

What Is the Role of Self-Monitoring of Blood Glucose in Non-Insulin-Treated Diabetes?

Schwedes U, Siebolds M, Mertes G. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care* 2002;25:1928–32.

Study Overview

Objective. To determine the effect of meal-related self-monitoring of blood glucose (SMBG) on diabetes control in non-insulin-treated patients.

Design. Multisite randomized controlled trial.

Setting and participants. Adults aged 45 to 70 years with diabetes treated either with diet or oral agents were eligible. Recruitment was done at 21 German and Austrian centers. All patients had a body mass index greater than 25 kg/m² and glycosylated hemoglobin (HbA_{1c}) between 7.5% and 10%. Patients were excluded if the duration of diagnosed diabetes was less than 3 months or if they could not keep a diary of diet and SMBG, could not perform SMBG independently, or had regularly used SMBG during the past 6 months.

Intervention. The SMBG group was assigned to check their blood glucose 6 times per day, 2 days per week (before and 1 hour after meals). Control groups received counseling on diet and lifestyle modification.

Main outcome measures. The primary endpoint was the change in HbA_{1c} at 24 weeks. Additional metabolic parameters were measured. Patient well-being and treatment satisfaction were assessed using a questionnaire.

Main results. 250 patients were randomized. Data from 223 patients were analyzed (113 SMBG and 110 controls). Patients who violated the protocol (11%) were excluded from analysis. HbA_{1c} decreased more in the SMBG group than in the control group ($1.0 \pm 1.08\%$ versus $0.54 \pm 1.41\%$; $P = 0.0086$). Both groups had improvements in well-being, but improvements tended to be larger in the SMBG group. Subgroup analysis of the SMBG patients who failed to improve showed that this group did perform SMBG frequently but did not successfully regulate their behavior in response to glucose values.

Conclusion. In a per protocol analysis, meal-related SMBG led to a modest but significant decline in HbA_{1c} without a negative impact on well-being.

Commentary

The link between diabetes control and SMBG in patients who do not use insulin is uncertain. Past randomized controlled trials have been limited by study quality and size and thus have had mixed results. A recent meta-analysis of randomized trials suggested SMBG in type 2 diabetes lowered HbA_{1c} by 0.25 but could not exclude the possibility that there was no effect of SMBG [1]. Observational studies also have had conflicting results. In one large prospective cohort, more frequent monitoring was associated with better HbA_{1c} control in insulin-treated, oral agent-treated, and diet alone-treated diabetes [2]. In another study done as a cross-sectional analysis, higher frequency of SMBG was not associated with better HbA_{1c} control in patients who were not using adjustable dose insulin, and SMBG was associated with greater psychological distress [3].

Schwedes et al's study does help allay the concerns raised by the latter study somewhat. In this randomized trial of meal-associated SMBG, psychological well-being tended to improve with SMBG. Perhaps more importantly, the 0.46% difference in HbA_{1c}, while modest, may be large enough to make a significant impact on diabetes outcomes. There are limitations to this study, however, that the authors do not acknowledge. 11% of patients were excluded from the analysis due to protocol violations. It is not clear if the per protocol analysis was the pre-chosen measure of their primary endpoint. Interpretation of their results would be easier if these patients were included.

Linking intensive SMBG to meals in patients using fixed medication regimens does make sense because it may lead to more active self-management through lifestyle modification, but this assumption needs to be better tested before universal recommendations can be made.

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Applications for Clinical Practice

While the exact role of SMBG in type 2 diabetes is not totally defined, intensive monitoring surrounding meal times 2 days per week may benefit some individuals with type 2 diabetes who are not on insulin. Providers can consider offering this approach to willing patients but should be alert to the fact that some patients will be unlikely to benefit.

—Review by Stephen D. Persell, MD

References

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