

Use of Structured Self-Monitoring of Blood Glucose Improves Glycemic Control in Real-World Clinical Practice: Findings from a Multinational and Retrospectively Controlled Trial

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Structured self-monitoring of blood glucose (SMBG) is an approach to diabetes management in which blood glucose data are generated according to a defined testing regimen, interpreted, and then used to make changes in therapy.¹ Findings from recent studies have demonstrated that appropriate use of structured SMBG improves glycemic control, facilitates therapy intensification, and promotes desired behavioral changes, leading to improved clinical outcomes.²⁻⁹

We have reported findings from a 3-month, noncontrolled, interventional study that used a modified version of the Structured Testing Program study intervention, demonstrating that this approach can be effectively adapted for use in general medical practice to improve hemoglobin A1c (HbA1c) levels.¹⁰ At study end, participants showed significant reductions in mean [standard deviation (SD)] HbA1c levels compared to baseline from 9.2% (1.6%) to 8.0% (1.4%), $p < .001$. Improvements in average blood glucose, body mass index, lipids, and blood pressure were also highly significant ($p < .001$). To further determine the efficacy of the intervention, we analyzed 6-month follow-up data from participants enrolled in our prior study and assessed changes in their glycemic control compared with that of participants who did not use structured SMBG.

In our 6-month retrospectively controlled study, 526 diabetes patients (99 type 1, 423 type 2) were asked to generate a blood glucose profile before their 3-month and 6-month clinic visits, using a paper-based tool (ACCU-CHEK® 360° View Blood Glucose Analysis System, Roche Diagnostics, Mannheim, Germany). Measurements were taken before and 2 h after main meals and before bedtime on three consecutive days. End points included change from baseline in HbA1c and other parameters of diabetes complications. Data were also obtained from an additional 122 patients (control subjects) who did not use structured SMBG during the same time period. Baseline HbA1c values for the active and control groups were 9.5 (1.6%) and 9.1 (1.1%), respectively.

At 6 months, paired HbA1c values were obtained for 281 active and 122 control group participants. Active group participants showed significantly greater reductions in mean (SD) HbA1c levels at 6 months compared with control group patients: -1.9% (2.0) vs -0.3% (0.1); $p < .0001$. The percentage of participants who reported at least one severe hypoglycemic event was significantly greater in the control group than in the active group: 34.4% ($n = 42$) vs 3.9% ($n = 21$).

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Abbreviation: (HbA1c) hemoglobin A1c, (SD) standard deviation, (SMBG) self-monitoring of blood glucose

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Our findings suggest that use of structured SMBG results in greater HbA1c improvement with markedly less hypoglycemia than use of nonstructured SMBG in poorly controlled type 1 diabetes mellitus and type 2 diabetes mellitus patients and that structured SMBG is practical in real-world clinical settings. Moreover, our results are consistent with findings from several trials in which structured SMBG was used as a component of treatment.²⁻⁹

Given the increasing prevalence of diabetes worldwide, it is important that treatment tools and approaches are used effectively to facilitate improved clinical outcomes and to reduce the costs associated with poorly managed diabetes. Contrary to random or unfocused glucose monitoring, structured SMBG has been shown to be a valuable, practical component of effective diabetes management in real-world clinical settings. Additional studies are needed to elucidate how structured SMBG can be used most effectively in various patient populations and practice settings.

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Disclosures:

Mallem Nourredine has consulted for Roche Diagnostics, Eli Lilly and Company and Novo Nordisk. Christopher Parkin has consulted for Roche Diagnostics and DexCom. Ulrich Scheweppe and Ildiko Amann-Zalan are employees of Roche Diagnostics Deutschland GmbH, Mannheim, Germany.

References:

1. Parkin CG, Buskirk A, Hinnen DA, Axel-Schweitzer M. Results that matter: Structured vs. unstructured self-monitoring of blood glucose in type 2 diabetes. *Diabetes Res Clin Pract.* 2012;97:6-15.
2. Duran A, Martin P, Runkle I, Pérez N, Abad R, Fernández M, Del Valle L, Sanz MF, Calle-Pascual AL. Benefits of self-monitoring blood glucose in the management of new-onset Type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups. *J Diabetes.* 2010;2:203-11.
3. Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. *Diabetes Care.* 2011;34:262-7.
4. Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A, Cucco L, Ghidelli R, Sartore G, Sciangula L, Nicolucci A. ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. *Diabet Med.* 2011;28(7):789-96.
5. Bonomo K, De Salve A, Fiora E, Mularoni E, Massucco P, Poy P, Pomero A, Cavalot F, Anfossi G, Trovati M. Evaluation of a simple policy for pre- and post-prandial blood glucose self-monitoring in people with type 2 diabetes not on insulin. *Diabetes Res Clin Pract.* 2010;87:246-51.
6. Kempf K, Kruse J, Martin S. ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. *Diabetes Technol Ther.* 2010;12:547-53.
7. Mohan V, Ravikumar R, Poongothai S, Amutha A, Sowmya S, Karkhuzali K, Parkin CG. A single-center, open, comparative study of the effect of using self-monitoring of blood glucose to guide therapy on preclinical atherosclerotic markers in type 2 diabetic subjects. *J Diabetes Sci Technol.* 2010;4:942-8.
8. Kato N, Kato M. Use of structured SMBG helps reduce A1C levels in insulin-treated diabetic patients. *Diabetes.* 2011;60(Suppl.1):A239.
9. Shiraiwa T, Takahara M, Kaneto H, Miyatsuka T, Yamamoto K, Yoshiuchi K, Sakamoto K, Matsuoka TA, Matsuhisa M, Yamasaki Y, Shimomura I. Efficacy of occasional self-monitoring of postprandial blood glucose levels in type 2 diabetic patients without insulin therapy. *Diabetes Res Clin Pract.* 2010;90:e91-2.
10. Lalić N, Tankova T, Nourredine M, Parkin C, Scheweppe U, Amann-Zalan I: Value and utility of structured self-monitoring of blood glucose in real world clinical practice: findings from a multinational observational study. *Diabetes Technol Ther.* 2012;14(4):338-43.