systolic blood pressure, DBP, diastolic blood pressure

Table 4. Categorical distribution of patients in glycemic control and diabetic nephropathy according to group distribution

Values	Number of (%) of patients			P
	Group 1 (n = 111)	Group 2 (n = 133)	Group 3 (n = 105)	
HbA1c (%)*				0.601
< 6.5	36 (34.5)	30 (22.6)	27 (25.7)	
6.5- 7.5	41 (39.9)	46 (34.6)	32 (30.5)	
≥ 7.5	34 (30.6)	57 (42.9)	46 (43.8)	
ACR*				0.551
< 30 mg/g	89 (80.9)	92 (79.3)	92 (74.8)	
30-300 mg/g	17 (15.5)	19 (16.4)	24 (19.5)	
≥ 300 mg/g	4 (3.6)	5 (4.3)	7 (5.7)	

*ADA: guideline for HbA1c and criteria for ACR was used; HbA1c, glycohemoglobin; ACR, albumin-creatinine ratio

DISCUSSION

The results of this study have shown that regular use of SMBG was not effective for glycemic control, but it seemed to be effective on prevention of diabetic complications, particularly diabetic nephropathy. The present study indicated that self-monitoring of blood glucose at home was not effectively used and it had no significant effect on metabolic control and prevention of complications in patients with T2DM. Majority of Turkish diabetic patients have one of the tools such as glucometer for SMBG, and most of them have irregularly used it. Although no significant difference was found in glycemic control and development of complications, it was observed that the more frequent SMBG, the better glycemic control and the less complications developed.

In the study, it was observed that the patients with higher education level were more likely to regularly use SMBG. It confirmed that educating the diabetic patients increases their harmony for glycemic and metabolic control. Low literacy is common among diabetic patients and associated with poor knowledge about DM (11, 22). Scillinger et al. found that patients with type 2 diabetes who had inadequate health literacy were independently associated with worse glycemic control and higher rates of retinopathy (23). Similarly, this study has found that the patients with higher education level had significantly poor glycemic control and the number of patients with microalbuminuria and complications was higher (data not shown). Meanwhile, the ratio of current smokers was observed as higher among patients who have never and irregularly used SMBG, compared to those who have regularly used it. It suggested that diabetic patients with low education level or who were less aware of their DM were more likely to heed.

Results consistent with our study have been shown in numerous studies. Farmer et al. did not show significant difference in HbA1c levels between diabetic patients performing and performing SMBG (24). In several studies, the relation between frequency of SMBG and metabolic control in patients with diabetes mellitus type I and II was investigated. Whether self-monitoring of blood glucose can improve glycemia is subject to debate and controversial in type II diabetes mellitus without insulin treatment (25, 26). Davidson

et al. reported that HbA1c level decreased for 0.2 % in patients with type 2 DM in SMBG group, compared to non-SMBG group (27). Stratton et al. found that HbA1c level statistically decreased for 0.39% in patients with type 2 DM in SMBG group, compared to control group (2/). Chubb et al. provided that SMBG data was predictive for both FBG and HbA1c in patients with type 2 DM (29). On the other hand, Meier et al. reported that SMBG more than twice a week was not effective in glycemic control in patients with type 2 (30). O'Kane et al. also found that SMBG had no effect on glycemic control in patients with newly diagnosed type 2 diabetes mellitus (31). Among our patient groups, there was approximately 0.2-0.3 % difference in mean HbA1c level, although it was not significant.

Bajkowska-Fiedziukiewicz et al. found no correlation between frequency of SMBG and HbA1c level (32). Similarly, no correlation of SMBG frequency and HbA1c level was found in the study. In contrast, McIntosh et al. reported in a meta-analysis of 2010 that self-monitoring of blood glucose levels was associated with a modest, statistically significant reduction in hemoglobin A1c concentrations, regardless of whether patients were provided with education on how to interpret and use the test results (33).

Microalbuminuria indicates early, reversible, diabetic nephropathy. The random urine ACR is a convenient effective screening test, which in the 30 to 300 (mg/d) indicate microalbuminuria (34). Levin et al. reported that intensive glycemic control retards microalbuminuria in patients who have had type 2 DM for several years but may not lessen the progressive deterioration of glomerular function (35). In this study, it was found that ACR in patients in group 1 was lower than in other two groups. Ozmen et al. reported that there was no relation between SMBG implementation and complications such as nephropathy and neuropathy, but between HbA1c and SMBG implementation (17). The mean ACR among the patients in group 1 was significantly different from the group 2 and group 3, but no significant difference was observed between the group 2 and group 3 in this study, and no correlation between SMBG frequency and ACR was found. Despite the low ratio of patients with albuminuria who had regularly used SMBG, it was not statistically significant.

Based on screening literature, there were a few studies on effectiveness of SMBG on glycemic control in Turkish type 2 diabetic patients. Ozgur et al. conducted a study with 94 type 2 diabetic patients, and reported that HbA1c level was affected by SMBG frequency (18). Aydin et al. found that glycemic control could be more achieved with increased SMBG frequency in insulin treated patients with type 2 DM (36).

The study limitations include the use of cross-sectional and observational data with short-term, unknown levels of patient adherence, and assumptions regarding the duration of clinical outcomes. The study included non-homogeneous educational level of patients. Those were also a weak side of the study. The strong side of the study was that effectiveness of SMBG was not only evaluated with glycemic control, but also

with metabolic control parameters and status of complications development.

In conclusion, there was significant difference in mean albumin-creatinine ratio between regular SMBG group and both irregular/never use of SMBG, but there was no significant difference in the status of overall developed diabetic complications and glycemic control among the groups. Therefore, it could suggest that SMBG should be recommended for type 2 diabetic patients with high education level, treated with oral regimens rather than insulin therapy, to achieve our purpose of the use of SMBG.

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