Journal of Diabetes Science and Technology
Volume 5, Issue 2, March 2011

ORIGINAL ARTICLES

Effects of a Structured Self-Monitoring of Blood Glucose Method on Patient Self-Management Behavior and Metabolic Outcomes in Type 2 Diabetes Mellitus

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Abstract

Background:

The purpose of this study was to evaluate the effect of structured self-monitoring of blood glucose (SMBG) on patient self-management behavior and metabolic outcomes in patients with type 2 diabetes mellitus (T2DM).

Methods:

From January to June 2009, 30 patients with basic diabetes education were followed for a period of 90 days. To provide assessment of glycemic control and frequency of dysglycemia, patients, underwent 3 consecutive days of seven-point SMBG during each month for 3 consecutive months, using the ACCU-CHEK 360° View tool. Glucose profiles of the first and third month were used for comparison.

Results:

Hemoglobin A1c (HbA1c) improved significantly during the 90-day period in all patients [confidence interval (CI) 95%, 0.32–1.64%, $p < .05$] and those with poor metabolic control (group B; CI 95%, 0.86–2.64%, $p < .05$). Mean blood glucose (MBG) values decreased significantly in group B (CI 95%, 0.56–24.78 mg/dl, $p < .05$) and all cases (CI 95%, 1.61–19.73 mg/dl, $p < .05$). Meanwhile, there was an average decrease of 15.7 mg/dl in fasting blood sugar (FBS) levels in the whole subjects. Mean postprandial blood glucose levels (MPP) decreased by 19.3 and 11.3 mg/dl in group B and in all cases, respectively. However, there were no significant changes in HbA1c, MBG, FBS, and MPP in people with good metabolic control.

Conclusion:

A structured SMBG program improves HbA1c, FBS, MPP, and MBG in people with poorly controlled diabetes. This improvement shows the importance of patient self-management behavior on metabolic outcomes in T2DM.

J Diabetes Sci Technol 2011;5(2):388-393

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Abbreviations: (ASIA) Auto-Surveillance Intervention Active study, (BMI) body mass index, (CI) confidence interval, (DiGEM) Diabetes Glycemic Education and Monitoring study, (FBS) fasting blood sugar, (HbA1c) hemoglobin A1c, (IEM) Institute of Endocrinology and Metabolism, (MBG) mean blood glucose, (MPP) mean postprandial blood glucose, (SD) standard deviation, (SMBG) self-monitoring of blood glucose, (T2DM) type 2 diabetes mellitus

Keywords: diabetes, metabolic outcomes, self-management behavior, self-monitoring of blood glucose

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Introduction

The prevalence of diabetes has reached epidemic proportions in most populations. Epidemiologic evidences suggest that unless effective preventive measures are implemented, the prevalence will continue to rise globally.[1] It is estimated that the number is expected to grow to 366 million by 2030, more than twice the number in 2000.[2] In a national survey in Iran, the prevalence of type 2 diabetes mellitus (T2DM) was reported to be 7.7% in people younger than 65 years.[3]

Intensive glycemic control has a beneficial effect on diabetes-related complications.[4] Hemoglobin A1c (HbA1c) reflects the overall blood glucose control.[5–7] Landmark studies confirmed that postprandial hyperglycemia is an independent risk factor for vascular events.[8,9] Dysglycemia in diabetes is not limited to sustained chronic hyperglycemia. Acute glycemic variability seems to activate oxidative stress and plays a major role in the pathogenesis of diabetic complications.[7,10,11] Self-monitoring of blood glucose (SMBG) enables physicians and patients to evaluate glycemic state and its variability.[12–14] It may also reduce the risk of asymptomatic hypoglycemia and/or hyperglycemia.[14–16] Conflicting evidence exists regarding the beneficial effect of SMBG in T2DM.[17–21]

The purpose of this observational study was to investigate the effect of patient self-management behaviors on metabolic outcomes in a group of people with T2DM using a structured self-monitoring method.

Participants and Methods

Study Design

The Institute of Endocrinology and Metabolism (IEM) at Tehran University of Medical Sciences conducted this study to assess the merits of a structured testing-based tool (ACCU-CHEK 360° View) in adults with T2DM.[22]

After exclusion of those with advanced chronic complications, pregnancy, and other concurrent illness, 30 people with T2DM were included in the study from January to June 2009. At baseline, all patients received education about the meter device as well as essential instructions in order to record the results in a data collection paper tool. This tool provides an adequate basis for seven-point SMBG for 3 consecutive days and includes three premeals, three postmeals, and bedtime blood glucose values during each day. There is enough space for patients to mark preceding portion size as small, medium, or large. Also, patients could put their comments about level of physical activity at determined points at the bottom of the paper.

Basic core education was provided to the subjects so that they could act upon the results by changing portion size of the meals and level of physical activity. In this phase, compliance of the subjects was evaluated and those with good compliance were enrolled in the study. Good compliance was defined as recording more than 85% of the dates correctly on the paper tool.

All patients were supplied with meters, strips, lancets, and lancing devices, plus the 360° View forms and were asked to record their blood glucose values, portion size, and level of physical activity at the end of each month on 3 consecutive days: S1 (days 28–30), S2 (days 58–60), and S3 (days 88–90). All subjects received a reminder call 1 day prior to S1, S2, and S3 and were asked to analyze test results in relation to portion size and level of physical activity, and act on the results according to the instructions they received at the time of enrollment. A double-check system was applied to all test results by downloading data from the meters using an infrared port. Medical treatment for all subjects remained unchanged during the study. The major cause of dropouts was change in treatment protocol. S1 and S3 glucose profiles were used for comparison.

HbA1c was measured twice in each patient, at inclusion and at the end of study, using ion exchange chromatography (Drew-DS5, Drew Scientific Co. Limited, Cumbria, England). Poor glycemic control was defined as HbA1c ≥8% at inclusion. Two groups were identified according to HbA1c: 15 patients with HbA1c less than 8% (group A) and 15 patients with HbA1c ≥8% (group B). Ethical approval was granted from the ethics board at IEM.

Statistical Analysis

All data are presented as mean ± standard deviation (SD). Significant differences in general characteristics were determined by Chi-square and Student's *t*-test. SPSS for Windows (Version 16; SPSS Inc., Chicago, IL) was used for data analyses and p values < .05 were considered statistically significant.

Results

Twenty-three patients (10 patients in group A and 13 patients in group B) completed the study. There were no significant differences in baseline characteristics, including age, duration of diabetes, and SMBG frequency. However, subjects in group B had a significantly higher baseline HbA1c (mean (SD) 6.57% (1.01) vs 9.72% (1.35); p value < .001) (**Table 1**). Each of the 23 patients included in the final analysis had four series of 72–84 readings of SMBG results recorded in ACCU-CHEK 360° View forms (a total of at least 1656 and at most 1921 SMBG readings in each of the four series).

Outcome Measures

HbA1c

The primary end point, HbA1c, improved during the 90-day period with a statistically significant decrease in group B [confidence interval (CI) 95%, 0.86–2.64%, p < .05), and in all cases (CI 95%, 0.32–1.64%, p < .05) (**Table 2**). As expected, there was no significant change in HbA1c values in group A. It was also noted that 53% of subjects in group B reached an HbA1c of less than 8% at the end of the study.

Mean Blood Glucose

Mean blood glucose (MBG) values significantly decreased in group B (CI 95%, 0.56–24.78 mg/dl, p < .05), and in all subjects (CI 95%, 1.61–19.73 mg/dl, p < .05). However, MBG did not show any significant difference in group A (**Table 3**).

Fasting Blood Sugar

Table 3 shows an average decrease of 15.7 mg/dl in fasting blood sugar (FBS) levels in all subjects (95% CI, 0.66–30.84 mg/dl, p < .05). The decrease in mean FBS values of groups A and B were not statistically significant.

Mean Postprandial Blood Glucose

Also of note was the 19.3 mg/dl decrease in mean postprandial blood glucose levels (MPP) in group B (CI 95%, 5.51–33.20 mg/dl, p < .05), and the 11.3 mg/dl decrease in all subjects (CI 95%, 0.43–22.12 mg/dl, p < .05). However, there was no significant change in MPP in group A (**Table 3**).

Discussion

The purpose of this study was to evaluate the effect of structured SMBG on self-management behavior and metabolic outcomes in people with T2DM. We found that this strategy improves HbA1c, FBS, MPP, and MBG

Table 1.
Baseline Characteristics of All Subjects Included in the Study According to HbA1c Values[a]

	Group A (HbA1c <8%)	Group B (HbA1c ≥8%)	All
Number of patients (men/women)	10 (6/4)	13 (5/8)	23 (11/12)
Age (year)	52.4 ± (10.6)	58.4 ± (8.7)	55.8 ± (9.8)
Duration of diabetes mellitus (year)	7.0 ± (5.6)	9.7 ± (5.1)	8.5 ± (5.4)
SMBG frequency (test/day)	0.2 ± (0.4)	0.7 ± (1.0)	0.5 ± (0.8)
HbA1c (%)[b]	6.57 ± (1.01)	9.72 ± (1.35)	8.35 ± (1.99)

[a] Data are means (SD) or count unless indicated otherwise.
[b] Statistically significant difference between groups A and B, *t*-test.

Table 2.
Comparison of HbA1c Values between Groups of Inclusion and End of the Study

	Inclusion	End of the study	p value
HbA1c (%)[a]			
All cases	8.35 (1.99)	7.37 (1.07)	.005[b]
Group A	6.57 (1.01)	6.59 (0.51)	.945
Group B	9.72 (1.35)	7.96 (1.00)	.001[b]

[a] Group A: HbA1c <8%; Group B: HbA1c ≥8%; data are means (SD)
[b] Statistically significant difference, *t*-test

Table 3.
Comparison of Blood Glucose Values between Groups at S1 and S3[a]

	S1 values	S3 values	p value
Mean blood glucose (mg/dl)			
All cases	171.5 (40.3)	160.8 (31.5)	0.023[b]
Group A	165.7 (41.0)	157.7 (29.2)	0.293
Group B	175.9 (40.9)	163.2 (34.2)	0.042[b]
Mean fasting blood glucose (mg/dl)			
All cases	145.4 (44.4)	129.7 (29.7)	0.041[b]
Group A	143.9 (36.0)	132.1 (23.3)	0.181
Group B	146.5 (51.0)	127.8 (34.6)	0.094
Mean postprandial glucose (mg/dl)			
All cases	188.0 (43.2)	176.7 (33.8)	0.042[b]
Group A	180.7 (46.4)	180.0 (35.5)	0.924
Group B	193.6 (41.7)	174.3 (33.6)	0.010[b]

[a] Group A: HbA1c <8%, Group B: HbA1c ≥8%; data are means (SD)
[b] Statistically significant difference, *t*-test

in patients with poor glycemic control. Interestingly, this effect was independent of medical treatment and showed the importance of lifestyle changes.

Guerci and colleagues[23] reported the effectiveness of SMBG on metabolic control in patients with T2DM in a multicenter controlled prospective trail. They showed SMBG is more beneficial in patients with higher HbA1c at baseline, a finding that is similar to ours. In this study, however, no standard counseling on diet and lifestyle was done for the patients.

In a study by Rutten and colleagues,[24] the beneficial effect of SMBG on weight and HbA1c was shown. Similar results were reported in a prospective randomized controlled multicenter study on glycemic control in patients with T2DM.[21] In this study, SMBG in combination with a structured canceling program improved meal-related glucose levels.

In DINAMIC 1,[25] the value of SMBG on reduction of HbA1c was shown in a randomized parallel study in patients with T2DM who were on oral antidiabetic therapy. In the Auto-Surveillance Intervention Active (ASIA) study,[23] metabolic outcomes were compared over 6 months in patients on usual recommendations to those with these recommendations combined with SMBG. None of the subjects were taking insulin. The authors observed better quality of metabolic control in the SMBG group. The HbA1c level at baseline was the most important predicting factor for improvement of metabolic control. The same results were obtained from our study in relation to the baseline HbA1c level and effect of SMBG on metabolic outcome. In the ASIA study, however, no specific information was provided to the patients in order to incorporate SMBG findings into self-care behaviors. Meanwhile, patients in the SMBG group were asked to titrate their medication according to fasting plasma glucose.

These results are in contrast with those reported in the Diabetes Glycemic Education and Monitoring (DiGEM) study, which found no beneficial effect of SMBG on glycemic control in noninsulin-treated T2DM.[26] Considering the economic burden of SMBG and its effects on quality of life, the DiGEM trial group reported higher cost and lower quality of life in patients with noninsulin-treated T2DM. However, they mentioned that SMBG might be cost-effective in patients who adhere tightly to the treatment recommendations.

In our study, we included patients with high compliance. So, the improvement in glycemic control might have reflected the incorporation of SMBG findings into self-care and a meaningful lifestyle response to the data obtained from SMBG. Meanwhile, we observed a beneficial effect of SMBG on glycemic control in poorly controlled T2DM patients with higher HbA1c level at baseline. Some other studies also showed no significant difference on metabolic outcome using SMBG.[27,28] Karter and colleagues[19] reported the impact of SMBG on the management of patients who were not treated with insulin. They claimed that SMBG with or without instruction might not improve glycemic control compared with usual care in well-controlled T2DM patients, similar to the results we reported in our study in the subgroup of patients with HbA1c less than 8%.

In the ESMON study,[29] noninsulin-treated newly diagnosed people with T2DM were randomized to SMBG and a control group in order to evaluate the efficacy of SMBG on glycemic control, body mass index (BMI), and psychological indices. SMBG had no beneficial effect on HbA1c after 1 year, and no significant differences in BMI were reported between the SMBG and control groups. Meanwhile, SMBG was associated with a slightly higher score on a depression subscale.

There are some possibilities to explain these controversial issues. One possibility is that nonstructured SMBG might not provide sufficient and valid information for the patients to act upon the results. In other words, random measurements do not provide adequate information for decision-making and this may lead to patient dissatisfaction and anxiety.[25] In a large epidemiological study, Karter and colleagues[19] reported a link between HbA1c and frequency of SMBG. Another explanation is the absence of clear instructions to incorporate finding into self-care practice. As a result, patients might not use the information to change their lifestyle.[30] Aikens and colleagues[31] reported that self-care behaviors improved diabetes outcomes. Other studies also showed that knowledge as well as behavior change are effective on patient lifestyle, which is important regarding diabetes control and cardiovascular outcomes.[32,33]

Using a simple SMBG tool that can be integrated easily into a comprehensive diabetes management approach was the most significant point of strength in our study. We showed that lifestyle adaptation is intuitively the right way to manage patients with diabetes. Verification of SMBG results by data download giving "hard" data was another point of strength. However, the most important limitation of our study was the small sample size.

Conclusion

This study showed effectiveness of structured SMBG on patient empowerment and better metabolic control in people with T2DM. This improvement results from more active participation of patients in self-care management, better compliance with treatment protocols, and smaller attrition rate compared to other interventions.

In our study, we showed that adherence to the structured SMBG enabled patients to interpret the results in relation to their level of activity and portion size, and motivated them to act upon the results in order to have a better metabolic outcome.

Funding:

This project was supported by DarmanYab Darou Co., a representative of Roche Diagnostics GmbH (Mannheim, Germany) in Iran.

References:

1. Alberti KG, Zimmet P, Shaw J. International Diabetes Federation: a consensus on type 2 diabetes prevention. Diabet Med. 2007;24(5):451-63.
2. Diabetes Atlas Brussels: International Diabetes Federation; 2006. *http://da3.diabetesatlas.org/*.
3. Esteghamati A, Gouya MM, Abbasi M, Delavari A, Alikhani S, Alaedini F, Safaie A, Forouzanfar M, Gregg EW. Prevalence of diabetes and impaired fasting glucose in the adult population of Iran: National Survey of Risk Factors for Non-Communicable Diseases of Iran. Diabetes Care. 2008;31(1):96-8.
4. Khunti K, Gadsby R, Millett C, Majeed A, Davies M. Quality of diabetes care in the UK: comparison of published quality-of-care reports with results of the Quality and Outcomes Framework for Diabetes. Diabet Med. 2007;24(12):1436-41.
5. Hirsch IB, Brownlee M. Should minimal blood glucose variability become the gold standard of glycemic control? J Diabetes Complications. 2005;19(3):178-81.
6. Del Prato S. In search of normoglycaemia in diabetes: controlling postprandial glucose. Int J Obes Relat Metab Disord. 2002; 26(Suppl 3):S9-17.
7. Monnier L, Colette C. Glycemic variability: should we and can we prevent it? Diabetes Care. 2008;31(Suppl 2):S150-4.
8. Ceriello A, Hanefeld M, Leiter L, Monnier L, Moses A, Owens D, Tajima N, Tuomilehto J. Postprandial glucose regulation and diabetic complications. Arch Intern Med. 2004;164(19):2090-5.
9. Cavalot F, Petrelli A, Traversa M, Bonomo K, Fiora E, Conti M, Anfossi G, Costa G, Trovati M. Postprandial blood glucose is a stronger predictor of cardiovascular events than fasting blood glucose in type 2 diabetes mellitus, particularly in women: lessons from the San Luigi Gonzaga Diabetes Study. J Clin Endocrinol Metab. 2006;91(3):813-9.
10. Brownlee M. The pathobiology of diabetic complications: a unifying mechanism. Diabetes. 2005;54(6):1615-25.
11. Pistrosch F, Reissmann E, Wildbrett J, Koehler C, Hanefeld M. Relationship between diurnal blood pressure variation and diurnal blood glucose levels in type 2 diabetic patients. Am J Hypertens. 2007;20(5):541-5.
12. Kirk JK, Stegner J. Self-monitoring of blood glucose: practical aspects. J Diabetes Sci Technol. 2010;4(2):435-9.
13. Renard E. Monitoring glycemic control: the importance of self-monitoring of blood glucose. Am J Med. 2005;118(Suppl 9A):12S-19S.
14. Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM, Sacks DB. Tests of glycemia in diabetes. Diabetes Care. 2004;27(7):1761-73.
15. Monnier L, Colette C, Lapinski H, Boniface H. Self-monitoring of blood glucose in diabetic patients: from the least common denominator to the greatest common multiple. Diabetes Metab. 2004;30(2):113-9.
16. Tseng KH. Standards of medical care in diabetes--2006: response to the American Diabetes Association. Diabetes Care. 2006;29(11):2563-4.
17. Klonoff DC, Bergenstal R, Blonde L, Boren SA, Church TS, Gaffaney J, Jovanovic L, Kendall DM, Kollman C, Kovatchev BP, Leippert C, Owens DR, Polonsky WH, Reach G, Renard E, Riddell MC, Rubin RR, Schnell O, Siminiero LM, Vigersky RA, Wilson DM, Wollitzer AO. Consensus report of the Coalition for Clinical Research—Self-Monitoring of Blood Glucose. J Diabetes Sci Technol. 2008;2(6):1030-53.
18. IDF Clinical Guidelines Task Force. Global Guideline for Type 2 Diabetes: recommendations for standard, comprehensive, and minimal care. Diabet Med. 2006;23(6):579-93.
19. Karter AJ, Ackerson LM, Darbinian JA, D'Agostino RB Jr, Ferrara A, Liu J, Selby JV. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry. Am J Med. 2001;111(1):1-9.
20. Harris MI; National Health and Nutrition Examination Survey (NHANES III). Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. Diabetes Care. 2001;24(6):979-82.
21. Schwedes U, Siebolds M, Mertes G; SMBG Study Group. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. Diabetes Care. 2002;25(11):1928-32.
22. Polonsky W, Fisher L, Schikman C, Hinnen D, Parkin C, Jelsovsky Z, Amstutz L, Schweitzer M, Wagner R. The value of episodic, intensive blood glucose monitoring in non-insulin treated persons with type 2 diabetes: design of the Structured Testing Program (STeP) study, a cluster-randomised, clinical trial [NCT00674986]. BMC Fam Pract. 2010;18;11:37.
23. Guerci B, Drouin P, Grangé V, Bougnères P, Fontaine P, Kerlan V, Passa P, Thivolet Ch, Vialettes B, Charbonnel B; ASIA Group. Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. Diabetes Metab. 2003;29(6): 587-94.

24. Rutten G, van Eijk J, de Nobel E, Beek M, van der Velden H. Feasibility and effects of a diabetes type II protocol with blood glucose self-monitoring in general practice. Fam Pract. 1990;7(4):273-8.

25. Barnett AH, Krentz AJ, Strojek K, Sieradzki J, Azizi F, Embong M, Imamoglu S, Perusicová J, Uliciansky V, Winkler G. The efficacy of self-monitoring of blood glucose in the management of patients with type 2 diabetes treated with a gliclazide modified release-based regimen. A multicentre, randomized, parallel-group, 6-month evaluation (DINAMIC 1 study). Diabetes Obes Metab. 2008;10(12):1239-47.

26. Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, Holman R, Kinmonth AL, Neil A. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. BMJ. 2007;335(7611):132.

27. Fontbonne A, Billault B, Acosta M, Percheron C, Varenne P, Besse A, Eschwege E, Monnier L, Slama G, Passa P. Is glucose self-monitoring beneficial in non-insulin-treated diabetic patients? Results of a randomized comparative trial. Diabete Metab. 1989;15(5):255-60.

28. Allen BT, DeLong ER, Feussner JR. Impact of glucose self-monitoring on non-insulin-treated patients with type II diabetes mellitus. Randomized controlled trial comparing blood and urine testing. Diabetes Care. 1990;13(10):1044-50.

29. O'Kane MJ, Bunting B, Copeland M, Coates VE; ESMON study group. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. BMJ. 2008;336(7654):1174-7.

30. Wing RR, Epstein LH, Nowalk MP, Scott N, Koeske R, Hagg S. Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? Am J Med. 1986;81(5):830-6.

31. Aikens JE, Bingham R, Piette JD. Patient-provider communication and self-care behavior among type 2 diabetes patients. Diabetes Educ. 2005;31(5):681-90.

32. Sánchez CD, Newby LK, McGuire DK, Hasselblad V, Feinglos MN, Ohman EM. Diabetes-related knowledge, atherosclerotic risk factor control, and outcomes in acute coronary syndromes. Am J Cardiol. 2005;95(11):1290-4.

33. Bazata DD, Robinson JG, Fox KM, Grandy S; SHIELD Study Group. Affecting behavior change in individuals with diabetes: findings from the Study to Help Improve Early Evaluation and Management of Risk Factors Leading to Diabetes (SHIELD). Diabetes Educ. 2008;34(6):1025-36.