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The Efficacy of Self-Monitoring of Blood Glucose in NIDDM Subjects: A criteria-based literature review

[Review/Commentary/Position Statement: Review Article]

Faas, A. MD, PhD; Schellevis, F. G. MD, PhD; van Eijk, J. T. M. PhD

From the Institute for Research in Extramural Medicine (EMGO Institute), Vrije Universiteit, Amsterdam, The Netherlands.
Address correspondence and reprint requests to A. Faas, MD, PhD, Institute for Research in Extramural Medicine (EMGO Institute), Vrije Universiteit, van der Boechorststraat 7, 1081 BT Amsterdam, The Netherlands.
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Outline

Graphics

Abstract^

OBJECTIVE -To determine the efficacy of self-monitoring of blood glucose (SMBG) in NIDDM patients from studies published during the years 1976-1996.

RESEARCH DESIGN AND METHODS -A systematic literature search was conducted. The selected studies were assessed for their methodological quality and reviewed on the reported efficacy and on the following topics: characteristics of the study population, follow-up duration, nature of the efficacy measures, use of a therapy decision scheme, nature of the intervention, nature of the SMBG device, patient instruction, type of SMBG regime, assessment of the frequency of self-measurement, and whether feedback was given on the measured glucose levels. Studies with positive conclusions on the efficacy of SMBG were compared with studies with negative conclusions on the basis of these characteristics to determine which factors could have contributed to the results.

RESULTS -Of the 11 studies identified, only 4 met all quality criteria. Six of the studies were randomized controlled trials, of which only one showed positive conclusions regarding the efficacy of SMBG. Although the studies differed on most topics, no factor could be identified as responsible for the results of the studies.

CONCLUSIONS -The efficacy of SMBG in NIDDM patients is still questionable and should be tested in rigorous high-quality randomized controlled trial, for which some recommendations are given.

Abbreviations: RCT, randomized controlled trial; SMBG, self-monitoring of blood glucose.

Self-monitoring of blood glucose (SMBG) by IDDM patients is a widely accepted treatment method. SMBG aims at collecting detailed information on blood glucose levels at many time points, enabling maintenance of a more-constant glucose level by more-precise insulin dosing. Moreover, by participating in the treatment, the patient can cope more independently with his or her disease.

On the contrary, for patients with NIDDM, the value of SMBG is still open for discussion [1]. The American Diabetes Association has advised SMBG for patients using insulin, commenting that "although controversial, SMBG may be useful for patients not treated with insulin" [2], without indicating for which subgroup of NIDDM patients SMBG can be useful. Theoretically, SMBG by patients with NIDDM could lead to better compliance with diet and exercise advice and with medication regimens, eventually resulting in better glycemic regulation. This hypothesis assumes that lifestyle change is facilitated by SMBG. Moreover, SMBG in NIDDM patients could lead to more autonomous disease management and, in view of the growing number of NIDDM patients anticipated in the near future, could reduce the expected increase in health care consumption [3].

This literature review aims to clarify the efficacy of SMBG in NIDDM patients using diet or diet with oral antidiabetic medications as determined in published studies.

RESEARCH DESIGN AND METHODS^

Selection of studies^

A Medline search on CD-ROM was performed covering the period from 1976 to February 1996 using the key words (major subheadings) "diabetes mellitus non-insulin dependent" and "blood glucose self monitoring." Only patient-based studies were included. Studies in patients using exclusively insulin to control blood glucose levels were excluded. The reference lists of the selected studies were checked for other publications on the same topics. To check the completeness of our search, a second Medline search covering the same period was performed using the major subheadings "diabetes mellitus non-insulin dependent" and "blood glucose" in combination with "self care" or "patient education."

Quality assessment^

For all included studies, a qualitative methodological assessment was performed. For the qualitative assessment, we adopted the following criteria from Deyo [4] and ter Riet et al. [5]:

1. Has the proposition of the research been formulated?

2. Have hypotheses been formulated that are being tested?

3. Are the variables unambiguously formulated?

4. Is there a statement about the reliability and validity of the measurement methodology?

5. Is the population defined; are there specified criteria for inclusion or exclusion?

6. Have appropriate statistical methods been employed?

7. Are the answers to the proposition logically concluded from the research described?

Scoring for each criterion was carried out by the first author (A.F.) using a three-point scale: conforms to, conforms somewhat to, and does not conform to the criterion.

Review topics^

Because the randomized controlled trial (RCT) is considered the best methodological instrument for measuring efficacy, only RCTs were used for further review based on the following topics:

- study population (size, type of NIDDM patients, type of NIDDM treatment);

- duration of follow-up;

- nature of efficacy measures;

- use of a therapy decision scheme by the care provider;

- nature of intervention (contrast);

- nature of SMBG device (strips, meter);

- key points of patient instruction (technical instruction, checking on appropriate use) and patient education (relationship of diet and exercise with SMBG);

- self-monitoring regimen (fixed or on-demand regimen, monitoring frequency);

- whether self-monitoring frequency was assessed;

- whether patients received feedback from the care provider on self-measured glucose levels;

- mean glycated hemoglobin (HbA_{1c}) level at baseline and after follow-up;

- conclusion of the authors concerning efficacy.

Analysis^

Trials with positive results were compared with trials with negative conclusions on the basis of the other above-mentioned review topics. A difference was considered relevant if a specific topic occurred in one or more trials with positive results and not in any trial with negative results, or the reverse.

RESULTS^

Selection of studies^

The first Medline search yielded 77 publications. Nine patient-based studies met the inclusion criteria. An additional three studies were found by searching the reference lists. One study was excluded because patients were mainly using insulin [6]. The second Medline search yielded 813 publications, but no additional qualified studies could be identified. Of the 11 remaining studies, 4 [7-10] were uncontrolled prospective studies (Table 1), 1 was a retrospective study comparing two groups [11], and 6 were RCTs [12,17].

Table 1. Studies on the efficacy of SMBG in NIDDM patients

Methodological quality^

Of the 11 studies included, only 4 met all qualitative criteria; these 4 were all RCTs (Table 2). The most frequent methodological deficiencies were ambiguous formulation of variables, lack of statement about reliability and validity of measurements, and no clear definition of the included population.

Table 2. Quality of studies on the efficacy of SMBG in NIDDM patients

Characteristics of the RCTs^

The number of patients included in each trial group ranged from 12 to 73. All RCTs except for one included both patients using diet and patients using diet with oral antidiabetic medications (Table 3). One study also included patients using insulin; in this study, half of the patients used insulin [12]. Two studies included only patients with poor glycemic control (fasting blood glucose >8.8 mmol/l), and one study included only obese patients. The mean baseline HbA_{1c} levels of the different study groups ranged between 6.1 and 12.4%. All but one study had a follow-up period of 6 months or longer. All trials except for one used HbA_{1c} level and body weight as the main efficacy measures.

Table 3. Characteristics of six RCTs on the efficacy of SMBG in NIDDM patients

Devices, instruction, education, and SMBG regime^

In two RCTs, patients used strips without a meter, and in two others, both strips and a meter. In the remaining two RCTs, no description of the device used was found (Table 4). In all six RCTs, patients received technical instruction on how to use the device, but in only three of them was a check on the accuracy of the patients' performance carried out. In four trials, patients were not only instructed to use SMBG but also educated how to use SMBG in relation to diet and physical exercise. The SMBG regimens differed among the six RCTs. In two RCTs, no fixed regimen was practiced, and in the RCTs with a fixed SMBG regimen, four different regimens were used. In four studies, the frequency of self-monitoring (by measuring blood or urine glucose) was assessed; in the same studies, patients received feedback from their physician on the self-measured glucose levels. In three studies, a therapy decision scheme was used, but in one of these studies [15], this scheme was applied only in the SMBG group.

Table 4. SMBG device, instruction, accuracy check, and SMBG regime in trials on the efficacy of SMBG

Efficacy^

The authors' conclusions from the six RCTs are predominantly negative (Table 5). Three studies did not show any difference between SMBG and urine testing. One other study did not show any efficacy of SMBG above usual care without SMBG. Only one RCT [15] reported a significantly positive result of SMBG compared with no SMBG. In two trials, slightly positive but nonsignificant results of SMBG were found regarding the mean change in HbA_{1c} level (SMBG group: -0.50%; urine testing group: -0.13%; non-SMBG group: -0.36%) [13] and the mean weight loss (SMBG group: -2 kg; non-SMBG group: 0 kg) [14].

Table 5. The efficacy of SMBG in six RCTs

The main conclusion from the study by Estey et al. [16] comparing SMBG alone with SMBG in combination with education on compliance is that the latter situation leads to better compliance with performing SMBG but not to better glycemic control.

No difference on the basis of any characteristic was found between the RCTs with positive and negative conclusions. Of the four RCTs meeting all quality criteria [12-15], three showed a negative and one a positive conclusion on the efficacy of SMBG.

CONCLUSIONS^

The main conclusion from this review is that the efficacy of SMBG in NIDDM patients is still questionable.

Because we used a Medline and a reference-based search, the completeness of our list of publications is, in our opinion, as high as possible. Exclusion criteria for non-patient-based research and for papers with patients using exclusively insulin were clear and unambiguous and therefore could not have introduced selection bias. Our decisions to exclude one study in which patients mainly used insulin [6] and to include one study in which only half of the patients used insulin [12] could be criticized. Because we aimed to draw conclusions on the efficacy of SMBG for NIDDM patients using only diet or diet with oral antidiabetic medications, we believe that these decisions were correct.

The five RCTs comparing SMBG with no SMBG or with urine testing [12-15,17] had appropriate designs to answer the question of SMBG efficacy. Only the Rutten et al. [15] study reported a positive effect of SMBG on glycemic control. The comparison of characteristics of this study with characteristics of studies with negative conclusions revealed no differences. In the two RCTs with nonsignificant positive results [13,14] larger study-group sizes would possibly have resulted in statistically significant differences, although the number of patients included in one of these trials [13] is comparable to the number of patients included in the study with the positive results.

The frequency of measuring blood glucose by patients practicing SMBG could be a point of difference between the RCTs with positive and negative results. The positive RCT [15] used no fixed SMBG regimen, so patients were free to measure blood glucose whenever necessary in their own view. Two trials with negative conclusions [12,13] used fixed regimens. Frequencies of glucose measurement in the open and fixed regimens could have been different. However, as the Rutten et al. [15] study did not report on the measurement frequencies, conclusions on this point cannot be drawn.

Results of SMBG trials are potentially biased if optimal antidiabetic therapy, for example, the use of a therapy decision scheme, is not applied in both study groups. In two studies with a negative result and in the only study with a positive result, such a scheme was used. However, because in the latter study [15] this scheme was applied only in the SMBG group and not in the control group, it remains unclear whether SMBG or the use of a therapy decision scheme is responsible for the positive results.

Additionally, we analyzed the uncontrolled studies [7-11] for possible determinants of efficacy of SMBG. Three uncontrolled studies showed a positive trend toward SMBG efficacy in glycemic control [7,9,10]. Uncontrolled elements, such as attention of doctors and nurses and patient education, could have contributed to the positive results. We could not identify any factor enhancing SMBG efficacy that had not been taken into account in the RCTs in these studies.

The published studies do not provide clear-cut suggestions on the design of a study in which the question of the efficacy of SMBG can be answered definitively. Nevertheless, we give some suggestions that, in our view, will increase the chances for carrying out a successful study. For such a study, only an RCT design should be used. The power of the study should be calculated a priori, so that the number of included patients per group will guarantee detection of a relevant difference between the study groups. The contrast of SMBG versus non-SMBG is more appropriate for establishing the efficacy of SMBG than is the contrast of SMBG versus urine testing. Non-SMBG should include usual care under careful protocols. An identical antidiabetic therapy decision scheme should be applied in both the experimental and control groups. Furthermore, we agree with the conclusion of Estey et al. [16] that in future research, intervention regarding SMBG should be comprehensive, stimulating patients not only to perform SMBG but to combine it with a program of lifestyle change. We think that emphasis on changing lifestyle habits and on training patients and physicians on how to cope with these lifestyle changes could lead to positive effects of SMBG on glycemic control. These aspects should be carefully described and included in the study protocol. Lifestyle education of patients in the non-SMBG control group should cover the same topics with the same intensity as in the SMBG group. In this way, the contrast between the study groups consists of the performance of SMBG and the availability of information on blood glucose levels, which can be used as an additional incentive for lifestyle changes. We believe that effective coping of patients and physicians with lifestyle changes in combination with SMBG is the most promising strategy for achieving a positive effect of SMBG. To test this hypothesis, outcome measures regarding changes in lifestyle should also be added.

The application of SMBG should have protocols. Preferably, a semi-fixed regimen should be used (a minimum of four measurements per week, two fasting and two after meals; additional measurements on indication and on demand) that includes detailed patient instruction and the possibility of measurement of compliance with the SMBG regimen (by using devices with memory, for example, although Page et al. [18] stated that for this more advanced type of meter, efficacy is questionable and costs are high). Additionally, the care giver should give feedback on the patients' self-measured glucose levels. In such a study, emphasis should be on the unambiguous formulation of the study variables, on the validity and reliability of the measurements, and on the clear definition of eligible patients. For an efficacy study, we would recommend including only patients with poor glycemic control. This would increase the chances for establishing a positive outcome; moreover, this patient group would be the first in which SMBG is introduced in daily practice if efficacy is proven. After having established the efficacy of SMBG, an effectiveness study could be undertaken in which well-controlled patients are included. HbA_{1c} should be used as the main outcome variable, since it is the best parameter for long-term glycemic control, which is the main objective to be influenced by the introduction of SMBG [19,20]. Moreover, HbA_{1c} correlates well with the mean glucose concentration [21] and has proven to be responsive to gradually occurring changes [22].

In the meantime, we would recommend the use of SMBG in daily clinical practice for NIDDM patients with poor glycemic control despite optimal antidiabetic therapy, with the annotation that SMBG has yet to be proven effective as a technique to improve glycemic control.

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