COMMENTARY

# Self-monitoring of blood glucose for individuals with type 2 diabetes not using insulin: Leaving no cornerstone unturned.

Patients with diabetes are engaging in self-monitoring of blood glucose (SMBG) more than ever. Over the past 12 years, the overall utilization of SMBG has increased by 250% (1). Historically, testing has been encouraged by diabetes educators and care providers with the intuitive sense that real-time data on blood glucose (BG) would be of use to those living with diabetes. Indeed, SMBG is considered to be a cornerstone of diabetes self-care and management. On the surface, it might seem that for people living with type 2 diabetes, knowledge of blood glucose would appear important, and may inform healthy choices with respect to diabetes self-care. In this issue of the *Canadian Journal of Diabetes*, Woo and colleagues provide a commentary on the potential benefits of SMBG and illustrate how SMBG among those not using insulin is generally encouraged in international clinical practice guidelines.

However, the value of SMBG deserves rigorous scrutiny when applied in a patient population whose condition is generally stable, only slowly progressive over the long term with little day-to-day variability (2). The information derived from SMBG may be infrequently analyzed to affect changes in therapy and the testing becomes more a habit for patients often promoted by uncritical care providers. These features of natural history are particularly relevant in those individuals with type 2 diabetes not using insulin (who constitute the vast majority of people with diabetes) and in whom the utility of SMBG has been hotly debated (3,4). For such patients, decisions on the need to escalate therapy might be simply based on increases in periodically measured glycated hemoglobin (A1C) tests and results above the target level.

Woo and colleagues provided a selective review of available literature, suggesting that the potential benefits of SMBG can only be determined indirectly using their approach. Such a suggestion seems to be the antithesis of an evidence-based approach to diabetes management as espoused in the Canadian Diabetes Association (CDA) clinical practice guidelines (5). If a comprehensive evidence-based approach is taken and all the evidence is examined for SMBG in those with type 2 diabetes not treated with insulin, and this evidence is considered in the context of economic realities as well as in terms of benefit to patients, it is clear that the time has come for a critical review of the practice. In short, it may be time to overturn a practice long considered to be a cornerstone of therapy, especially given that this practice was established in the absence of evidence.

Woo and colleagues suggest the clinical benefits of SMBG are improved glycemic control and prevention of hypoglycemia. We believe that a more complete review of the evidence would, in fact, indicate there is little evidence that SMBG provides either of these benefits in patients with type 2 diabetes not using insulin. There is, in fact, evidence that SMBG may cause harm in this patient population. Moreover, the available clinical evidence does not support the substantial healthcare dollars being spent on this technology—money that might be spent for greater benefit on other healthcare interventions clearly shown to benefit patients with diabetes.

## SMBG and glycemic control

A number of meta-analyses of randomized controlled trials have demonstrated that the use of SMBG, compared with no self-monitoring, is associated with a 0.17–0.42% reduction in A1C. A reduction of <0.5% in A1C, has little, if any, clinical significance, even when it is statistically significant. Using the UKPDS Outcomes Model, for example, Cameron and colleagues have shown that an A1C reduction of 0.25% is associated with small clinical differences between those who engage in SMBG and those who do not. After 40 years of testing, the absolute risk reduction in diabetic complications experienced by those who test would be <1% (6).

It has been argued that trials examining the effect of SMBG on glycemic control have been poorly designed to evaluate the value of SMBG. Advocates of SMBG state that trials of SMBG efficacy to date are fundamentally flawed as they examine the benefit of SMBG as an intervention. In their view, SMBG is not an intervention but a diagnostic tool prompts a behaviour change, be it an adjustment in diet, physical activity or diabetic medication, which has not been considered in SMBG trials. Woo and colleagues state that "no clinical trial has been conducted with a structured self-management education component as part of the SMBG intervention vs. SMBG alone." This is incorrect. The Diabetes Glycemic Education and Monitoring Trial Group (DiGEM) (7), which Woo and colleagues, subjectively, criticize for being too small, randomized 453 patients with diabetes not treated with insulin to either a highly intensive, less intensive or standard SMBG strategy. The primary

outcome of this trial was glycemic control at 12 months as measured by A1C. The highly intensive SMBG group received extensive instruction on the interpretation of SMBG results and education on how to adjust diet, activity and medication to optimize glycemic control. The less intensive group received basic instruction in SMBG interpretation and was encouraged to speak with their physician about SMBG results, while no specific SMBG instruction was provided to the standard group. This study evaluated the value of contextualized SMBG and found no significant differences between the intensive groups and standard SMBG group with respect to glycemic control. The authors of the DiGEM trial concluded that the effect of SMBG, with or without instruction in incorporating findings into self-care, did not result in improved glycemic control (7).

**SMBG and hypoglycemia**

Hypoglycemia is clearly a worrisome adverse event for those with diabetes. Woo and colleagues suggest that clinical studies of SMBG and frequency of hypoglycemia are lacking. Again, we disagree. While no trials examine incidence of hypoglycemia as a primary outcome, 6 trials of SMBG have reported on hypoglycemia as a secondary endpoint, including the studies identified and reviewed by Woo and colleagues (7-12). The results have been inconsistent across studies, but there is a suggestion that hypoglycemia is *actually* increased among those who test more frequently. It is unlikely that increased SMBG is actually the cause of the hypoglycemia in these studies, but rather reflects a failure to respond appropriately to SMBG data. We must also keep in mind the relatively low frequency of hypoglycemia in this population; failure to find a difference between SMBG and non-SMBG approaches in these trials may also reflect a lack of statistical power. From a purely pragmatic clinical perspective it is hard to construct a hypothesis where regularly scheduled SMBG might reduce the frequency of such an unpredictable event as hypoglycemia, even in those on higher risk therapies. Regardless, there is no evidence that regular SMBG, with or without instruction, reduces the risk of hypoglycemia.

**SMBG and potential harms**

In their selected review of the literature, Woo and colleagues did not acknowledge research that suggests SMBG may actually induce harm in this patient population. For example, not included in their review was the ESMON study (8), a randomized controlled trial assessing the effect of SMBG in patients with newly diagnosed type 2 diabetes. In this trial, SMBG had no effect on glycemic control or the incidence of hypoglycemia, but was associated with increased feelings of depression and anxiety. These findings are consistent with previous reports from cohort (13) and qualitative (14) studies. These important concerns and unintended consequences should not be ignored when considering the overall value of technologies we recommend to our patients.

**SMBG and healthcare costs**

When examining the value of a given practice we need to consider both clinical and cost-effectiveness. Woo and colleagues recognize this important consideration by highlighting the healthcare burden of managing hypoglycemia, but neglect to highlight the costs of SMBG. These costs are also considerable and clearly overshadow the costs of managing hypoglycemia. In this issue of the *Canadian Journal of Diabetes*, Cameron and colleagues report that in 2006, the public drug plans of 8 Canadian provinces spent $247 million dollars on SMBG supplies and private drug plans paid $81 million. The majority of the claimants were patients not on insulin. Earlier this year, Cameron and colleagues published a cost-effectiveness analysis in *CMAJ* which suggested SMBG is not a cost-saving practice and is actually very cost inefficient (6).

We agree wholeheartedly with the conclusion of Woo and colleauges that inappropriate use of SMBG should be discouraged because of the cost and resource implications, though they provide no indication of how this might be achieved and their definition of 'appropriateness' might be a thorny issue. It is, nonetheless, gratifying that cost-effectiveness is becoming part of the consciousness of the CDA Clinical Practice Guidelines. If clinical practice guidelines are to be used as tools for advocacy, ever-increasing costs for newer technologies must be justified by unequivocal evidence of benefit (15).

**Conclusion**

Considering the full evidence available to date, the clinical benefits of SMBG among patients not using insulin are underwhelming at best. We are in need of knowledge on how best to apply SMBG in a limited and hopefully more clinically effective way among those not on insulin. It has been suggested that policies that support unlimited testing among those treated with insulin, and limiting testing supplies and using strategic SMBG in those not on insulin, would significantly reduce use and costs associated with SMBG (1). Research that defines and evaluates strategic and tailored testing strategies, from both clinical and economic perspectives, is sorely needed.

Continuing to encourage SMBG for all people with diabetes is not a financially sustainable option, nor will it significantly benefit our patients. We believe that misguided advocacy for investment in technologies with little clinical benefit (or worse, that cause harm) would be a disservice to our patients, siphoning away limited resources from proven effective interventions from which they would gain greater benefit.

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