SEE IPP ET AL. (P. 1528)

Counterpoint: Self-Monitoring of Blood Glucose in Type 2 Diabetic Patients not Receiving Insulin

A waste of money

Most people would agree that treatment plans, especially those that have invasive components and/or are expensive, should result in improved clinical outcomes. Self-monitoring of blood glucose (SMBG), as part of a treatment plan, fulfills both of these criteria but does have the potential to improve outcomes by lowering glycemia and thereby decreasing diabetic retinopathy, nephropathy, and neuropathy. In insulin-requiring patients, A1C levels are inversely related to the frequency of SMBG measurements (1–7), attesting to the beneficial effect of this component of the treatment plan. However, simply measuring blood glucose is ineffective. In one study (8), increased frequency of SMBG resulted in lower A1C levels only in those who self-adjusted their insulin doses, not in the insulin-requiring patients who did not (strongly suggesting that acting on the values is necessary).

What about type 2 diabetic patients not receiving insulin? A large number of studies have been carried out to answer this question, and the evidence is distinctly underwhelming. Randomized clinical trials are considered the best approach to evaluate these kinds of clinical questions, and six studies in which the patients were randomized have been published. In the earliest one, which included both insulin- and non–insulin-requring patients and lasted for 6 months (2), 68 non–insulin-requiring patients were randomized to SMBG, 72 to measuring urine glucose semiquantitatively (both groups being asked to do so twice every other day), and 68 to a control group. Compliance with requested SMBG testing was 50%. The baseline A1C levels were 7.8, 8.5, and 7.7%, respectively. The changes in A1C levels in each group at the end of the study were −0.4, −0.1, and −0.5%, respectively, which were not statistically significant.

In a second study (9), 27 patients were randomized to SMBG and 27 to measuring urine glucose semiquantitatively, both before each meal every other day. The study lasted 6 months, and the minimum number of measurements was to be at least 36 per month. Compliance with the minimum number of requested SMBG tests was 87%. The baseline A1C levels were 12.4 and 11.7%, respectively, and fell 2.0% in each group.

In a third study (10), 12 patients were randomized to the SMBG group, which was instructed in carbohydrate counting and asked to measure levels six times a day for the first 4 weeks, before and after a single meal daily for the next 16 weeks, and to select the frequency after 20 weeks. Compliance with the large number of requested SMBG tests for the first 20 weeks was 25%. The patients were followed closely for 28 weeks and less so until 44 weeks. The control group of 11 patients was educated in the general principles of diets for diabetic patients. The baseline A1C levels in the two groups were 8.8 and 9.6%, respectively. Changes at the end of the study were 1.5 and 0.8%, respectively. Although this difference was not statistically significant (probably because of the small number of patients in each group), it should be noted that the SMBG group received more intense nutritional counseling, i.e., instruction in carbohydrate counting, than the control group.

In a fourth study (11), 113 patients were randomized to SMBG and 110 to a control group. The SMBG group was asked to measure levels six times a day, twice a week and received an intensive counseling program that included providing an ongoing dietary history. The control group received general counseling. Compliance with the requested number of SMBG tests was 100%. The study duration was for 6 months with 6 months of follow-up. The baseline A1C levels in the two groups were 8.5 and 8.4%, respectively, which fell by 1.0 and 0.5%, respectively. Although the difference between these changes was statistically significant, the difference in counseling between the two groups does not allow the lowered glycemia to be ascribed to SMBG alone.

In a fifth study (12), 345 patients were randomized to SMBG and 344 to a control group. The SMBG group was asked to test six times a week on at least 3 separate days. Compliance with the requested number of SMBG tests was not clear. Baseline A1C levels in the two groups were 9.0 and 8.9%, respectively. Six months later, the decreases in A1C levels were 0.9 and 0.5%, respectively. Although this difference was statistically significant, >40% of the patients dropped out of the study before completion, 48% in the SMBG group and 40% in the control group. If the subjects in the SMBG group who failed to complete the study (nearly half) were enriched in those who were showing the least response, the results could be due to self-selection.

In the most recent study (13), which involved type 2 diabetic patients who were all on oral antidiabetes drugs, 43 were randomized to SMBG and 45 served as control subjects. All 88 patients were scheduled to see a dietitian five times during the 6-month study. Patients in the SMBG group were asked to test before and between 1 and 2 h after eating a single meal 6 days a week (two breakfasts, two lunches, and two suppers) and to record what was eaten. Compliance with the requested number of SMBG tests was 45%. The dietitian utilized the SMBG values and the dietary information in his nutritional counseling. Therapeutic decisions were made by a nurse who followed detailed algorithms and was unaware of the patient groupings. The baseline A1C levels in the SMBG and control groups were

8.4 and 8.5% and fell by 0.8 and 0.6%, respectively, a nonsignificant difference.

Thus, the evidence from randomized clinical trials does not really support the use of SMBG in type 2 diabetic patients not receiving insulin. One could argue that perhaps if compliance had been better, the results might have supported the use of this expensive invasive modality. However, subjects in clinical trials are usually more compliant than in the "real world," and it is unlikely that patients instructed to carry out SMBG by their providers would be more likely to measure than the clinical trial participants.

A number of nonrandomized studies (6,7,14–24) have been carried out evaluating the relationship between monitoring and A1C levels in type 2 diabetic patients not receiving insulin. Most (2,6,14–21) have shown no relationship. Three studies (7,22,23) have shown an alleged benefit of SMBG on A1C levels, but a closer inspection of these strongly suggests that either special consideration was given to the group performing the monitoring (22) or self-selection accounted for the results (7,23). In the first instance (22), a "therapy decision scheme" was applied to the SMBG group but not to the control group, casting doubt on whether SMBG per se was responsible for the difference. In the second (7), frequency of SMBG was assessed through pharmacy refills of strips in 12,786 type 2 diabetic patients receiving oral antidiabetes medications and 4,815 patients on diet therapy only in a large health care plan. Although patients who performed more SMBG had significantly lower A1C levels, self-selection could conceivably explain these results. This interpretation is supported by the results of a self-administered questionnaire or a computer-assisted telephone interview given to the plan members, 83% of whom responded. Self-care practices and healthy lifestyle behaviors were more common in individuals who performed SMBG more frequently (7).

The final study (23) examined whether a policy that provided free glucose monitors improved A1C levels. Results at 2-month intervals for 1 year before the policy was implemented were compared with values obtained 1 year after implementation. In those receiving sulfonylurea agents, there were no changes in 248 patients with baseline A1C levels ≤10.0% but a significant decrease of 0.6% in 90 whose baseline A1C levels were >10.0%. Self-selection also could have played a role. There were no changes over that period of time in A1C values in the 387 patients receiving sulfonylurea agents who did not perform SMBG, which included 43 with baseline A1C levels >10.0%.

There are at least three possible explanations for the lack of an effect of SMBG in patients. First, patients receive little or no feedback on their results. Second, related to the first, they are not taught the self-management skills required to lower the measured glucose values. Third, in my experience, the vast majority of patients measure their glucose level either fasting or preprandially, rather than postprandially. Fasting values serve neither to educate (there is no information on the effect of meal composition or size) nor to effectively motivate (postprandial values are much higher). Furthermore, there are a limited number of behaviors possible for patients not receiving insulin to counter a high preprandial SMBG value. Options include delaying the meal, eating less (especially carbohydrates), exercising at that point, or, if taking repaglinide, increasing the dose for that meal. Even if taught, given patients' usual lifestyles, these self-management activities are not very likely to occur. Except for "mild" type 2 diabetes, in which the preprandial glucose values are near normal, the most important determinant of postprandial glycemia is the preprandial level. Therefore, in my view, if SMBG is to be recommended in patients not receiving insulin, it should be carried out before and 1–2 h after a meal to maximize the educational value of how the size and composition of the meal contributes to the postprandial glucose concentration (from the difference between the two SMBG values) and the motivational aspect by showing the patient how high the postprandial glucose level reaches. However, given the lack of evidence for a beneficial effect of SMBG on A1C levels in these patients, I personally do not recommend it.

In addition to its drawbacks of invasiveness and lack of efficacy, SMBG is expensive. In the Kaiser Permanente Northern California Region, the cost for strips alone in 1998 was the fourth largest outpatient pharmacy expenditure, accounting for 2% of the entire budget (7). Some of these costs would, of course, be attributed to patients receiving insulin. Although it is not possible to completely isolate SMBG costs for diabetic patients not taking insulin, the Medicare B fee-for-service program run by the government affords a fairly accurate estimate of this cost. The ICD-9 code 250.00 (type 2 diabetes, uncomplicated, not uncontrolled) is the one most often used for diabetic patients on either diet alone or taking oral antidiabetes medications. The total cost in 2002 for reagent strips, lancets, lancing devices, meters, batteries, and calibration solutions or chips was $465,503,576, which represented 58.8% of the total outlay of the Medicare B program for the ICD-9 code 250.00 (personal communication, staff, Center for Medicare & Medicaid Services). To the extent that type 2 diabetic patients receiving insulin were given this ICD-9 code, this cost would be an overestimate. On the other hand, to the extent that type 2 diabetic patients not taking insulin were given another ICD-9 code, this cost would be an underestimate. However, since this cost does not include the 10% of Medicare beneficiaries enrolled in HMO Managed Medicare, this figure is certainly an underestimate of the total cost for SMBG in type 2 diabetic Medicare patients not taking insulin. Given that this nearly one-half billion dollars is only for Medicare patients, the total cost for SMBG for all type 2 diabetic patients not taking insulin is obviously much higher.

The conclusion of this Counterpoint, that SMBG in type 2 diabetic patients not receiving insulin is ineffective in lowering A1C levels, is consistent with the conclusions of several reviews (24,25) and a meta-analysis (26). A meta-analysis in a third review appearing in this issue of *Diabetes Care* (27) found a small (−0.39%), but statistically significant, decrease in A1C levels in patients performing SMBG compared with control groups. However, the authors conclude that this statistically significant difference should be interpreted with caution because of the poor methodological quality of most of the trials and the clinical heterogeneity of the study populations and interventions used. This small difference, regardless of whether it is clinically meaningful, must be weighed against the tremendous costs involved. In my view, under present practice patterns, much money is being wasted on this invasive, expensive procedure that could be better spent on other aspects of diabetes care. In the present era

of evidence-based medicine and limited resources, this issue needs addressing.

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