

Self-Monitoring of Blood Glucose in Noninsulin-Treated Patients with Type 2 Diabetes: A Never Ending Story?

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Recommendations for self-monitoring of blood glucose (SMBG) in the global guidelines for the treatment of patients with type 2 diabetes of the International Diabetes Federation (IDF) summarize our current knowledge and evidence from studies.¹ In standard care, the global IDF guidelines recommend SMBG for all newly diagnosed people with type 2 diabetes. In both standard and comprehensive care, the use of SMBG is advised for people with type 2 diabetes on insulin and oral agents.¹ Use of SMBG should be considered in the standard care of people with diabetes using oral agents to provide information on hypoglycemia and glucose variability. The guidelines emphasize that SMBG is an integral part of self-management.

Benefits of SMBG in the management of patients with type 2 diabetes not receiving insulin have been observed in the Kaiser Permanente Northern California Medical Care Program² and the ROSSO study.^{3,4} Furthermore, a meta-analysis of 1307 noninsulin-treated patients with type 2 diabetes demonstrated a 0.42% lower HbA1c level in those patients who performed SMBG as compared to those who did not apply SMBG.⁵ It goes without saying that SMBG has to be accompanied by structured educational programs, which not only empower patients to modify nutrition and physical activity according to measured blood glucose values, but also encourage them

to critically look at targets of metabolic control and also to potentially suggest the need for an alteration of medication.

The hope and expectation were that the Diabetes Glycemic Education and Monitoring (DiGEM) study^{5,6} may broaden our still limited knowledge about the (potential) benefits of SMBG on metabolic control and throw further light on the complex impact on diabetes care. Unfortunately, it has instead produced shadows and disturbances. The study aimed at assessing whether SMBG, alone or with instruction in incorporating the results into self-care, is more effective than the absence of SMBG in noninsulin-treated patients with type 2 diabetes. A total of 453 patients with noninsulin-treated type 2 diabetes with a mean HbA1c level of 7.5% as a basal value were studied over a 12-month period. Patients were allocated randomly to three groups: no SMBG and SMBG with and without advice. To make a long story short, the study was unable to demonstrate a benefit of SMBG; SMBG alone or with additional instructions did not translate into a significant improvement of metabolic control (= reduction in HbA1c) in such patients.^{5,6}

We need to be aware of the multiple limitations of this study, which may be used by health care providers in many countries to cut down the expenses for SMBG

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Abbreviations: (BMI) body mass index, (DiGEM) Diabetes Glycemic Education and Monitoring, (IDF) International Diabetes Federation, (OADs) oral antidiabetic agents, (SMBG) self-monitoring of blood glucose

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in such patients. These limitations most probably have counteracted a potential benefit for the patients in this study. For example, the patients were eligible for randomization with an HbA1c level of $\geq 6.2\%$. Mean HbA1c values of the patients in the three different groups ranged from 7.41 to 7.53%.^{6,7} Inclusion of patients with a stable and relatively good metabolic control (close to treatment goal in many patients!) at entry into the study may have attenuated the need for a modification or intensification of treatment within any of the three groups. This view is supported by the observation that usage of oral antidiabetic agents (OADs) was increased only in less than one-third of the patients!⁷ In both the less intensive and the more intensive intervention groups, OADs were not increased more frequently as compared with the control group (29 and 32% vs 30%).⁷ No specific algorithm for modification of treatment plans was mentioned in the publications and, therefore, the definition of intensification of treatment remains unclear. Also, the difference in the number of SMBG measurements per week was small between groups with intensive SMBG vs standard SMBG (seven times vs five times). We should also keep in mind that because the 453 patients enrolled were skimmed out of 2986 total eligible ones, the enrolled patients were a highly selected population.

The fact that the body mass index (BMI) of the patients, whose mean basal BMI was >30 kg/m², remained unchanged during the 1-year follow-up supports the view that effects of the "intervention protocol," which included motivation, interpretation of readings and training to apply goals for lifestyle changes, and adherence to physical activity,^{6,7} were rather minor. Previously it was shown convincingly that in overweight type 2 diabetic patients, lifestyle intervention not only is associated with considerable weight loss, but also with a significant decrease in HbA1c from 7.2 to 6.6%.⁸

The aim of the DiGEM study was to test whether self-monitoring of blood glucose, alone or with instruction in incorporating the results into self-care, is more effective than no self-monitoring in improving glycemic control. The patients who were included may not have been properly selected to address the potential goal of the study. Nearly one-third of the patients allocated to the study had already performed self-monitoring of blood glucose prior to inclusion.^{5,6} The authors mentioned that 31.6% of the patients, who were even allocated to the control group (no self-monitoring), had previously been using a glucose meter up to once weekly.⁷ In the groups with self-monitoring alone and with additional instructions, 26.7 and 32.5 % had been using glucose

meters before inclusion into the study. During the study, adherence to self-monitoring was also generally low. The design of the study was further weakened by the fact that those allocated to the group with self-monitoring alone were somehow more likely to continue the use of the meter (67%) as compared to those applying self-monitoring with instructions (52%). This does not support the view that an effective intervention concept was applied.⁷

Based on the current evidence of the effects of self-monitoring on diabetes care, the diabetes community could set up better studies. It is crystal clear that simply performing SMBG and noting the measured number in a diary are not enough. Patients (and physicians) must be well trained to convert data into meaningful information and appropriate therapeutic action. Clearly, this requires a substantial commitment for diabetes care from the patients themselves each and every day! Considering also recent evidence on the role of postprandial glucose excursions and glycemic variability in the pathogenesis of vascular complications (= long-term outcome of hard end points), SMBG opens a potential for well-designed and well-performed studies.

Unfortunately, in view of their limitations, results of the DiGEM study in reality have not further broadened our current knowledge on SMBG. In contrast, this trial has rather added some confusion as a consequence of the somehow invalid conclusions drawn. The limitations of the study design might have largely outweighed potential benefits, which had been previously observed for SMBG in noninsulin-treated patients with type 2 diabetes. The urge for large and well-designed trials, which analyze the potential beneficial effects of SMBG, especially in this patient group, has further increased.

Disclosure:

Lutz Heinemann is the CEO of the Clinical Research Institute Profil. In cooperation with a number of diagnostic companies, Profil runs clinical trials. LH is also a member of a number of scientific advisory boards of such companies.

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