The Use and Abuse of Self Monitoring of Blood Glucose

a report by
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Diabetes mellitus is a condition characterized biochemically by increased blood glucose concentrations and associated with both small blood vessel complications in the eyes (retinopathy), kidneys (nephropathy), and peripheral nerves (neuropathy) and large blood vessel complications of the heart (causing heart attacks), head and neck (causing strokes), and legs (leading to gangrene and amputations). Diabetic retinopathy is the leading cause of blindness in industrialized countries in people between the ages of 20 and 74 years. Diabetic nephropathy is the leading cause of people requiring dialysis for kidney failure. Diabetic neuropathy underlies most cases of lower extremity amputations, much more so than the large vessel complication in the legs. There is overwhelming evidence that keeping blood glucose near normal will have a marked beneficial effect of limiting (and possibly preventing) the small vessel complications. Although one recent article showed that lowering blood glucose concentrations in type 1 diabetic patients had a beneficial effect on coronary artery disease (CAD) many years later, five previous articles in type 2 diabetic patients did not.

Glucose sticks to proteins through a process called glycation. The higher the glucose concentrations in the blood and the longer it remains high, the more glucose becomes attached to proteins. One of the proteins that is glycated is hemoglobin, which is carried in red blood cells. Red blood cells last about 120 days and they are exposed to glucose in the blood for that entire period of time. Therefore, how high the blood glucose levels are and the length of time they are high is reflected in the amount of glycated hemoglobin in the red blood cells. A common term for the test that measures glycated hemoglobin is hemoglobin A1c, often abbreviated A1C. This value reflects the average blood glucose for the preceding three to four months and is the test used to determine how well a person with diabetes is controlled. ('Controlled' means how close to normal the average blood glucose concentration is.)

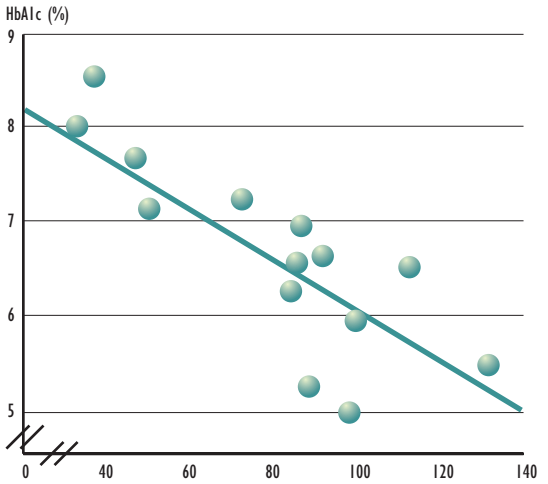
The upper limit of normal for A1C is approximately 6%. Five studies in over 2,000 diabetic patients followed from six to nine years showed that average A1C levels below 7% were associated with very little or no progression of the small vessel complications. Values between 7% and 8% were associated with mild small vessel complications and values over 8% with marked increases. An A1C level of 6% reflects an average glucose concentration all day and night of 135mg/dl; 7%, of 170mg/dl; 8%, of 205mg/dl, etc., i.e. 35mg/dl for every 1% increase in A1C levels. Thus, one can see the importance of following A1C levels in diabetic patients.

In contrast to the average blood glucose concentration reflected in an A1C level, the measurement of blood glucose itself, termed self monitoring of blood glucose (SMBG), only reflects what is going on at that moment. This has both advantages and disadvantages. One advantage is that, at least theoretically, interventions can be carried out by the patient at that moment to counter the high (or low) blood glucose concentration. Furthermore, when adjusting insulin doses, it is important to know the pattern of blood glucose values, i.e., when during the day the levels are high, in range, or low, since different parts of the insulin prescription affect glucose concentrations at various times after injection. The disadvantage is that the value only reflects one instance in time and glucose concentrations fluctuate throughout the day and night. Therefore, one value does not accurately portray what the overall levels of glucose are. It is certainly not unheard for patients to manipulate their behavior to 'look good' (i.e., have a glucose concentration near normal) when seen by their doctor by restricting their diets several days before, omitting food for 18–24 hours before the visit, taking extra insulin, etc. In that vein, it has been amply demonstrated that up to a quarter of patients will falsify their SMBG values when writing the results in their log books. In that case, they usually conveniently forget to bring in the meter, most of which contain a memory chip. Discrepancies between A1C levels and proffered SMBG values usually flush out this misguided behavior.

Most people would agree that treatments, especially those that have invasive components and/or are expensive, should result in improved clinical outcomes. SMBG, as part of a treatment plan, is both expensive and

invasive but does have the potential to improve outcomes by helping to lower glucose concentrations and thereby decrease the small vessel complications of diabetes. In patients taking insulin, performing SMBG offers the opportunity to correct high measured values at that moment by injecting additional rapid-acting insulin. More importantly, the pattern of results over longer periods of time enables the physician (or selected patients) to make insulin dose adjustments to counteract blood glucose concentrations exceeding the desired range. Therefore, it is not surprising that in at least eight studies, A1C levels were inversely related to the frequency of SMBG measurements in insulin-requiring patients, i.e., the more frequently that patients tested, the lower their A1C levels (see *Figure 1*). However, simply measuring blood glucose is ineffective. In one of the studies, 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. This strongly suggests that acting on the measured values is necessary.

Figure 1: Inverse Correlation (r = -0.85) Between Number of SMBG Readings Recorded in a Glucose Meter (MR) for 21 days in 14 Type 1 Diabetic Patients



Modified from Ziegler O, Kolopp M, Got I et al., "Reliability of self-monitoring of blood glucose by CSII-treated patients with type 1 diabetes", Diabetes Care *(1989);12: pp. 184–188.*

At least 19 studies have been carried out to evaluate the effect of SMBG on A1C levels in diabetic patients not receiving insulin. Only five have been positive, i.e., showing that performing SMBG in these patients was associated with statistically significant lower A1C levels than in control groups that did not carry out SMBG. However, in each one of them, factors other than SMBG were probably responsible for the positive results. These include greater attention to education and decision-making in the group performing SMBG compared with the control group, self-selection or a preferential drop-out rate. In the first case, those in the SMBG group either received more intensive nutritional counseling or decisions on changing therapy were made more frequently than in their matched control group. In the second case, patients were given the choice of performing SMBG or not. Those who chose to also had better self-care practices and healthy lifestyle behaviors documented by a questionnaire, thus invalidating the conclusion that SMBG *per se* is what led to the lower A1C levels. Finally, in one study, nearly 50% failed to finish it. If the nearly half of the SMBG group that failed to complete the study were enriched in those who were showing the least response, these results could also be due to self selection.

The gold standard for carrying out clinical studies is randomization and blinding. This means that the subjects are randomly chosen to be placed in the control or intervention group (which avoids self selection) and the person(s) carrying out the study are blinded so that they do not know whether the subject is in the control or intervention group (which avoids preferential treatment of one group). A nurse-directed diabetes disease management program afforded the author the opportunity to carry out such a study evaluating SMBG in type 2 diabetic patients who were taking pills but no insulin. In this program, a nurse (under the supervision of a physician) followed detailed treatment algorithms. Patients on pills were randomized to perform SMBG or not. Both groups were seen by a dietitian who taught the selected patients SMBG and provided nutritional counseling to both groups five times during a six-month period. The dietitian utilized the SMBG values (recommended before and after one meal every day but Sunday and carried out 45% of the time) in his nutritional counseling. Neither the nurse nor the physician when consulted by the nurse knew which patients were performing SMBG. Although A1C levels fell significantly in both groups, the decrease was not statistically significantly different between the groups. In other words, SMBG had no beneficial effect when patients not taking insulin received good diabetes care.

There are at least three possible explanations for the lack of an effect of SMBG in patients not taking insulin. First, patients receive little or no feedback on their results. This was not the case in the randomized blinded study described above. Second, related to the first, they are not taught the self-management skills to use to lower the measured glucose values. However, there are a limited number of behaviors possible for patients not receiving insulin to counter a high SMBG value. If the measurement was taken before a meal, options include delaying that meal, eating less (especially carbohydrates), exercising at that point, or increasing the dose of a pill before that meal that rapidly increases insulin secretion. (That medication, however, is used by only a very small minority of patients.) Even if taught, given patients'

usual lifestyles, these self management activities are not very likely to occur.

Third, in the author's experience, the vast majority of patients measure their glucose level before meals, rather than after meals. This limits the two potential benefits of SMBG in patients not taking insulin – motivation and education. Fasting values serve neither to educate (there is no information on the effect of the meal composition or size) nor to motivate well (postprandial values are much higher). Except for early type 2 diabetes, in which the before-meal glucose values are near normal, the most important determinant of after-meal glucose concentrations is the before-meal value. Therefore, in the author's view, if SMBG is to be recommended in patients not receiving insulin, it should be carried out before and one to two hours after a meal to maximize the educational value of how the size and composition of the meal contributes to the rise of glucose concentrations after eating (from the difference between the two SMBG values) and the motivational aspect by showing the patient how high the glucose level rises. However, given the lack of evidence for a beneficial effect of SMBG on A1C levels in these patients, the author personally does 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 out-patient pharmacy expenditure, accounting for 2% of the entire budget. 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, calibration solutions or calibration chips was US$465,503,576, which represented 58.8% of the total outlay of the Medicare B program for the ICD-9 code of 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 health maintenance organiztion (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 half a billion dollars is only for Medicare patients, the total cost for SMBG for all type 2 diabetic patients not taking insulin is obviously much, much higher.

In the author's 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 serious attention. ■

Further Reading

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