Self-Monitoring of Blood Glucose in Type 2 Diabetes

Time for evidence of efficacy

The second half of the 20th century saw a major shift away from the paternalistic "doctor knows best" philosophy, which characterized patients as passive unquestioning recipients of care at the hands of all-powerful, all-knowing medical practitioners. Most patients, given sufficient information, now wish to be active participants, fully involved (usually with a multidisciplinary health care team rather than a single autocratic doctor) in making decisions relating to their medical assessment and management. Because diabetes is a complex lifelong condition, the good sense of such an approach seems obviously self-evident. The development of glucose meters that combine technological sophistication with speed and ease of use has greatly enhanced the potential for all diabetic patients to monitor their blood glucose. Detection of subtle hypoglycemia, asymptomatic hyperglycemia, and unnaturally wide glycemic excursions should, in theory, empower patients to make appropriate changes in lifestyle and/or pharmacological treatment, which will lead to more physiological glucose profiles and lower HbA_{1c} levels.

However, another late 20th century philosophical shift—toward the practice of evidence-based medicine and away from a combination of anecdote, personal bias, and instinct—renders "obviously self-evident," as a verdict, "obviously insufficient." For sure, self-monitoring of blood glucose (SMBG) was a key component, but not the only one, in landmark studies such as the Stockholm Diabetes Intervention Study, the Diabetes Control and Complications Trial, and the Kumamoto study, which proved beyond doubt that intensive insulin treatment of both type 1 and type 2 diabetes can result in lower HbA_{1c} and less risk of microvascular complications. It is worth noting, however, that the U.K. Prospective Diabetes Study essentially achieved the same scientific goal of improved glycemic control (as reflected by lower HbA_{1c}) and better long-term microvascular outcome, without SMBG being a required element in type 2 diabetic patients treated by diet or diet plus oral agents (1,2).

The official position of the American Diabetes Association (ADA) on SMBG is that all patients "should be taught how to use the data to adjust medical nutrition therapy, exercise, or pharmacological therapy to achieve specific glycemic goals" and that "the optimal frequency of SMBG for patients with type 2 diabetes is not known, but should be sufficient to facilitate reaching glucose goals" (3). The assumption is, therefore, that SMBG can and will facilitate reaching glucose goals in patients treated with oral agents, though the ADA is more circumspect when it comes to diet-treated patients, in whom, it acknowledges, "the role of SMBG [. . .] is not known" (3).

In this issue of *Diabetes Care,* Harris (4) presents data from the third National Health and Nutrition Examination Survey (NHANES III), collected between 1988 and 1994, showing that, irrespective of official exhortation, the great majority of patients treated with oral agents or diet alone monitored their blood glucose only rarely, if at all. In fact, self-monitoring at least once per day was undertaken by only 5–6% of such patients, while 80% of those on diet and 65% of those treated with oral agents admitted to having monitored either never or less than once per month. Moreover, there was no correlation between frequency of monitoring and HbA_{1c} levels in any of the treatment categories. A previous survey from the same period, but using a different database, gave similar results and found that self-monitoring was performed even less frequently by African-American and Mexican-American than by Caucasian patients (5). Unsurprisingly, patients who had been to a diabetes education class or had frequent physician visits were more likely to self-monitor.

What should be our reaction to this apparent apathy toward a self-help activity in the face of exhortation from the health professionals? The first thing to recognize is that these figures almost certainly underestimate what is happening today. The last decade has seen a great expansion in diabetes education programs and in the number of health professionals becoming CDEs. Glucose meters have become progressively more user-friendly. Also, as Harris (4) pointed out, Medicare policy changed in 1998 so that reimbursement for glucose meters and strips, previously available only to insulin-treated patients, was made available irrespective of treatment modality. It is not surprising, therefore, that a more recent survey found that 44% of all diabetic patients self-monitor at least once per day (6).

But should we be concerned, in 2001, that many non–insulin-treated patients are not self-monitoring regularly or frequently? Surely, the honest answer to this question can be no more than a resoundingly equivocal "Well, maybe." Why so?

An examination of the published evidence shows precious little support for the notion that SMBG does actually help induce the lifestyle and/or pharmacological changes necessary for better glycemic control in such patients. Reviewing the topic 4 years ago, Faas et al. (7) identified six prospective randomized controlled trials addressing this specific concern. In one trial, there was significant improvement in HbA_{1c} after 1 year in patients randomized to perform SMBG, whereas patients not monitoring blood glucose had a rise in HbA_{1c} (8). However, a "therapy decision scheme," which would have improved glycemic control anyway, was applied only in the SMBG group, casting doubt on the true impact of the SMBG. In the other five trials, lasting between 12 and 62 weeks, SMBG had no significant impact on either HbA_{1c} or fructosamine. Both retrospective and observational studies, either before (9–11) or since

(12–14) that review, have yielded similarly negative results.

Am I advocating the abandonment of SMBG in these patients? Well, in some cases, yes. I am sure that I am not unique in having patients (often elderly) who ask whether the inconvenience and minor discomfort of finger pricking is absolutely essential to their care. If the HbA_{1c} has responded satisfactorily to diet, exercise, and the addition of oral agents, why should we insist on continuing a practice that, so far, has failed to meet the standards of evidence-based medicine? Furthermore, a persistent emphasis on a management strategy of unproven efficacy may deflect the patient's attention away from other aspects of diabetes care, such as the importance of blood pressure and lipid control, both of which pass the evidence-based tests with flying colors.

On the other hand, there is no denying the enthusiasm with which many type 2 diabetic patients embrace SMBG, or the sense of control it gives them over their diabetes. So, the data presented by Harris (4) and the studies referred to above should, I believe, serve as a challenge to all of us involved in diabetes care and education to examine this aspect of care with the same rigor and scientific skepticism we would examine any other unproven technique or treatment.

- Do patients choose not to monitor because they perceive it to be a futile exercise?
- Does monitoring in itself lead to improved quality of life and better health, regardless of the effect on glycemic control?
- Why does self-monitoring not consistently lead to improved glycemic control in type 2 diabetes?
- Do we give patients insufficient or inadequate advice on how to act on the results?
- Is there too much emphasis on fasting glucose and not enough on postprandial levels?
- Will even more intensive monitoring, maybe four or five times a day, just as in insulin-treated patients, be more successful?

These and other relevant questions are capable of resolution by appropriately designed trials. The cost of monitoring is far from negligible; if 16 million patients tested only once per day at one dollar per test, this translates into almost six billion dollars per year. So, this is an issue that should be addressed by the National Institutes of Health, the ADA, all agencies that fund health care delivery, and (one might add) by the commercial companies that benefit from the sale of meters and testing strips.

And here, surely, is the crux of the matter. There should be appropriate trials to try to answer these questions; otherwise, how can we justify continuing, as a matter of course, to urge our patients to undertake (sometimes several times per day) a cumbersome, inconvenient, and not inexpensive procedure with no proven benefit?

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