ORIGINAL ARTICLE

Self-monitoring of blood glucose and glycaemic control in type 2 diabetes

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Abstract

Objective. Previous studies have shown inconsistent results with regard to whether or not self-monitoring of blood glucose (SMBG) is related to better glycaemic control in type 2 diabetes. The aim of this study was to explore the use of SMBG and its association with glycaemic control in patients with type 2 diabetes in primary care. **Design.** A cross-sectional observational study was conducted in 2003 at 18 primary health care centres in Sweden, in which all known patients with diabetes were surveyed. The study included 6495 patients with type 2 diabetes. A sample of 896 patients was selected for further exploration of data from medical records. A telephone interview was performed with all patients in this group using SMBG (533 patients). **Results.** There were no differences in HbA1c levels between users (6.9%) and non-users (6.8%) of SMBG in patients treated with insulin or in patients treated with oral agents (6.3% in both groups). In patients treated with diet only, users of SMBG had higher levels of HbA1c compared with non-users (5.5% vs. 5.4%, $p=0.002$). Comparing medical records between users and non-users of SMBG showed no differences in diabetes-related complications in any treatment category group. **Conclusion.** The use of SMBG was not associated with improved glycaemic control in any therapy category of patients with type 2 diabetes in primary care. The absence of difference in glycaemic control between users and non-users of SMBG could not be explained by differences in comorbidity between users and non-users of SMBG.

Key Words: Family practice, glycaemic control, primary care, self-monitoring, type 2 diabetes

Rigorous blood glucose control is associated with a lower risk for virtually all diabetes-related endpoints, diabetes-related deaths, and all-cause mortality in patients with type 2 diabetes [1–3]. Self-monitoring of blood glucose has been recommended as a useful technique for improving glycaemic control [4] and is an important component in treatment programmes for patients with diabetes mellitus [5].

An increased frequency of self-monitoring of blood glucose (SMBG) in patients with type 1 diabetes is generally associated with improved glycaemic control [6,7]. However, prior studies of patients with type 2 diabetes exploring the association between the frequency of testing and HbA1c values have shown inconsistent results [8–14]. Since widespread use of SMBG has resulted in a considerable cost for society, it is justifiable to question

There is a substantial use of test strips for self-monitoring of blood glucose (SMBG) in type 2 diabetes in primary care.

- The frequency of patients with type 2 diabetes using SMBG is 36% in the group treated with diet only, 54% in patients on oral agents, and 79% in patients with insulin treatment.
- The use of SMBG in primary care is not associated with improved glycaemic control for patients with type 2 diabetes in any treatment category.

whether or not the use of SMBG is beneficial for glycaemic control in patients with type 2 diabetes.

The aim of this study was to explore the association between glycaemic control, measured by HbA1c levels, and the use and frequency of SMBG in a population with type 2 diabetes in primary care, accounting for differences in prevalence of concomitant medication as well as diabetes-related complications between users and non-users of SMBG.

Material and methods

During November–December 2003 a total survey of all patients with diabetes mellitus was performed at 18 primary care health centres in the counties of Östergötland and Jönköping, Sweden, serving a total population of 208 490 people. In Sweden almost all patients with type 2 diabetes are taken care of by general practitioners in primary care. All primary care health centres in this study also had a nurse with special training in diabetes, responsible for coordinating the medical care for patients with diabetes.

The patients were categorized as having type 1 or type 2 diabetes according to information from their medical records and were registered with regard to age, gender, treatment category, HbA1c, and number of visits to the healthcare centre. Depending on whether test strips for SMBG had been prescribed within the last year or not, patients were categorized as users or non-users of SMBG. Glycaemic control

was estimated by HbA1c, normal range 4.0–5.3%. HbA1c was measured by means of the Mono-s method which corresponds to about 1.15% higher HbA1c levels according to the DCCT standard, which is more commonly used internationally [15].

After exclusion of 176 patients with type 1 diabetes and 423 elderly patients living in nursing homes, 3299 men and 3196 women with type 2 diabetes remained for further analyses. A sample of 896 patients (533 users and 363 non-users of SMBG) was selected and stratified with equal numbers of men and women, patients under and above 65 years in all three therapy groups. From the patients in the sample more data from medical records were collected from the primary healthcare centres. From the sample, the 533 users of SMBG were also subjected to a telephone interview concerning their opinions and SMBG habits. A general outline of the procedure is illustrated in Figure 1.

The interviews were performed by four research nurses working at the centres of research and development in Jönköping and Linköping, respectively. A structured questionnaire was used including questions about diabetes history, the patients' opinions about SMBG and the frequency of SMBG testing.

HbA1c was considered good if HbA1c levels were <6.5%.

Figure 1. Design of the study. From a total population of 208 490 subjects all known patients with type 2 diabetes were surveyed and further analyses were made from a stratified randomized sample.

Statistics

The SPSS Base System for Windows 12.0 was used for data analyses. Differences in age and gender were accounted for by multivariate analyses or by stratification. Associations between categorical variables were estimated by logistic regression and presented as odds ratios (OR) with 95% confidence intervals (CI). All tests were two sided and statistical significance was assumed when $p < 0.05$.

Ethics

The study was approved by the Regional Ethical Review Board in Linköping.

Results

From a population of 208 490 individuals, we identified 6495 patients with type 2 diabetes. The characteristics of the subjects are presented by treatment category in Table I. It shows that 2080 patients received dietary recommendations only, 2401 were on oral agents, and 2014 were treated with insulin. The mean age was 69 years with small differences in age between the therapy groups. The frequency of SMBG use was 36% in the group with diet only, 54% in patients on oral agents, and 79% in patients with insulin treatment.

When adjusted for age and gender there were no differences in HbA1c levels between users (6.9%) and non-users (6.8%) of SMBG in patients treated with insulin or in patients treated with oral agents (6.3% in both groups). In patients treated with diet only, users of SMBG had higher levels HbA1c compared with non-users (5.5% vs. 5.4%, $p = 0.002$) (Figure 2).

The Odds Ratio for HbA1c $< 6.5\%$ for users of SMBG compared with non-users was for patients with diet treatment 0.80 (CI 0.57–1.11), for patients

on oral agents 0.99 (CI 0.8–1.18), and for patients with insulin treatment 0.86 (CI 0.69–1.06).

Data from medical records in the stratified sample of 452 men and 444 women (Table II) showed that non-users of SMBG treated with diet only were older, mean age 68.4 vs. 65.6 years ($p = 0.048$), and were more frequently on diuretics, 39.8% vs. 26.1% ($p = 0.047$) than users of SMBG. Patients on oral agents not using SMBG had a higher creatinine level, 90 vs. 80 $\mu\text{mol/l}$ ($p = 0.006$) than users of SMBG. In the insulin treatment category there was a higher use of calcium channel blockers among non-users of SMBG, 23.9% vs. 13.8% ($p = 0.041$). There were no differences in HbA1c levels, blood pressure, dyslipidemia, microalbuminuria, prevalence of ischaemic heart disease, or smoking status between users and non-users of SMBG in any treatment category group.

A telephone interview with the 533 users of SMBG regarding the frequency of SMBG testing showed that the consumption of test strips varied from 0 to 42 test strips during the week prior to the interview. Some 32% of patients on insulin treatment performed SMBG testing at least once daily while the corresponding figures for patients on oral agents and diet recommendations were 8% and 6%, respectively. No correlation was found between the frequency of SMBG tests and HbA1c levels (Figure 3). In a linear regression adjusted for age and gender, there was no association between frequency of SMBG tests and levels of HbA1c in the different treatment categories, respectively (diet $p = 0.62$, oral agents $p = 0.13$, insulin $p = 0.57$).

Discussion

This population-based study, involving virtually all subjects with type 2 diabetes, from 18 primary healthcare centres, showed that the use of SMBG

Table I. Baseline characteristics of 6495 patients with type 2 diabetes, by treatment category, at 18 primary care health centres in the counties of Jönköping and Östergötland, Sweden, 2003.

	All n = 6495	Diet only = 2080	Oral agents n = 2401	Insulin n = 2014
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	68.9 (12.1)	69.1 (12.5)	68.2 (12.1)	69.5 (11.8)
Visits to nurse last year (n)	1.5 (1.5)	1.1 (1.2)	1.5 (1.4)	1.9 (1.9)
Visits to GP last year (n)	1.9 (1.9)	1.8 (1.7)	1.8 (1.6)	2.0 (3.5)
HbA1c (%)	6.2 (1.2)	5.4 (0.8)	6.3 (1.1)	6.9 (1.3)
Users of SMBG ¹	3621 (55.8)	741 (35.6)	1298 (54.1)	1582 (78.6)
Gender, men ¹	3299 (50.8)	1009 (48.5)	1273 (53.0)	1017 (50.5)
Duration of diabetes ¹				
< 2 years	1026 (15.9)	680 (32.8)	265 (11.1)	81 (4.0)
2–4 years	1551 (24.0)	731 (35.3)	633 (26.5)	187 (9.3)
> 4 years	3888 (60.1)	662 (31.9)	1492 (62.4)	1734 (86.6)

¹For categorical variables data are *n* and per cent (%).

Figure 2. Glycaemic control measured by mean levels of HbA1c $\pm$ 1 SD in different treatment categories in 6495 patients with type 2 diabetes.

Table II. Characteristics in a sample of 896 patients with type 2 diabetes in the counties of Jönköping and Östergötland, Sweden, 2003. Data are shown for users and non-users of SMBG respectively by treatment category

	Diet only			Oral agents			Insulin		
	Non-user	User	p	Non-user	User	p	Non-user	User	p
	n = 133	n = 176		n = 117	n = 190		n = 113	n = 167	
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Age (years)	68.4 (13.1)	65.6 (11.2)	0.048	66.4 (13.1)	64.7 (11.1)	ns	68.3 (12.8)	67.0 (11.4)	ns
HbA1c (%)	5.4 (0.8)	5.5 (0.8)	ns	6.4 (1.1)	6.3 (0.9)	ns	6.7 (1.2)	6.8 (1.2)	ns
Systolic BP (mmHg)	142 (17)	141 (18)	ns	142 (19)	142 (16)	ns	142 (18)	139 (16)	ns
Diastolic BP (mmHg)	80 (9)	79 (9)	ns	79 (10)	78 (9)	ns	76 (10)	76 (9)	ns
S-cholesterol (mmol/l)	5.4 (0.9)	5.2 (1.0)	ns	5.2 (1.0)	5.2 (1.0)	ns	5.2 (0.8)	5.1 (1.0)	ns
S-creatinine (μ mol/l)	83 (21)	83 (23)	ns	90 (31)	80 (18)	0.006	95 (36)	87 (23)	ns
Number of strips/week(n)	0 (0)	3.2 (4.0)	–	0 (0)	4.0 (5.2)	–	0 (0)	6.6 (7.1)	–
Gender men ¹	70 (52.6)	87 (49.4)	ns	60 (51.3)	93 (48.9)	ns	60 (53.1)	82 (49.1)	ns
Current smoking ¹	18 (16.4)	30 (21.1)	ns	19 (21.3)	28 (18.2)	ns	15 (16.9)	24 (18.6)	ns
Ischaemic heart disease ¹	28 (21.1)	20 (11.4)	ns	20 (17.1)	36 (18.9)	ns	32 (28.3)	44 (26.3)	ns
Microalbuminuria ¹	16 (17.0)	18 (15.1)	ns	22 (24.2)	30 (18.8)	ns	30 (33.3)	48 (36.6)	ns
Beta blockers ¹	60 (45.1)	67 (38.1)	ns	51 (44)	79 (41.6)	ns	49 (43.4)	68 (40.7)	ns
Diuretics ¹	53 (39.8)	46 (26.1)	0.047	39 (33.6)	48 (25.3)	ns	39 (34.8)	67 (40.1)	ns
Calcium blockers ¹	24 (18.2)	33 (18.8)	ns	24 (20.7)	33 (17.4)	ns	27 (23.9)	23 (13.8)	0.041
ACE inhibitors/ARB ¹	43 (32.3)	48 (27.3)	ns	53 (45.7)	62 (32.6)	ns	57 (50.4)	74 (44.3)	ns
Statins ¹	38 (28.6)	48 (27.3)	ns	42 (36.2)	83 (43.7)	ns	50 (44.2)	64 (38.3)	ns
ASA ¹	43 (32.3)	45 (25.6)	ns	39 (33.6)	55 (28.9)	ns	42 (37.2)	51 (30.5)	ns

¹For categorical variables data are n and per cent (%).

Figure 3. Scatter diagram of HbA1c (%) and frequency of test strips consumed the week prior to telephone interview, for 533 users of SMBG with type 2 diabetes.

was not associated with better glycaemic control in any therapy category. Moreover, there was no correlation between frequency of monitoring and HbA1c levels in any of the treatment categories.

The results are not entirely new on this point [8–14], but this is the first large-scale study concerning SMBG and glycaemic control in type 2 diabetes performed in primary care in northern Europe. More important is, however, that in contrast to most previous observational studies on SMBG, we have addressed the question concerning whether users and non-users of SMBG constitute different groups in terms of severity of the diabetic disease.

The users of SMBG on dietary recommendations were younger than non-users. Users of SMBG on oral agents had lower creatinine levels than non-users. There were also minor differences concerning anti-hypertensive medication showing that in some treatment groups the non-users of SMBG were on more anti-hypertensive medication than the users of SMBG. We found no differences in diabetes-related complications, comorbidity, or concomitant medications indicating a more complicated diabetes disease in the SMBG user group as compared with non-users of SMBG. Thus, we conclude that the lack of improved glycaemic control among users of SMBG

could not be explained by a higher prevalence of diabetes-related complications in this category.

The prevalence of type 2 diabetes in the population studied was 3.3%, which is in accordance with previous studies concerning the prevalence of diabetes in Sweden [16,17]. The baseline characteristics of the population described in Table I show that the therapy groups are of equal size and that there is a widespread use of SMBG in all groups. The frequency of testing showed a large individual variation, but the proportion of patients testing at least once daily did not differ from what has previously been reported for patients with type 2 diabetes [8,9,14].

Several reviews of the few randomized trials performed on this subject have found no benefit from SMBG [18–20] for patients with type 2 diabetes. The most recent review [21], however, on patients with non-insulin treated type 2 diabetes concluded that SMBG might be effective in improving glycaemic control, but the studies included were small and of low methodological quality and further trials were recommended. After this, a large longitudinal three-year study [14] failed to show any positive effect on metabolic control in patients with non-insulin treated type 2 diabetes.

The few studies that have shown positive effects on glycaemic control have either combined SMBG with an education programme [22,23] or the positive effect has been in subgroups with high HbA1c-levels [11] or patients who had documented experience of adjusting their insulin levels [9]. The only randomized and blinded study on SMBG for diabetic patients not taking insulin failed to show a positive effect of SMBG on glycaemic control, although the study was small [24]. The positive effect on glycaemic control shown in a previous observational study [10] has been interpreted [25] to be the result of self-selection since self-care practices and healthy lifestyle were more common in the individuals who performed SMBG according to the guidelines. A recent European retrospective study on SMBG and long-term outcome, the ROSSO-group study, showed that SMBG was associated with decreased diabetes-related morbidity and all-cause mortality in patients with type 2 diabetes [26]. However, the use of SMBG was not associated with improved glycaemic control and the results may thus be interpreted as showing that SMBG is associated with a healthier lifestyle. Accordingly, a potential bias in the ROSSO study might be that SMBG acts as a marker for patients with higher socioeconomic and educational status, since the cost for test strips is not reimbursed in Germany in the absence of insulin treatment [26].

Our study had a cross-sectional observational design and we cannot rule out that the use of SMBG has an effect on glycaemic control; the non-users of SMBG might be different from the users in a way we have not been able to control. However, in the absence of large prospective randomized studies on SMBG in type 2 diabetes, we conclude that in routine use in primary care, SMBG is not associated with better glycaemic control. A possible explanation for the lack of effect of SMBG on glycaemic control might be that SMBG needs to be a part of an education programme to empower the patient to adjust the medication according to the SMBG results. As type 2 diabetes is a heterogenic disease, many authors argue for more individualized treatment goals [27–29] for patients with diabetes. Accordingly, we believe that the use of SMBG should also be individualized. Guidelines for the use of SMBG are beneficial and the Swedish Society for Diabetology has issued recommendations on how to use SMBG [30]. Considering that the cost for test strips for SMBG is far from negligible, the need to implement an evidence-based monitoring strategy for patients with type 2 diabetes in primary care is evident.

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