COMMENTS AND RESPONSES

Response to Comment on: Bosi et al. Intensive Structured Self-Monitoring of Blood Glucose and Glycemic Control in Noninsulin-Treated Type 2 Diabetes: The PRISMA Randomized Trial. Diabetes Care 2013;36:2887–2894

We thank Kleefstra et al. (1) for their interest in our study (2). However, we disagree with the assertions regarding the clinical relevance of our findings on the use of self-monitoring of blood glucose (SMBG) in noninsulin-treated type 2 diabetes.

Although the traditional approach to evaluating the efficacy of pharmacological interventions in type 2 diabetes studies is to report between-group differences in HbA_{1c} reductions, this approach may not be appropriate for assessing the impact of "behavior-based" interventions such as structured SMBG. In pharmacological studies, a medication is administered and investigators measure its efficacy in lowering glucose by comparing the reduction in HbA_{1c} values over time in all patients in the intervention and control group (intent-to-treat [ITT] population). Several researchers, erroneously in our opinion, apply this approach also when evaluating the efficacy of SMBG, looking only at what happens when subjects are asked to perform SMBG, without considering whether patients and/or their clinicians actually do so and interpret and use the data to adjust therapy. In essence, they consider only the *performance* of SMBG as the intervention. Conversely, assessing the proportion of patients who truly complied with the study procedures related to use of structured SMBG (per protocol [PP] population) may provide a more accurate metric for evaluating this type of intervention because it reflects the impact of the complete mode of action (testing and interpreting/using the data) of the intervention (3,4). In fact, in our study the between-group difference in HbA_{1c} reduction over 12 months was greater in the PP population (−0.21% [95% CI −0.331 to −0.089], $P = 0.0007$) than in the ITT population (all randomized patients) (−0.12% [−0.210 to −0.024], $P = 0.013$). Similarly, the between-group proportion of patients achieving clinically significant reductions in HbA_{1c} at study end (e.g., either >0.3%, >0.4%, or >0.5%) was greater in the PP than ITT population.

Additionally, when evaluating the magnitude of HbA_{1c} reductions, the baseline HbA_{1c} values of study subjects must be considered. As has been shown in numerous intervention studies, diabetic patients with low baseline HbA_{1c} values generally achieve significantly smaller HbA_{1c} reductions compared with subjects with higher baseline values (5). Because approximately 57.3% ($n = 587$) of our subjects had a baseline HbA_{1c} of <7.5% (only 7.6% [$n = 78$] had HbA_{1c} values ≥8.5%), we did not expect large HbA_{1c} reductions. However, even with these low baseline values, significantly more intervention subjects achieved clinically significant HbA_{1c} reductions (>0.3% or >0.5%) than control subjects.

Given that diabetes is primarily a self-managed disease, future studies may consider using metrics in study design and data analyses that allow assessing the actual impact of behavior-based interventions. Furthermore, as suggested by the results of our study, we need to focus on subgroups of patients with noninsulin-treated type 2 diabetes who may benefit more from structured SMBG (e.g., patients with higher baseline HbA_{1c} values) or where structured SMBG may be a safer choice (e.g., patients with lower baseline HbA_{1c} values).

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