Self monitoring of blood glucose (SMBG) cannot replace HbA1c

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Abstract

The management of diabetes has focussed on achieving normal or near- normal glycemia, by a multitude of methods, including diet, exercise, oral drugs and insulin. Monitoring of glycemia can be done by checking urine sugar blood glucose through office /laboratory measurements or SMBG, as well as by assessing markers such as hemoglobin A1c (HbA1c), fructosamine or 1,5 anhydroglucitol. This article assesses the advantages of HbA1c as a monitoring tool in diabetes, while highlighting the limitations and short comings of SMBG.

ACCURACY

HbA1c measurements have been standardized over the past few years. National programmes in the USA, Japan, Sweden and other countries have ensured good reproducibility, reliability and comparability of methods. The coefficient of variation is less than 4% with all modern methods of HbA1c, including point – of –care HbA1c kits (1).

This contrasts favourably with the high coefficient of variation (15%) reported for most portable glucose sensing devices (PGDs) or SMBG meters (2).

The International Organization for Standardization recommends that ≥ 95 % of readings fall within 15 % for glucose readings <75 mg%, and within 20%, for higher blood glucose values (3). A survey of the commonly used PGDs in our country, however, shows that this is usually not achieved.

Operator –related errors and instrument –related errors both play a role in limiting the utility of SMBG.

Wrong calibration of the PGD, use of expired sticks, sticks exposed to humidity or high or low temperature can falsely elevate results. Improper use of control solutions, dirty meters, meters exposed to dust can also give wrong results (3).

While HbA1c is equally sensitive throughout the spectrum, SMBG is less reliable in the lower ranges of glycemia, and often overestimates glucose in the high ranges of glycemia (4).

TECHNIQUE

Intra –subject and inter –subject co-efficients of variation are much lower for HbA1c than for glucose measurements (44). The intra –subject variability for HbA1c is > 2% but 12-15%for fasting plasma glucose (5).

HbA1c measurements involve comparatively less steps, and hence, the chance of human error is minimal.

SMBG, on the other hand, suffers from many “human limitations”. Patients and diabetes care providers may not be aware of all the precautions needed to ensure an optimal result.

The hand should be washed with warm water (not alcohol), dried completely, rings removed from the appropriate finger, and the finger massaged from base to tip before doing SMBG (4).

More often than not, these steps are not followed, leading to a fallacious reading.

Too much of alcohol or water on the finger tip, inadequate drying, too much or too little massaging, a soft prick, and a below –optimal blood drop size can lead to a false SMBG report.

CONVENIENCE

Sample collection for HbA1c is much easier for SMBG. HbA1c can be measured at point –of-care and in the laboratory .The sample can be taken at any time of the day, requires no patient preparation, and is relatively stable at

room temperature (1).

SMBG should ideally be done at fixed times, and the meters are usually not effective at they extreme temperatures encountered in our country.

INTERFERENCE

While HbA1c does have its limitations in hemolytic anaemia and various hemoglobinopathies, most manufacturers have ensured that HbA1c determination can be done in most patients with hemoglobin variants.

HbA1c results are not affected by pharmacological concentration of any drugs in the blood stream, or by hemoglobin concentration (6).

Age, sex, ethnicity and non- fasting state do not confound HbA1c.

SMBG values, on the other hand, are confounded by hematocrit. Aspirin, paracetamol, mannitol vitamin C, vitamin E, and many other commonly used drugs interfere with, and falsify SMBG values.Maltose, incodextrin, galactose and xylase may interfere with some PGD results, and lead to wrong results (7).

A low hematocrit increases SMBG results because of the lower erythrocyte mass. Red blood estimations of glucose are 15 % lower than plasma values (8).The difference lessens with anaemia, as there is less glucopenic erythrocyte mass.Most PGDs are calibrated to assume a normal hematocrit, and may not be appropriate for an anaemic population.

These shortcomings seriously limit the use of SMBG in patients with diabetes.

A recent analysis has shown that 41% of instruments have significant bias which result in potential misclassification of > 12 % of patients (9).

DIAGNOSTIC USE

American Diabetes Association (ADA) recommends neither SMBG or HbA1c as a method for diagnosis of diabetes (10).

However, retinopathy has shown a less consistent relationship with fasting glucose than with HbA1c (11). As the diagnostic cut offs for diabetes are based on risk of developing chronic complications, HbA1c may be considered as a diagnostic tool in the near future (6).

With more accurate and sensitive assays available, HbA1c has been recommended as a diagnostic marker for diabetes by a international Expert Committee this year (6).

On the other hand, it is extremely unlikely that SMBG will replace venous plasma glucose determination in the diagnosis of the disease.

MONITORING USE

All international organizations mention HbA1c as the gold standard for monitoring glycemic control and treatment. Therapeutic decisions are based on HbA1c levels, and SMBG values are used as an adjunct, not as the primary criteria for decision making (12).

CORRELATION WITH CHRONIC COMPLICATIONS

The aim of tight glycemic control is to prevent chronic complications. Multiple authors have shown the correlation of HbA1c with retinopathy, nephropathy and cardiovascular disease (1,6).

It becomes imperative, therefore, to focus on HbA1c if one wants to prevent morbidity and mortality due to these illness.

No such robust data is available for SMBG, however.

COST

The cost of SMBG is considerable and may inhibit the effective use of the tool.

Hba1c, in relative terms, is less expensive than frequent SMBG, A reliable HbA1c costs Rs 300, which is equal to the price of 10-12 SMBGs.

A single bottle of 25 sticks should be finished within one month of opening, and will be much more expensive than HbA1c monitoring.

UTILIZATION OF RESULTS

SMBG and HbA1c results have no value if they are not acted upon. It is not enough to do SMBG; the patient has to be taught how to self- adjust doses (13). This variable significantly influences the efficacy of SMBG.

HbA1c values, on the other hand is easier to understand, and encourages appropriate action or therapeutic decision because of its simplicity.

EFFICACY OF SMBG

Many randomized controlled trials have studied the efficacy

of SMBG in lowering HbA1c, and results have been conflicting.

Wing et al found no statistically significant difference in HbA1c amongst 58 American insulin- treated patients, whether or not they practiced SMBG (14).

Similar results were noted by Fontbonne et al (15) in 208 French non insulin –treated type 2 patients, Allen et al (16) in 54 Americans and Estey et al (17) in 60 Canadians. Davidson et al (18), studying 88 Latino Americans of low socioeconomic status, also failed that SMBG does not improve HbA1c.

A literature renew of 6 randomized controlled trials, involving both insulin and non insulin treated type 2 patients (n=617), by Faas et al (19), showed no statistically significant difference in HbA1c between SMBG and no SMBG groups.

A similar metaanalysis of 4,randomized control trials studying 285 type 2 diabetics, found no significant improvement in HbA1c with either blood or urine monitoring (20).

The DiGEM a three arm randomized trial set in United Kingdom general practices , studied 453 non – insulin treated type 2 diabetes patients, and was not able to demonstrate any benefit on HbA1c after 12 months of SMBG (21).In fact, SMBG was associated wit higher costs and poorer quality of life (22).

Another prospective randomized controlled trial of 184 newly diagnosed type 2 diabetes revealed surprising finding (23) .SMBG had no effect on glycemic control, but was associated with higher scores of depression.

The largest such study, a cross-sectional observational design study, conducted in 6495 type 2 diabetes patients in 18 primary health care centres, revealed no benefit of SMBG on glycemic control, irrespective of the type of therapy given (24).

UTILITY WITH NEW DRUGS

The newer drugs available for management of diabetes, such as insulin analogues and incretin based therapies, are associated with a lower incidence of hypoglycemia.

This, therefore reduces the need for frequent SMBG, while the importance of HbA1c remains unchanged.

RECOMMENDATIONS

While definite recommendations are available for frequency of HbA1c estimation in all patients with diabetes, confusion prevails regarding the optimal frequency of SMBG in type 2 diabetes.

Definite recommendations are available only for gestational diabetes and type 1 diabetes patients, who form a very small percentage of all diabetic patients.

This reinforces the fact that SMBG cannot substitute HbA1c as a tool for monitoring glycemic control in the vast majority of diabetes patients.

A consensus panel has concluded that evidence is not adequate to support routine postgraduate blood glucose testing (25). Postprandial glucose have not been shown to predict cardiovascular complications beyond their effect on HbA1c.

CONCLUSION

HbA1c is the gold standard for monitoring glycemia, and it cannot be replaced by SMBG.

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