EDITORIAL (SEE POLONSKY ET AL., P. 262)

Home Blood Glucose Monitoring in Type 2 Diabetes

Broken health care system undermines study's impact

The Diabetes Control and Complications Trial (DCCT) (1) would not have been possible without the advent of several technologies, including self-monitoring of blood glucose (SMBG). After the results of that landmark study were reported in 1993, SMBG was considered the standard of care for type 1 diabetic patients. The same was true for insulin-requiring type 2 diabetic patients after the report of the UK Prospective Diabetes Study (UKPDS) in 1998 (2). However, cost pressures have now caused some to question SMBG in type 1 diabetes (3), and we continue to struggle with conflicting evidence for those patients with type 2 diabetes not receiving insulin. The fundamental problem has been difficulty in trial design with many of the challenges carrying over from clinical trials to clinical practice.

For example, is the patient with type 2 diabetes even willing and able to perform SMBG? And, based on the glucose data, is the patient engaged enough to make behavioral changes that would improve glucose control? And even for those individuals who are able to make significant lifestyle changes, will they be willing to initiate insulin therapy if indicated? From the provider's perspective, is there time to review the data and potentially intensify therapy with that information? Can the provider even easily access the data, especially if there is a large amount of information in the 2 or 3 weeks before a clinic appointment? If the clinician cannot download the data, will the patient be willing to share the information either with a paper logbook or perhaps a computerized tool such as a spreadsheet or even a smart-phone app? What becomes clear is that for data to be exchanged successfully, both the patient and the provider (including in a clinical trial) need to appreciate that exchange.

Another very practical question for SMBG among type 2 diabetic patients is what is its ideal frequency for a patient on metformin, with or without a sulfonylurea or glucagon-like peptide 1 agonist? For Medicare beneficiaries, patients not receiving insulin are allowed 100 test strips every 3 months (4). For these 100 strips, would it be best to test daily (at the same time or at different times of the day?) or to cluster the testing over a few days during this 3-month period?

The answers to some of these questions are addressed by Polonsky et al. in this issue of *Diabetes Care* (5). In this 12-month trial performed in 34 primary care practices, 483 type 2 diabetic patients (mean A1C = 8.9%) were randomized either to an active control group (ACG) where patients were instructed to use their meter based on their physicians' recommendations (but no additional prompting, training, or instruction) or to a structured testing group (STG) where subjects used a paper tool to help analyze SMBG results and patterns. Subjects in the STG were asked to record/plot a 7-point SMBG profile on 3 consecutive days prior to each of the 5 clinic visits scheduled in the 12-month period. Importantly, these participants were also taught how to identify glycemic patterns and how to best address problems with changes in physical activity, portion sizes, and/or meal composition. These completed forms were reviewed at each clinic visit and, accordingly, patients were instructed on how to make further adjustments in their lifestyle and medication changes were made.

The results were not surprising. Intention-to-treat analysis resulted in an A1C change favoring the STG participants by -0.3% ($P = 0.04$), while the per-protocol analysis showed an even greater reduction by -0.5% ($P < 0.003$). This difference is noteworthy in that it takes into account how well the participants complied with the protocol—a fact not necessarily appreciated when only reporting the intention-to-treat results. No matter the population studied (in this report, over half the population did not have any college education)—and even if the providers are engaged and the SMBG technology and the ability for analysis are ideal—patient behavior and desire for improved diabetes control are required.

Also not surprising is that structured, intensive SMBG performed in the STG compared with random testing in the ACG resulted in more treatment change recommendations, most notably at the 1-month visit. In the STG, almost twice as many subjects started insulin therapy, though the authors note that this alone was not responsible for the group's overall improvement. It is important to appreciate that the overall frequency of SMBG was lower in the STG, further emphasizing that structured, intensive SMBG when performed at key predetermined times can be an effective strategy. Averaging less than one test daily, the per-protocol STG had a twelve-month mean A1C of 7.6%. While not ideal, control was improved, hypoglycemia was not increased, and resources used (in terms of strip use) were minimal and not greater than what is currently allowed by Medicare for individuals not receiving insulin therapy.

That the ACG had a 0.9% reduction in A1C at the end of the study compared with baseline is noteworthy. This points to how additional attention (including free meters, strips, and additional clinic visits) to diabetes management can directly influence overall control. Further attention on top of this as seen in the STG resulted in additional reduction in A1C. The good news is that this supports a fundamental fact we all should appreciate: many patients can achieve reasonable diabetes control in a primary care setting without a dazzling array of sophisticated technology. The recipe for success would include a well-intentioned and motivated patient, an interested and engaged clinician, the usually available agents to treat type 2 diabetes (including basal insulin), glucose testing to be performed only at specific times to allow for pattern recognition, and at the very least a paper tool to allow both physician and patient to understand where changes need to be made. If any one of these factors is not present, success (as we have seen so many times) will be unlikely.

What else can we conclude? First, these results do not apply to patients who require more sophisticated diabetes regimens, including prandial insulin, where more frequent SMBG will be necessary to

determine appropriate insulin doses and to minimize hypoglycemia.

Furthermore, it also seems to me that while we have spent so much time, energy, and money examining the impact of SMBG on the management of type 2 diabetes, the more important problem is determining how we can better improve our systems of care so that the time spent by the primary care physicians in this study is the norm and not a contrived component of a study protocol. This is a fundamental problem with most of the studies assessing the impact of SMBG in the management of type 2 diabetes: the study protocols do not necessarily replicate a real-life practice setting. In this era of "clinical efficiency" and "increased productivity," the significance of much of this type of research is reduced.

While the article by Polonsky et al. is an important contribution to the literature, we have to be realistic that many if not most primary care physicians do not have the time or infrastructure to replicate these findings (6). While one could argue that time with the provider is as important as the glucose test strips themselves, future research should focus on how to better achieve improved glycemic outcomes with less clinician intervention. Potential solutions would begin with better use of web-based or smart-phone technology for patient instruction and management. Additional strategies would include more group visits, less physician and greater nonphysician interaction, and some degree of peer-to-peer involvement, all in addition to a strategy of care similar to the STG in the current study. Our future clinical trials will need to better replicate our current system of care. Until then, the controversy regarding SMBG in type 2 diabetes will not be resolved.

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