

Reflections in Hypertension

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Why Is Self-Monitoring Reimbursed for Blood Glucose but Not Blood Pressure?

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Our patients are taking a more active role in the management of their diseases than in the past; two prime examples of this are the use of self-monitoring of blood pressure (SMBP) and self-monitoring of blood glucose (SMBG). Both techniques are widely used, and both are advocated by professional organizations, but only glucose monitoring is reimbursed. In view of the fact that blood pressure (BP) control is arguably more important than blood glucose control in patients with type 2 diabetes,¹ this fact seems surprising.

The rationale in both cases is basically the same: BP and blood glucose are continually changing, and a single measurement made in a doctor's office may not be representative of the prevailing level. There are two important differences, however. In the case of diabetes, we have another blood test, the hemoglobin A1c (HbA1c), which measures the prevailing level, whereas we have no equivalent in hypertension. Perhaps the closest is left ventricular mass measured on the echocardiogram, but it is hardly a test that we can order routinely at each visit. In addition, with BP we are faced with the white-coat effect, which causes the pressure to be spuriously elevated in many patients; no similar phenomenon has been described for blood glucose.

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RECOMMENDATIONS BY PROFESSIONAL ORGANIZATIONS AND GUIDELINES

Both SMBP and SMBG are recommended by the corresponding organizations and guidelines. The current American Diabetes Association (ADA) recommendations² for SMBG are as follows: 1) SMBG is an integral component of diabetes therapy; 2) Include SMBG in the management plan; and 3) Instruct the patient in SMBG and routinely evaluate the patient's technique and ability to use data to adjust therapy. The recommendations also go on to say that for patients taking insulin, SMBG is recommended three or more times daily, but for those with type 2 diabetes the optimal frequency and timing are not known. Despite this, doubts are still being raised concerning the widespread applicability of SMBG.^{3,4}

SMBP has been recommended for use by hypertensive patients by the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) and JNC 7 Guidelines,^{5,6} the American Society of Hypertension,⁷ and the new guidelines to be published by the American Heart Association.

DOES SELF-MONITORING GIVE RELIABLE INFORMATION?

Both types of monitor give reasonably reliable information. Glucose monitors are expected to give measurements that are within 5% of the blood glucose measured in the conventional way, although when patients make the measurements themselves, the readings are not as accurate as when they are made by a trained technician using the same monitors.⁸ SMBG is more complicated to perform than SMBP, since the instruments must be coded correctly, and there may be too little blood to fill the strip properly.⁹

With SMBP there have been issues about devices that have not been validated, but it is generally agreed that there are a sufficient number of accurate devices available for this not to be a significant problem.¹⁰

SELF-MONITORING AND DIAGNOSIS

SMBG is not recommended for making the initial diagnosis of diabetes because “white-coat diabetes” has not been reported. But as with SMBP, one of the issues is whether intermittent readings taken with SMBG reflect the average level over 24 hours. At least one study has looked at this using a continuous glucose monitoring device that is implanted subcutaneously for 24 hours or more and comparing the readings with SMBG readings taken three times a day before meals in young insulin-dependent diabetics.¹¹ It was found that there was a close correlation between the average values measured by the two techniques ($r=0.78$), but the SMBG missed important peaks after meals and hypoglycemia during the night.

In contrast, SMBP plays an increasing role in the diagnosis of hypertension. It may be used as a first step in the evaluation of patients with suspected white-coat hypertension, as recommended in JNC VI and JNC 7.^{5,6}

SELF-MONITORING AND PREDICTION OF RISK

One reason for recommending self-monitoring is that it may give a better estimate of the patient’s level of risk. The classic study that initially led to support for SMBG in insulin-dependent diabetics was the Diabetes Control and Complications Trial (DCCT),¹² which found that an intensive control program of three or more insulin injections per day guided by frequent blood glucose monitoring reduced the occurrence or progression of retinopathy, neuropathy, and renal disease by 40%–76% in patients with type 1 diabetes when compared with standard care. However, this was not a study comparing SMBG against usual care, since SMBG was actually used in both groups; what was different between the groups was the intensiveness of the insulin injections, which were given three or more times daily in the intensive treatment group and only once or twice daily in the usual care group. No claims have been made that SMBG independently predicts micro- or macrovascular complications of diabetes, but ironically there is evidence that SMBP may be predictive. A study of 77 patients with type 1 diabetes and nephropathy found that over a 6-year follow-up, decline of renal function was predicted better by home than clinic BP, as well as by HbA1c.¹³

In the case of BP, there are two studies that have compared the predictive value of clinic and

office measurements, and both have shown that home measurements are potentially superior. In the first,¹⁴ which was conducted as a population survey in the town of Ohasama, Japan, 1789 people were evaluated with home, clinic, and 24-hour BP measurements. Over a 5-year follow-up it was found that the home pressure predicted risk better than the clinic readings. The second¹⁵ was conducted in France and recruited 4939 elderly hypertensives who were currently on treatment. It found that morbid events observed over a 3.2-year follow-up period were predicted by the home BP at baseline but not by the clinic pressure.¹⁵ One particularly interesting aspect of this study was that patients who had normal clinic pressures but high home pressures were at increased risk, a phenomenon known as masked hypertension.¹⁶

SELF-MONITORING AND ACHIEVEMENT OF CONTROL

The overwhelming justification for using SMBG has been the achievement of better control of blood glucose than obtained when intermittent office measurements are used. However, the value of SMBG in this respect has been controversial. Most trials comparing SMBG with urine testing or no monitoring have not demonstrated any beneficial effects, leading a reviewer to write in 1997 that “there is no convincing evidence that glycemic control is consistently influenced by self-monitoring of blood or urine.”³ Since then at least two randomized controlled studies of SMBG vs. usual care in type 2 diabetics have shown that SMBG improves HbA1C levels.^{17,18}

There is also a limited amount of data to indicate that SMBP can improve BP control. One study randomized hypertensive African Americans to usual care, SMBP, or “community based monitoring,” which involved having BP checked three times a week in a community health center. At 3 months, the BP had decreased the most in the SMBP group, with smaller changes in the community-monitored group and no change in the controls.¹⁹ Another study compared SMBP against usual care and found a significant reduction of 24-hour BP in the former and again no change in the control group.²⁰ The changes were most pronounced in African Americans, in whom mean arterial pressure decreased by 9.6 mm Hg in the monitored group and increased by 5.2 mm Hg in the usual care group.

One of the strongest arguments for using SMBP to assess the response to antihypertensive treatment comes from the Italian Study on Ambulatory Monitoring of Blood Pressure and Lisinopril Evaluation (SAMPLE)

study,²¹ which used three methods of BP measurement (clinic, ambulatory, and SMBP) to relate the changes in BP resulting from treatment with an angiotensin-converting enzyme inhibitor to the regression of left ventricular hypertrophy. The changes of clinic pressure showed no significant correlation with the changes in left ventricular mass, whereas both SMBP and ambulatory monitoring did show correlations. The implication of this finding is that when there is a discrepancy between the effects of antihypertensive drug treatment on clinic and home-measured BP, the latter may be more meaningful.

CURRENT USAGE OF SELF-MONITORING

The use of both modes of self-monitoring has been growing rapidly over the past few years, although exact numbers are hard to come by. In a survey of the National Health and Nutrition Survey III²² data collected between 1988 and 1994, it was reported that 71% of patients treated with insulin and 35% of those being treated with oral agents monitored their glucose at least some of the time. Patients with higher HbA1c were more likely to use SMBG. A Centers for Disease Control and Prevention survey²³ done between 1997 and 1999 found that 44% of all diabetic patients monitor at least once a day.

The use of SMBP is not known precisely, although it has been reported that the annual sales in the United States of monitors was \$142 million in 2001 (which would imply that 2 million monitors were purchased) and that sales would grow by 22% over the next 5 years.²⁴

COSTS OF SELF-MONITORING

The costs of both types of monitor is very similar—about \$70. However, there is a big difference in the cost of the monitoring procedure because SMBG requires the use of strips impregnated with reagent to measure the glucose level, which cost between 70 cents and \$1. Kennedy⁴ has estimated that if 16 million diabetic patients monitor their blood glucose once a day at \$1 per test, this translates into almost \$6 billion a year.

In contrast, the measurement of BP carries only the cost of the batteries (also required for the glucose monitors), making it virtually free. On this basis, the annual cost for 16 million people to monitor their BP would be just over \$1 billion—a huge difference.

REIMBURSEMENT OF SELF-MONITORING:

Largely as a consequence of the DCCT results quoted above, which showed that tight control of blood

glucose reduced the complications of diabetes, SMBG was covered for insulin-dependent diabetics before 1997, and section 4105 of the Balanced Budget Act of 1997²⁵ provided coverage for blood glucose monitors and testing strips for all diabetics. The Centers for Medicare and Medicaid Services (called the Health Care Financing Administration at the time) issued Program Memorandums extending the coverage, which became effective in July 1998. The criteria for approval were: 1) the patient had been diagnosed as having diabetes; 2) the patient's physician thinks that the patient is capable of using the monitor; and 3) the monitor is designed for home use. What prompted this change of policy is not clear, but probably had more to do with politics than science. At that time evidence that SMBG improved the control of blood glucose in type 2 diabetics was lacking, and it is still unproven whether or not diabetic complications are prevented by SMBG in these patients. The UK Prospective Diabetes Study, which did demonstrate an improved prognosis as a result of tighter control of BP and glucose, did not require self-monitoring of either modality.^{26,27}

SMBP is not reimbursed at the present time, and there does not seem to be any prospect of this changing in the near future. While for most people the cost of a BP monitor is not a problem, we should remember that BP control is still a major problem globally, and that it is worst in minority groups, for whom the cost of monitors may be an issue. These patients actually showed some of the greatest improvement in the studies of SMBP quoted above.

WHERE DO WE GO FROM HERE?

In an ideal world, we would like evidence that the use of SMBG and SMBP leads to a reduction of complications of diabetes and hypertension. At the present time, we do not have such evidence for either procedure, but this does not negate the justification of their use. There is now reasonable evidence that these two procedures can lead to an improvement of control of blood glucose and BP, which are in themselves worthy goals. After all, to obtain approval from the US Food and Drug Administration, a new antihypertensive medication only has to be shown to lower BP, not morbidity. When we look at the scorecard for both procedures (Table), however, there are some important differences.

SMBP is much cheaper than SMBG, it causes minimal discomfort to the patient, and it is useful both for predicting risk and for the diagnosis of hypertension, which SMBG cannot claim. For both procedures the main justification is monitoring the

Table. Scorecard for Self-Monitoring of Blood Pressure and Blood Glucose

VARIABLE	BLOOD PRESSURE	BLOOD GLUCOSE
Recommended by professional organization	Yes (JNC 7)	Yes (ADA)
Reimbursed by Medicare	No	Yes
Cost of monitors	\$70	\$70
Cost of measurement	None	\$0.70–\$1
Discomfort for patient	No	Yes
Predicts morbidity	Yes	Unproven
Used for diagnosis	Yes	No
Improves control	Yes	Yes
Lowers morbidity	Unproven	Unproven

JNC 7=The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; ADA=American Diabetes Association

response to treatment, but even here SMBP can claim superiority when compared with the use of SMBG in the majority of diabetic patients who do not require insulin. Blood glucose is not affected by the stress associated with a clinic visit to the same extent as BP, although it is affected more by meals, and as mentioned above, there is no BP equivalent of the HbA1c measurement for assessing long-term control. Furthermore, BP control is now accepted as being more cost-effective than blood glucose control for preventing complications in type 2 diabetes.²⁸

Self-monitoring is a critical component of the chronic care model, which treats the patient as a partner rather than a pupil, and which has the promise of leading to significant improvements in our currently inadequate management of chronic diseases such as hypertension and diabetes.²⁹ It is high time that organizations that pay for medical care recognize that reimbursement for self-monitoring of BP is in everyone's interest.

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