REVIEW ARTICLE

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Self-monitoring of blood glucose as control tool in the different management contexts for Type 2 Diabetes *Mellitus*. What is its current role in non-insulin users?

Automonitoreo glicémico como herramienta de control en los distintos contextos de manejo para diabetes mellitus tipo 2 ¿Cuál es su rol actual en no-usuarios de insulina?

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| Abstract |

Introduction: Self-monitoring blood glucose (SMBG) has been considered a key element in the management of Type 2 Diabetes *Mellitus* (T2DM). However, its role in glycemic control in non-insulin users has been long discussed.

Objective: To conduct a narrative literature review of the benefits of SMBG in non-insulin-treated patients with T2DM.

Materials and Methods: A scientific literature search was conducted in the following databases: Pubmed, ScienceDirect, Embase, SciELO, Cochrane and Medline. Relevant articles were selected according to the established criteria. In addition, some studies included in the references of the initially selected articles were added to the review since they were considered relevant for its objective.

Results: The following records were included in the review: 14 controlled clinical trials, 13 observational studies, 10 clinical practice guidelines, 7 narrative reviews, 5 meta-analyses, and 1 systematic review.

Conclusion: Based on the evidence found in this review it is possible to say that the use of SMBG in patients with T2DM is beneficial and that it has a positive impact on non-insulin users in terms of achieving glycemic control and defining therapeutic changes.

Keywords: Diabetes *mellitus*, Type 2; Diabetes *mellitus*; Blood Glucose Self-Monitoring; Disease Management; Health Education; Blood glucose (MeSH).

| Resumen |

Introducción. El automonitoreo glicémico es considerado un elemento clave en el manejo de la diabetes *mellitus* tipo 2; sin embargo, su rol en el control glicémico en pacientes no-usuarios de insulina ha sido discutido a lo largo de los años.

Objetivo. Realizar una revisión narrativa de la literatura acerca de los beneficios del automonitoreo glicémico en pacientes con diabetes *mellitus* tipo 2 no-usuarios de insulina.

Materiales y métodos. Se realizó una búsqueda de literatura científica en las bases de datos PubMed, ScienceDirect, Embase, SciELO, Cochrane y Medline. Se seleccionaron artículos pertinentes según criterio y se agregaron algunos de los mencionados en las referencias de las publicaciones seleccionadas de la búsqueda inicial que tenían utilidad para la revisión.

Resultados. Se incluyeron 14 ensayos clínicos controlados, 13 estudios observacionales, 10 guías de práctica clínica, 5 metanálisis, 1 revisiones sistémicas y 7 revisiones narrativas con información relevante para el desarrollo de la presente revisión.

Conclusión. La evidencia encontrada demuestra beneficios del automonitoreo glicémico en pacientes con diabetes *mellitus* tipo 2 y confirma su impacto positivo en no-usuarios de insulina para lograr control glicémico y definir cambios terapéuticos.

Palabras clave: Diabetes *mellitus* tipo 2; Diabetes mellitus; Automonitorización de la glucosa sanguínea; Manejo de la enfermedad; Educación en salud; Glucemia (DeCS).

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Introduction

Diabetes *mellitus* (DM) is usually a silent disease that constitutes one of the most challenging health problems of the 21st century worldwide. DM prevalence is rapidly increasing, and it has been estimated that by 2 030 approximately 550 million people will be affected by this disease globally. (1) Over the last decades, DM cases prevalence has experienced an increase that exceeds that of any other health condition (2-5); it can be developed by anyone, regardless of their socioeconomic status, and it has been associated with a decrease in quality of life, for it affects multiple organ systems; also it has been associated with micro and macro-vascular complications. (2-5) Large clinical trials have reported that achieving effective glycemic and metabolic control reduces the incidence of complications related to diabetes and improves its prognosis. (6,7)

Taking this into account, self-monitoring blood glucose (SMBG) is a primary tool for diabetes management, making possible the evaluation of the effectiveness of glycemic control, which in turn allows making relevant adjustments regarding the management of the disease. (8-10) Currently, it is an integral component of intensive insulin therapy in patients with Type 2 DM, as well as in patient education programs. (11-13) The American Diabetes Association (ADA), the Latin American Diabetes Association (ALAD) and the Canadian Diabetes Association (CDA) support SMBG in Type 1 and Type 2 Diabetes *Mellitus* (T2DM) patients using insulin since its main benefits include helping to achieve the glycosylated hemoglobin (HbA1c) level goal established, minimizing glycaemia variability, and helping predicting the risk of severe hypoglycemia. (12-17)

When performed several times a day, SMBG provides an opportunity to correct glycaemia and improve the quality of glycemic control once the insulin regimen has been established, which has led to believe that its benefits are less clear in Non-Insulin-Treated patients. (15) In this sense, a meta-analysis conducted in 2012 showed that SMBG carried out regularly by Non-Insulin-Treated T2DM patients was associated with a statistically significant glycemic control positive result, but without clinical relevance, for it reported a 0.26% decrease in HbA1c levels (95%CI: (-0.39)-(-0.13)) in favor of SMBG after 6 months of implementation. (16) Likewise, in 2013, SMBG in this population was supported by the T2DM management guidelines of ALAD (17), particularly for the initiation or adjustment of medication in intercurrent situations that may decompensate glycemic control and in cases where a better understanding of the factors associated with oscillations in glycaemia is desired. (17)

Also, the uncertainty on the role of SMBG in of non-insulin users with diabetes was addressed in 2014 by the ADA Association in a document on diabetes management guidelines where it is recommended to use this tool in a broader educational context and to help guiding treatment decisions in insulin and non-insulin users with T2DM. (13) In order to address SMBG role in non-insulin users it is necessary to review its importance in the different T2DM management strategies.

For SMBG to be an effective self-management tool in non-insulin-treated patients with T2DM, both the patient and the physician must actively engage in performing SMBG, interpreting the results obtained and acting based on said values. Thus, the objective of the present study is to interpret and describe the results of the different studies that have addressed this issue in order to present a comprehensive account of the current evidence on SMBG in non-insulin-treated T2DM patients, and to present other clinical scenarios where SMBG is required.

Materials and Methods

A narrative literature review on SMBG in T2DM patients was conducted. Stages of the literature review were as follows: bibliographic search, selection of articles and review of the selected studies references. In addition, some of the articles included in the references of the selected publications were also added in the final selection upon meeting certain criteria (described in the following paragraphs).

During the first stage of the review, a search strategy was established taking into account the different T2DM management scenarios according to the 2017 management guidelines of ADA. (18) Then, the initial search was made from March 2017 to July 2017 under the following parameters:

- Metasearch engines and digital databases: Pubmed, ScienceDirect, Embase, SciELO, Cochrane and Medline.
- Search strategy: ("Self-Monitoring Blood Glucose" AND "Health Education" AND "Type 2 Diabetes Mellitus") OR ("Self-Monitoring Blood Glucose" AND "Lifestyle Changes" AND "Type 2 Diabetes Mellitus") OR ("Self-Monitoring Blood Glucose" AND "Diabetes Mellitus-Non Insulin Dependent" AND "Type 2 Diabetes Mellitus"), OR ("Self-Monitoring Blood Glucose" AND "Diabetes Mellitus - Insulin Dependent" AND "Type 2 Diabetes Mellitus")
- Time frame: 2010-2017.
- Languages: English and Spanish.
- Type of studies: clinical practice guidelines, observational studies, controlled and randomized clinical trials, and systematic reviews or meta-analyses.
- Eligibility criteria: use of evidence and graduation scales of the recommendations, and being published by authors affiliated to institutions recognized worldwide.

After the initial search was done, a total of 1062 documents were found. The title and abstract of the 1062 records were read individually, and based on the eligibility criteria described above, the following articles were excluded: those with redundant information in relation to articles already selected, those addressing topics unrelated to SMBG in T2DM. Afterwards, duplicate records were removed, and 26 articles were selected.

Finally, after an exhaustive manual review of the references included in this 26 articles was made, some articles found in said references and which met the inclusion criteria described before were added to the final selection of studies regardless of their publication year. Likewise, these articles included some review articles known to the authors and useful historical references about SMBF in T2DM provided their full text access availability and that they were consistent with the objective of the literature review.

Results

A total of 1 062 records were found after the initial search was performed. After reading the title and abstract of each article, based on the inclusion criteria abovementioned, and after duplicates removal was done, 1 036 were excluded, which resulted in the selection of 26 articles. In addition, 24 more articles found in the references of these 26 articles and published before the time frame were also included. In the end, 14 controlled clinical trials, 13 observational studies, 10 clinical practice guidelines, 7 narrative reviews, 5 meta-analyses, and 1 systematic review were included in this narrative review. The screening and selection process are shown in Figure 1, while Table 1 present the main characteristics of the studies included.

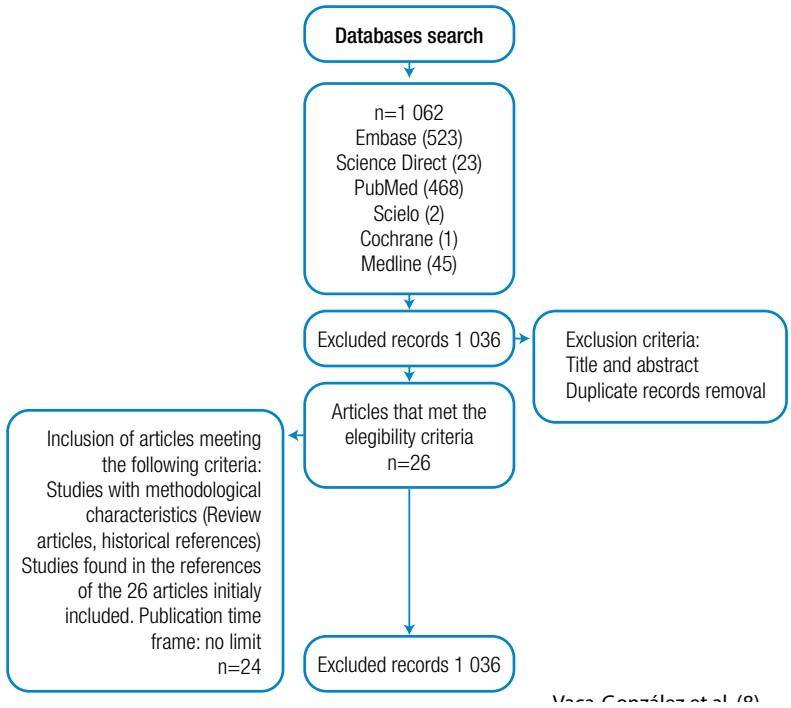

Figure 1. Flow diagram depicting the selection process of the articles included in the review. Source: Own elaboration.

Table 1. Characteristics of the studies included in the review. Part A.

Authors, year of publication	Country	Type of study	Study population	Conclusion
Whiting *et al.* (1) 2011	Belgium	Observational study	People with diabetes worldwide	Previous estimates have been very conservative. The new International Diabetes Federation estimates use a simple and transparent approach and are consistent with recent estimates provided by the Institute for Health Metrics and Evaluation in the Global Burden of Disease study.
Cowie *et al.* (2) 2009	United States	Observational study	7 267 people aged ≥12 years with diabetes o prediabetes.	Hyperglycemic conditions are present in over 40% of people aged ≥20 years. Worldwide, diabetes prevalence is higher in minority groups. Diabetes diagnosis cases have increased over time, but other conditions (hyperglycemia, prediabetes) have remained relatively stable
American Diabetes Association (3) 2008	United States	Observational study	People with diabetes in USA.	The economic costs of diabetes in the US do not include intangible social costs such as pain and suffering, care provided by nonpaid caregivers, extra medical charges associated with undiagnosed diabetes. Likewise, diabetes related health care expenditures are not included, including health care administrative costs, over-the-counter medicines, clinical training programs, and research-based and infrastructure-based development. Diabetes burden affects all sectors of society.
Engelgau (4) 2004	United States	Narrative Review	People with diabetes in USA.	The diabetes epidemic has already taken an extraordinary toll on the population of USA. Efforts must be directed at delaying or preventing the complications of diabetes and diabetes itself
Cowie *et al.* (5) 2006	United States	Observational study	20 years adults in USA.	The prevalence of diagnosed diabetes cases has increased significantly over the last decade, while undiagnosed diabetes and glomerular filtration rate (GFR) prevalence rates have remained relatively stable. Current prevalence of total diabetes and IFG are excessive in relation to national health objectives, particularly in minority groups.
UK Prospective Diabetes Study (UKPDS) Group (6) 1998	United Kingdom	Controlled clinical trial	25-65 years old patients newly diagnosed with T2DM	Intensive blood-glucose control with metformin decreases the risk of diabetes-related endpoints in overweight diabetic patients, and it is associated with less weight gain and fewer hypoglycemic shocks attacks than intensive blood-glucose control with sulphonylureas or insulin, therefore it may be the first-line pharmacological treatment in these patients.
Ohkubo *et al.* (7) 1995	Japan	Controlled clinical trial	Non-Insulin Treated T2DM patients	Intensive glycemic control by means of multiple insulin injection therapy can delay the onset and progression of diabetic retinopathy, nephropathy and neuropathy. The glycemic threshold to prevent the onset and progression of diabetic microangiopathy is HbA1c <6.5%, fasting blood sugar level <110 mg/dl, and 2-h post-prandial blood glucose concentration <180 mg/dl.

Table 1. Characteristics of the studies included in the review. Part A (Continued).

Authors, year of publication	Country	Type of study	Study population	Conclusion
Nauck *et al.* (8) 2014	Germany	Controlled clinical trial	Patients with T2DM who have initiated a conventional insulin regimen (basal or premixed insulin regimen with or without additional oral glucose-lowering agents)	SMBG profiles once a week or the disclosure of glycosylated hemoglobin results did not improve glycemic control in these patients, although hyperglycemia indicators increased the probability of therapy intensification. Greater intensification may be necessary to have an impact on glycemic control.
Clar *et al.* (9) 2010	Germany	Systematic review	T2DM patients who had not been treated with insulin therapy or who had initiated a basal insulin regimen in combination with oral agents	Clinical effectiveness of SMBG in improving glycemic control is limited in people with T2DM who are on an oral agents treatment or with a diet alone management approach, and therefore it is unlikely to be cost-effective. SMBG may only lead to a better glycemic control in the context of appropriate education interventions, both for patients and health-care professionals, on how to respond to these data in terms of lifestyle and treatment adjustment. Likewise, SMBG might be more effective if patients are able to self-adjust their drug treatment.
Farmer *et al.* (10) 2009	United Kingdom	Controlled clinical trial	Non-insulin-treated T2DM patients aged ≥25 years and with glycosylated hemoglobin (HbA1c) levels ≥ 6.2%.	SMBG in Non-Insulin-Treated patients, with or without instruction regarding the use of these findings to adjust self-care practices, did not lead to a significant improvement in glycemic control compared to usual care monitoring through glycosylated hemoglobin levels. There was no convincing evidence supporting the recommendation for routine self-monitoring in all patients, nor evidence of improved glycemic control in predefined patient subgroups.
Gruesser *et al.* (11) 1996	Germany	Observational study	Outpatients with T2DM undergoing conventional insulin treatment	An educational program proves to be efficient and practical for T2DM patients undergoing conventional insulin therapy in an outpatient care context.
Cheng *et al.* (12) 2013	Canada	Clinical practice guideline	Patients with diabetes	SMBG has beneficial effects in Type 1 DM and T2DM patients.
American Diabetes Association (13) 2014	United States	Clinical practice guideline	Patients with diabetes	SMBG has beneficial effects in T1DM and T2DM patients.
Schnell *et al.* (14) 2014	Germany	Narrative Review	Patients with T2DM	SMBG is a key component for the optimization of diabetes treatment in insulin-treated diabetes patients.
Nathan *et al.* (15) 1993	United States	Observational study	Insulin-Treated T2DM patients	Intensive insulin therapy in insulin-treated diabetes patients effectively delays the onset of diabetic retinopathy, nephropathy, and neuropathy and slows downs their progression.
Malanda *et al.* (16) 2012	Netherlands	Meta-analysis	Non-Insulin-Treated T2DM patients	After six months of implementing SMBG in Non-Insulin-Treated T2DM patients, its effect is small and it subsided after 12 months of implementation. It did not have an impact on patients' satisfaction, their general well-being or their health-related quality of life in general.
Pan American Health Organization. (17) 2013	Latin-America	Clinical practice guideline	Patients with diabetes	SMBG has beneficial effects in T2DM patients.
American Diabetes Association (18) 2017	United States	Clinical practice guideline	Patients with diabetes	SMBG has beneficial effects in T1DM and T2DM patients.
Elgart *et al.* (19) 2016	Argentina	Observational study	T2DM patients	Education interventions aimed at the patient and prescription audit may optimize the use of SMBG, as well as the outcomes of the treatment.
Polonsky *et al.* (20) 2011	United States	Controlled clinical trial	Non-Insulin-Treated and poorly controlled T2DM patients	Appropriate use of structured SMBG significantly improves glycemic control and facilitates more timely/aggressive treatment changes in Non-Insulin-Treated T2DM patients.
Kirkt *et al.* (21) 2010	United States	Narrative Review	T2DM patients	In patients using insulin SMBG is needed for self-management and for the adjustment of the dose. In the case of patients who are administered oral medication, profiling glucose trends and high or low blood glucose confirmation can be a useful complement for successful management of the disease.
Hirsch *et al.* (22) 2008	United States	Clinical practice guideline	T2DM patients	Successful glucose monitoring depends on the continuity of individualized care and several processes causing higher self-care levels.
Bunker *et al.* (23) 2010	United States	Narrative Review	T2DM patients	SMBG has beneficial effects in T2DM patients.
Funnell *et al.* (24) 2011	United States	Clinical practice guideline	T2DM patients	SMBG has beneficial effects in T2DM.

Table 1. Characteristics of the studies included in the review. Part A (Continued).

Authors, year of publication	Country	Type of study	Study population	Conclusion
Al-Keilani *et al.* (25) 2017	Jordan	Observational study	Patients with diabetes	Treatment regimen and health education on SMBG are predictors of adherence to it
Chidum *et al.* (26) 2011	Trinidad and Tobago	Controlled clinical trial	T2DM patients	SMBG significantly improved glycemic control and cardiovascular risk profile,
Parkin *et al.* (27) 2011	United States	Narrative Review	Non-Insulin-Treated T2DM patients	SMBG helps guiding glycemic management strategies and has the potential to improve problem-solving and decision-making skills for both patients and clinicians. The adequate use of structured SMBG facilitates this important behavioral and emotional process that eventually leads to patient's empowerment.
Schnell *et al.* (28). 2009	Germany	Clinical practice guideline	T2DM patients	SMBG is recommended in all types of treatment approaches for diabetes management in order to achieve near normal glucose control without increasing the risk of developing hypoglycemia. The recommended frequency and pattern of SMBG depends on the type of diabetes, the treatment approach and the glycosylated hemoglobin and pre- and postprandial blood glucose levels that have been individually established.
Wadden *et al.* (29) 2006	United States	Controlled clinical trial	T2DM patients with overweight	Lifestyle interventions, patient education and diabetes support reduce cardiovascular morbidity and mortality rates in overweight individuals with T2DM.
World Health Organization (30) 2003	Switzerland	Narrative Review	People with chronic conditions	Adherence to therapies is a primary determinant of treatment success. Poor adherence mitigates optimum clinical benefits and therefore overall effectiveness of health systems is reduced.
García de la Torre *et al.* (31) 2013	Spain	Controlled clinical trial	Patients newly diagnosed with T2DM	The use of SMBG in an educational program effectively increases the regression rate in newly diagnosed T2DM in a 3 years follow-up period. SMBG-based educational programs should be extended to primary care scenarios.
Durán *et al.* (32) 2010	Spain	Controlled clinical trial	Patients newly diagnosed with T2DM	SMBG-based educational and pharmacological programs empower patients to achieve nutritional and physical activity goals, and encourage physicians and patients to use SMBG to optimize therapy outcomes.
American Diabetes Association (33) 2016	United States	Clinical practice guideline	T2DM patients	SMBG has beneficial effects in T1DM and T2DM patients.
Wambui-Charity *et al.* (34) 2016	Kenya	Observational study	T2DM patients	Patient education and the free provision of glucostrips are recommended strategies to improve treatment adherence and glycemic control using SMBG.
Poolsup *et al.* (35) 2009	Thailand	Meta-analysis	T2DM patients	SMBG improves glycemic control in Non-Insulin-Treated T2DM patients, particularly in those with a glycosylated hemoglobin baseline ≥8%
Towfigh *et al.* (36) 2008	United States	Meta-analysis	Non-Insulin-Treated T2DM patients	SMBG produces a statistically significant but clinically modest effect in controlling blood glucose levels in patients with diabetes who are not using insulin.
Claude-Mbanya *et al.* (37) 2017	Cameroon	Observational study	Patients with diabetes	SMBG is important for self-management, since it improves glycemic control. There is a need to educate healthcare payers and providers and patients in order achieve better access to and affordability of self-management tools and patient education strategies.
International Diabetes Federation (38) 2009	Belgium	Clinical practice guideline	T2DM patients	SMBG has beneficial effects in Non-Insulin-Treated T2DM patients.
Young *et al.* (39) 2017	United States	Controlled clinical trial	Non-Insulin-Treated T2DM patients	After one year if implementing SMBG there is not clinically or statistically significant differences in terms of glycemic control between those who used SMBG and those who did not.
Farmer *et al.* (40) 2012	United Kingdom	Meta-analysis	Non-Insulin-Treated T2DM patients	SMBG does not have any clinically significant effect in the clinical management of Non-Insulin-Treated T2DM patients, but it has statistically significant effects in glycosylated hemoglobin levels control.
Weinger *et al.* (41) 2011	United States	Controlled clinical trial	Poorly controlled patients with diabetes	A behavioral program is effective in improving glycemic levels in adults with long-duration diabetes.
Klonoff *et al.* (42) 2011	United States	Narrative Review	Non-Insulin-Treated T2DM patients	Educational interventions aimed at patients and healthcare professionals on how to act depending on the data provided by SMBG are required for the latter to be effective.
Allemann *et al.* (43) 2009	Switzerland	Meta-analysis	Non-Insulin-Treated T2DM patients	SMBG is associated with a significant improvement in glycemic control in Non-Insulin Treated T2DM patients.
Schnell *et al.* (44) 2011	Germany	Clinical practice guideline	T2DM patients	SMBGBG performance, length and frequency depend on each patient's clinical circumstances and the quality of glycemic control.
Evans *et al.* (45) 2012	United Kingdom	Observational study	T2DM patients	There has been an increase in the number of reagent strips provided for SMBG, yet this procedure is not recommended in T2DM patients.
Karter *et al.* (46) 2011	United States	Observational study	T2DM patients	A higher frequency of SMBG was associated with a clinically and statistically improvement of glycemic control regardless of diabetes type or treatment.

Table 1. Characteristics of the studies included in the review. Part A (Continued).

Authors, year of publication	Country	Type of study	Study population	Conclusion
Murata *et al.* (47) 2006	United States	Observational study	T2DM patients	Intensified blood glucose monitoring improved glycemic control in a large cohort of stable, insulin-treated veterans with T2DM. SMBG provided a strong stimulus to improved self-care, which resulted into clinically important and sustained reductions in glycosylated hemoglobin levels.
Rutten *et al.* (48) 1990	Netherlands	Controlled clinical trial	T2DM patients	SMBG has beneficial effects in patients with T2DM.
Muchmore *et al.* (49) 1994	United States	Controlled clinical trial	T2DM patients	SMBG has beneficial effects in glycosylated hemoglobin levels of patients with T2DM.
Mohan *et al.* (50) 2010	India	Controlled clinical trial	T2DM patients	Use of SMBG postprandial data to make therapy adjustments was associated with a significant regression of carotid intima-medial thickening, and with a reduction in glycosylated hemoglobin levels.

T1DM: Type 1 diabetes *mellitus*; T2DM: Type 2 diabetes *mellitus*; SMBG: Self-monitoring blood glucose
Source: Own elaboration.

Discussion

Based on the literature review carried out here, it is possible to say that SMBG practice and how it is perceived depends on the different T2DM management scenarios. Moreover, it was also revealed that adherence to SMBG is affected by several factors including patients' education level, health professionals' education level on DM and SMBG, availability of medical insurance, treatment regimen, and the frequency the patient goes to the physician office for follow-up purposes.

Also, there is evidence supporting that SMBG, together with a proper results interpretation, can empower patients and promote self-management. Likewise, there are many studies reporting an association between SMBG frequency and the degree of glucose control in Non-Insulin-Treated T2DM patients.

Self-monitoring of blood glucose and patient education

SMBG is the measurement of blood glucose by using a glucose electrochemical biosensor in a capillary blood sample obtained from the tip of a finger, then this information is recorded by the patient, either on a notebook or a computer, for follow-up purposes. Afterwards, these data are used by patients and health providers to determine the presence of hyperglycemia or hypoglycemia and to make decisions regarding the adjustment of insulin doses, the use of other medications, or modifications in the patient's lifestyle, including dietary and physical activity habits. (14,16,19)

In order to ensure that the information provided by SMBG is accurate a series of steps are required, besides it is also necessary that the patient fully understands the blood glucose measurement process. Next are the main considerations to take into account in order to obtain an adequate blood glucose measurement (21):

- Clean and completely dry the area where the sample is going to be taken from. Also, the electrochemical glucose biosensor, the test strips and the Quartz Crystal Microbalances must be handled with clean and dry hands.
- Test strips are single use only for each electrochemical glucose biosensor, and must be kept in the original container at all times before use, since their component can be affected by moisture. Also, expiration date must always be checked.
- The equipment and supplies necessary for making the measurement must be obtained beforehand: lancing devices may vary, but generally these are made up of a microlance needle that punctures the skin. Thin and sharp microlens are more comfortable, and must not be reused or cleaned.
- The settings of the lancing device must be adjusted in order to control the depth of the puncture, thus achieving a less painful experience and a better blood sample size.
- Application of the microlance needle: press it against the already prepared area to puncture the skin. The puncture will be less painful if made on the sides of the fingers or at the level of the palm. Preferably use the third, fourth or fifth finger.
- Obtaining the blood sample: the sample is obtained from the base of the finger to one end of the microlance needle. It is not recommended to press it directly.
- Place the blood sample in the electrochemical glucose biosensor for its analysis and get the glycemic value.
- Non-reusable supplies and the lancet device must be disposed properly according to local waste management regulations.
- Link the glycemic value that was recorded locally (on a notebook or a computer) with the information already recorded and stored in the electronic platform with Internet Access.

Provided that there is a wide variety of electrochemical glucose biosensor devices available on the market, some features like specific functions, error messages, and date and time settings should be consulted in their respective user manuals. In some cases blood glucose measurement accuracy may be affected by the use of medications, room temperature factors, hematocrit levels, and the technique used to carry out the measurement. (22) Electrochemical glucose biosensors with glycemic 20% error margin have been recommended for use in SMBG. Recognition of the biosensors margin error is important in the variability of its accuracy, for in many cases patients perform a second blood glucose measurement and they are concerned by the difference between both results. (23)

In the management of diabetes, the patient's level of education on diabetes and the ability to understand the basic considerations required for SMBG must be considered. Likewise, goals setting by the health care provider is a useful strategy for obtaining results from SMBG. When results obtained before having breakfast are consistent with a high glycaemia, drugs acting on hepatic glucose production can be used. On the other hand, postprandial glucose levels (2 hours after eating) will help understanding the impact of food intake on glycaemia, and in some cases they might be used to suggest dietary modifications or using medications such as oral anti-diabetic medications or insulin. (21)

Physical activity and dietary habits are to be considered when assessing appropriate adjustments in SMBG, and when developing a treatment strategy; also, the goals that have been set in order to achieve self-care behaviors should be taken into account. (24)

SMBG specific schedule will vary in each patient depending on the progression of the treatment and the particular clinical context.

Short and intense periods of SMBG, before and after each meal, and before going to sleep at night allow identifying glycaemia patterns, as well as the existence of hyperglycemia, (before breakfast, preprandial or postprandial). (21-24)

Al-Keilani *et al.* (25), in a study conducted in Jordan, assessed the adherence of diabetic patients to SMBG, as well as its predictive factors, reporting that the frequency of SMBG implementation was related to the treatment regimen, since it was found that in those undergoing insulin therapy or using oral hypoglycemic agents SMBG implementation was more frequent than in other groups ($p<0.001$). Likewise, these researchers also reported that the frequency of said implementation was associated with the reasons why these patients were actually performing SMBG, stating that the highest values were observed in those who carried out SMBG to determine if they had hypoglycemia (48.9%) or hyperglycemia (48%), or to inform their treating physicians about this situation. (25)

Due to its cost-effectiveness, SMBG could be recommended based on each patient's individual treatment for diabetes, but this is still under discussion. In this sense, a prospective study showed that the provision of the necessary supplies for SMBG implementation in non-insulin-treated T2DM patients was associated with a decrease in their HbA1c levels after 3 and 6 months of its application (1.8% and 1.7%, respectively). (26) Furthermore, an adequate before breakfast glucose correlation with glucose levels measured by SMBG was found, and a decreased risk of coronary heart disease, within a 10 year period, compared to the control group was reported. (26)

Alternatively, patients can use a staggered schedule and check their blood glucose levels several times a day during the whole week, for example a preprandial and 2-postprandial implementation strategy, since it will allow the patient to have feedback regarding food choices for a given meal. Some recommendations to take into account when teaching how to perform SMBG include (24):

- Provide simple and specific instructions according to the patient's level of understanding.
- Ensure that the patient proves he is able to follow the instructions to carry out SMBG.
- Provide the patient with written recommendations on frequency, time of assessment and desired results.
- Observe how the procedure is performed by the patient in the follow-up visits.
- Inform the patient of problematic SMBG values and discuss possible solutions.
- Acknowledge any achievement obtained through SMBG.
- Find out the relationship between SMBG and physical activity, diet, use of medications or stress
- Give clear recommendations on how to proceed in case of blood sugar imbalance (hyperglycemia or hypoglycemia).

SMBG should be performed depending on the assessment of the disease, whether it is a preprandial or postprandial measurement, or at times where glycaemia might be potentially low. Those patients who turn to carbohydrate consumption to adjust insulin doses and postprandial glycaemia levels are required to set SMBG goals that may be more intensive than those for patients who maintain a good control by using oral medications. While therapeutic adjustments are in process, SMBG shall be frequent, but once the therapy has been finally established, its frequency and intensity can be modified based on the patient's schedule. (17,18)

Once T2DM has been diagnosed, patients must enter a structured educational program, in which detailed information on the disease is provided to empower the, to achieve self-control. (18) It is recommended that these patients initially receive instructions on how to perform SMBG and routine follow-up in order to use appropriately the information obtained in the therapeutic adjustments; likewise, SMBG application technique should be evaluated at regular intervals, for the patient may lose the ability and competence provided by said empowerment. (18)

Finally, concerning patient reeducation, there are few studies reporting the effectiveness of long-term educational interventions, but positive results have been described regarding glycemic control and anthropometric parameters in education programs lasting from 2 to 5 years. (27-29) Based on these findings, the implementation of re-education interventions on SMBG every 2-5 years is suggested. (17)

Self-monitoring of blood glucose in patients whose diabetes treatment is based on lifestyle changes

As in any other intervention for treating any disease, patient's adherence is fundamental to achieve good results. The World Health Organization (WHO) defines adherence as the degree to which a person's behavior coincides with the recommendations given by a health professional (use of medications, adopting healthy eating or lifestyle habits). (30).

In patients recently diagnosed with T2DM further research is required to determine whether lifestyle changes will lead to going back to normoglycemia, since so far the observed long-term adherence is not homogeneous and results have not been conclusive. In this case, SMBG constitutes a tool encouraging patients to adapt their lifestyles more effectively in order to achieve a better glycemic control, which empowers them to play a more active role in controlling the disease. (31)

In this regard, in a randomized, controlled clinical trial a comparison between SMBG and HbA1c in terms of the management of newly diagnosed T2DM patients was made, and it was reported that the implementation of SMBG was associated with a higher regression rate (HbA1c <6% only metformin) and remission rate (HbA1c 6%-6.4%) compared to the control group (39% vs. 5% [$p<0.001$], and 37% vs. 30% [$p<0.001$], respectively). (32) Also, a higher percentage of patients in the cases group who achieved a meta score on a pre-established lifestyle scale compared to those in the control study (38.4% vs. 9.7% respectively, $p<0.001$) was observed, as well as an inverse correlation between SMBG and HbA1c levels ($p<0.04$). (32) This means that the association of SMBG with lifestyle changes effectively improves metabolic control in people recently diagnosed with T2DM, improving their adherence to nutritional recommendations and increasing their level of satisfaction without increasing the risk of developing severe hypoglycemia. On the other hand, SMBG implementation also allows healthcare personnel identifying if therapeutic adjustments are needed when glycaemia levels in SMBG values are not as expected. (32) This suggests that programs based on SMBG should be extended to primary care contexts, where patients with diabetes are usually treated. (31,32)

Self-monitoring of blood glucose in T2DM non-insulin pharmacological management

Studies on SMBG in T2DM patients treated with a non-insulin pharmacological therapy are of contemporary emergence. (33-37) Currently, the ADA states that SMBG can be a useful tool in making decisions on treatment or self-care in non-insulin users. (18) On the contrary, in its diabetes management guidelines, the International Diabetes Federation (IDF) says that there is still limited evidence regarding SMBG regimens in T2DM insulin-free management, but that it does not have to be performed daily. (38)

In this regard, Polonsky *et al.* (20), in a controlled clinical trial, found that after 12 months of implementing structured SMBG in patients with a poor metabolic control, a significant reduction of HbA1c levels was observed (1.2%, p=0.04), which was associated with an improved glycemic control, thus making possible to make therapeutic changes in a timely and aggressive manner in Non-Insulin-Treated T2DM patients, without diminishing their general well-being. (20)

Malanda *et al.*, in a systematic review and meta-analysis that summarizes clinical trials evidence on the effects of SMBG since 1989, reported that the effect of SMBG after 6 months of implementation in non-insulin users whose T2DM diagnosis was ≥1 year was low, with a 0.26% HbA1c level reduction (95%CI: (-0.39)-(-0.13)), and that after 12 months, said effect was even smaller and not statistically significant (0.13% [95%CI: (-0.31)-(0.04)]); also, evidence supporting that SMBG had an impact on the patient's satisfaction, well-being or quality of life was not found. (16)

In 2017, Young *et al.* (39), in a controlled and randomized clinical trial conducted in patients with non-insulin-dependent T2DM, compared three average blood glucose (AG) approaches in terms of HbA1c effects and improvement of quality of life indexes , namely: absence of SMBG, SMBG once a day, and SMBG application once a day with improved feedback for the patient, yet no significant differences regarding HbA1c reduction were observed in the three groups (p=0.74), with an estimated average HbA1c reduction of 0.09% in the group where SMBG with improved feedback was implemented (95%CI: (-0.32)-(0.14%)) vs. a 0.05% reduction in the non-using SMBG group (95%CI: (-0.27%)-(0.17%)). (39) Likewise, no significant differences were found regarding quality of life indexes and key adverse events such as hypoglycemia frequency, health resources use or insulin initiation. (39)

In addition, Farmer *et al.* (40), in a meta-analysis with 2 552 subjects from 6 clinical trials, reported that after 6 months of SMBG implementation in non-insulin-treated T2DM patients a 0.25% HbA1c reduction (-2.7mmol / mol [95%CI: (-3.9)-(-1.6)]) was observed in comparison with those who did engage in SMBG. Furthermore, other clinical trials have shown greater reductions in HbA1c levels by associating SMBG with therapeutic, educational or behavioral interventions aiming to achieve better glycemic control practices. (41,42) Regarding its frequency, no differences were found regarding glycemic control when SMBG was used with a greater intensity, and it is suggested that both the frequency and intensity of self-monitoring should be related to the progression of the disease and the complexity of the treatment. (43,44) Given the importance SMBG represents for non-insulin users, it is necessary to determine its frequency and intensity based on the management of the disease at the time of its implementation. (40-43)

Self-monitoring of blood glucose in in insulin-treated type 2 diabetes *mellitus*

Currently, SMBG is considered an essential component in the management of insulin-treated T2DM patients and its use is mandatory. (17,18) In this regard, Schnell *et al.* (45) found that use of SMBG in these patients increased by 23% between 1993 and 2009. Also, there are many prospective and observational studies addressing the use of SMBG in insulin-treated T2DM patients. (7,46,47) For example, two controlled and randomized studies described the importance of SMBG in this type of patients when it was associated with a structured plan to treat elevations in their glucose levels. (48,49)

Another example can be found in the study conducted by Ohkubo *et al.*(7), where it was reported that intensive insulin therapy guided by SMBG might reduce the risk of developing micro-vascular complications in T2DM in comparison with conventional therapies. On the other hand, Murata *et al.* (47) in a study where an intensive SMBG implementation was performed for 8 weeks in a metabolically stable insulin-dependent population group of veterans with T2DM, reported a 0.3% HbA1c reduction approximately one year after the implementation. Somehow, it should be noted that these positive results were only possible if the patient's adherence to the established SMBG regimen was ≥75% or if the HbA1c baseline was ≥8% (64 mmol/mol). (47)

Regarding the frequency of application, it has been recommended that SMBG should be performed before having meals or snacks, and occasionally after eating (postprandial measurement), and before going to bed or exercising when hypoglycemia is suspected and after it has been treated, and before engaging in activities such as driving a vehicle. (18) Although every individual has different needs, SMBG intensity, schedules and frequency must be determined based on the complexity of the insulin schemes, and the measurement may be required from 6 to 8 times per day. (17,18,38,50)

Finally, it is worth noting that improving HbA1c levels is not the main purpose of using SMBG in insulin-treated T2DM patients, but decreasing the risk of developing severe hypoglycemia, as well as providing the patient the necessary knowledge, through educational interventions, to solve hypoglycemia instances happening at home. (17,18,47-50).

Self-monitoring of blood glucose in daily life

The implementation of SMBG as a habit in daily life represents an important step forward in the management of diabetes, since it offers benefits such as optimizing the treatment of complications, encouraging patients to participate in the control and treatment of the disease, and allowing them to develop self-confidence. (19). In the clinical practice, deciding whether patients need SMBG or not, as well as its frequency, will depend on aspects such as the type of therapy they were prescribed for treating the condition, the need to titrate the insulin dose or change the insulin regimen, and their individual preferences, skills and visual acuity. It is also important to note that SMBG frequency may also depend on financial considerations and health care systems coverage. (20)

As far as T2DM can be prevented, it is important to continue with an effective medical management, as its prevalence is increasing rapidly. (1-5) Self-management of diabetes involves effective patient education as an evidence-based component of treatment and care that aims to achieve optimal metabolic control, better compliance with medical treatments, prevention of complications, and a better quality of life. (11-13)

The lack of clear and easy-to-follow guidelines is a major obstacle hindering the effective use of SMBG. Somehow, developing a coherent set of recommendations is especially challenging due to the disparities in resource availability among health care systems, variations in diabetes management practices, and diverse sociocultural settings. (20-22)

The goal of using SMBG is to obtain detailed information of the glycemic profile at different times in order to provide feedback in the context of self-care and an established pharmacotherapy. Therefore, it can facilitate making lifestyle changes and therapeutic adjustments, as well as empowering patients and improving their adherence to treatment. (16,19-21)

The role of patient education in self-care is to make patients aware of their condition and the importance of controlling the disease, since this will help improving their health condition and their quality of life. (22-24)

Ideally, anyone with diabetes should use SMBG to achieve good glycemic control and thus avoiding or delaying the onset of chronic complications. (31,32) Both the physician and the patient must have the necessary knowledge and be encouraged to evaluate blood glucose levels frequently. This way, better decisions regarding the management of the disease will be made. (14,16,19-21)

The frequency and schedules for performing capillary blood glucose tests should be individualized based on the objectives to accomplish in each patient, the type of drug that has been prescribed for use, the degree of control, the risk of developing hypoglycemia, and the need for short-term control. (17-19)

In the case of Non-Insulin-Treated diabetes patients, usually the disease has a few years of evolution or an adequate pancreatic reserve of insulin is maintained, which allows a favorable response when dose adjustments are made or when a second or third medication is added. In addition, several studies have found an association between the frequency of SMBG use and an improved glycemic control in this therapeutic context. (20,34-37,39-43).

The expectation caused by using SMBG in a non-insulin dependent patient will depend on the evolution of the disease. Therefore, the health provider must always give the patient clear information on the objectives of glycemic control. (33-38). Also, while it is a fact that there are several factors influencing glycemic control, by implementing SMBG in a structured way HbA1c levels can be reduced by 1.2% under the best circumstances. (20)

In the particular case of patients using insulin, it is assumed that there is a greater commitment of their pancreatic reserve, which in turn requires its replacement with insulin. Therefore, they must be given recommendations in terms of eating and physical activity habits so that they don't constitute a negative element in the control of the disease. Likewise, in order to achieve the established control goals, patients are required to monitor their glucose on a daily basis. (7,17,18,46,47) Ideally, capillary blood glucose should be measured before each of the three main daily meals and 2 hours after each measurement is made, so that there are enough data to assess the fasting glycaemia as postprandial excursions and make the relevant insulin dosage adjustments. (17,18,38,50) It is widely known that self-monitoring will help achieving good glycemic control, however strict control may also increase the risk of developing hypoglycemia. (47-50)

Finally, the following recommendations on SMB in T2DM are proposed (table 2):

Table 2. Self-monitoring recommendations in type 2 diabetes *mellitus*.

Glycemic self-monitoring in Type 2 Diabetes Mellitus	
Initial frequency scheme: Each time you attend a medical consultation with your treating physician. Bimonthly self-monitoring • Recent diagnosis • Diabetes management through lifestyle changes	Self-monitoring frequency scheme: Staggered daily self-monitoring. • HbA1c >7% • Non-insulin pharmacological management
Self-monitoring frequency scheme: Staggered daily self-monitoring. • HbA1c >7% • Low dose insulin pharmacological management.	Self-monitoring frequency scheme after dose adjustment: Staggered daily self-monitoring. • Permanent insulin user. • Multiple insulin doses.

Source: Own elaboration.

Although the long-term influence of SMBG in T2DM is supported by several studies (6,8,14-16,19-21), an association between anxiety or depression and SMBG application has been described in some cases (9), yet it is worth noting that said mental conditions may have already existed before SMBG implementation or comprise a base comorbidity, and might not be directly caused by SMBG itself.

Conclusions

SMBG effects will be positive as long as both the patient and the health professional are well informed about it, which is only achievable through appropriate educational interventions. In the case of health professionals, they must be provided with sufficient knowledge on SMBG application frequency and schedules, while in the case of patients, they must be instructed on SMBG application techniques and what the objectives of this tool are, which in turn will make them have expectations in relation to the prognosis of the disease.

Although the results reported in several studies on SMBG in Non-Insulin-Treated T2DM patients vary, and its use is still under debate, it is possible to say that SMBG is a tool that has been reported to have a great impact on glycemic control and in decision-making processes regarding timely and appropriate therapeutic changes to be made.

It is important to bear in mind that the individual approach of the patient is a key requirement to obtain positive results after its implementation. Furthermore, SMBG frequency, intensity and schedules will depend on the progression of the disease. Finally, in spite of the advances reported by the current evidence regarding the association between SMBG and T2DM management, further research is required to confirm said association.

Conflicts of interest

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