ORIGINAL ARTICLE

Is self-blood glucose monitoring in type 2 diabetic patients on diet and/or oral agents cost-effective?

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BACKGROUND: Home blood glucose (HBG) monitoring has become an established practice in management of diabetes mellitus. However, it is unlikely to affect glycemic control unless the patients can and do act promptly, i.e., adjust insulin dose or type, in response to blood glucose readings. Moreover, the patients treated with diet and/or oral drugs are unable to take a prompt similar action. Finally, patients with type 2 diabetes rarely manifest extreme excursions of diurnal glycemia; however, the data in this regard are sparse.

AIMS: This study assessed the influence of (1) HBG testing, (2) home urine glucose (HUG) testing, and (3) no testing (NT) on metabolic control, i.e., fasting plasma glucose, glycohemoglobin (HbA_{1C}), and lipids, in 42 patients with type 2 diabetes.

METHODOLOGY: All subjects underwent each testing phase lasting 4 months in a randomized sequence. HBG or HUG testing was performed four times daily, prior to meal and at bedtime.

RESULTS: No significant differences were observed in fasting plasma glucose and HbA_{1C} concentrations or lipid profiles at the end of each testing.

CONCLUSION: It is apparent that HBG testing alone without an opportunity for prompt intervention, i.e., insulin administration, may be a wasteful exercise. We recommend an efficient cost-saving strategy of HBG testing with visual strips alone in patients not receiving insulin, only in the presence of symptoms of hypoglycemia or hyperglycemia, and at the onset of acute illness.

KEY WORDS: Cost efficacy, self-blood glucose monitoring, type 2 DM.

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Introduction

Home blood glucose (HBG) monitoring has become an established practice in the management of diabetes mellitus (DM). However, patients treated with premixed SC administration of rapid- or short-acting insulin can act promptly; i.e., adjust either the insulin dose or the intake of carbohydrates in response to their blood glucose readings either high or low, respectively, whereas patients treated with di*et al*one or with oral drugs are unable to take a similar action. Moreover, patients with type 2 DM treated with diet and/or oral drugs rarely manifest extreme excursions of diurnal glycemia[1] because of their continued ability to induce postmeal insulin secretion. Finally, the cost-effectiveness of HBG monitoring in the management of type 2 DM is uncertain because the outcome data in this population are sparse in the literature.[2]

Methodology

The study protocol was approved by the Medical Center's Research and Development Committee, as well as the Human Studies Subcommittee. Forty-two randomly selected men with type 2 DM attending diabetes clinic at the VAMC, Phoenix, Arizona, participated in the study protocol after obtaining informed consent. Mean age was 62 ± 4 years with a range between 45 and 77 years. Duration of diabetes ranged between 2 and 14 years with a mean of 6 ± 3 years. Body mass index (kg/m²) was 32 ± 3, with a range of 26-39. All subjects were being treated with diet and oral sulfonylurea: 23 with tolazamide, 3 with chlorpromide, 9 with glyburide, and 7 with glipizide GTS.

The study protocol consisted of the following three crossover phases, each lasting four months, arranged in

a randomized sequence:[1] HBG testing,[2] home urine glucose testing,[3] and no testing. HBG or home urine glucose testing was performed four times daily, once before breakfast and other times being prior to other meals and at bedtime. Metabolic control was assessed at the end of each phase by determinations of fasting plasma glucose, glycohemoglobin (HbA_{1C}), and serum lipid profile, i.e., total LDL and HDL cholesterol and triglyceride levels. All blood determinations were conducted by the Central Laboratory at the Medical Center using commercial kits. Highest normal level for HbA_{1C} was 6.4% in the laboratory. The coefficients of variations for inter- and intra-assay determinations ranged between 10 and 15% in the laboratory.

Prior to entry into the study protocol, once again the subjects received detailed instructions by a nutritionist regarding diet and exercise patterns. They were also instructed by a certified diabetes educator on performance of capillary blood and urine glucose testing, as described previously.[3,4] Moreover, they were watched while performing blood glucose testing at each follow-up visit during the phase of HBG monitoring in order to maintain precision and reliability. At the same time, capillary blood glucose was also determined by CDE and compared with the results obtained by the individual subject. The subjects were further instructed if the difference between two readings was greater than 10%. All subjects continued the same oral drug regimen and were advised to maintain the same diets and activity profile throughout the study protocol.

Results

Prior to entry into the study protocol, glycemic control was desirable (HbA_{1C} < 7.4%) as recommended by the American Diabetes Association (less than 1% above the highest normal concentration in the local laboratory) in 12 subjects. Glycemic control was deemed "fair" (HbA_{1C}, 7.5-9.4%) in 19 subjects, whereas in 11 subjects, glycemic control was deemed poor as reflected by HbA_{1C} concentrations of greater than 9.4%. No significant differences were noted between body weights, fasting plasma glucose concentrations, HbA_{1C} levels, and lipid profiles determined following all three phases among all 42 subjects assessed as a group [Table 1). Finally, none of the individual subjects manifested a significant improvement or a deterioration of glycemic control ($\Delta HbA_{1C} \geq 1\%$) following a crossover from one phase to another.

Table 1: Body weight (BW), fasting plasma glucose (FPG), HbA_{1C}, total cholesterol (C), serum triglyceride (TG), LDLC, and HDL C levels in 42 subjects with type 2 DM prior to entry into the study protocol (Pre-Rx) and at the end of each phase lasting 4 months.

	GT	UT	NT
BW (kg)	100 ± 6	99 ± 6.7	100 ± 8
FPG (mg/dl)	176 ± 16	187 ± 18	185 ± 15
HbA_{1C} (%)	10.5 ± 0.4	10.5 ± 0.5	10.4 ± 0.6
Cholesterol (mg/dl)	221 ± 12	223 ± 14	219 ± 15
Triglyceride (mg/dl)	224 ± 19	213 ± 6	201 ± 18
LDLC (mg/dl)	139 ± 15	14 ± 17	126 ± 16
HDLC (mg/dl)	44 ± 7	40 ± 6	46 ± 8

Self-blood glucose testing (GT), self urine glucose testing (UT), and no testing (NT)

Discussion

This study demonstrates that glycemic control and lipid profiles are not improved by a sheer HBG monitoring in subjects with type 2 DM receiving oral drug treatment regimens. Similar observations have been reported in previous studies.[5–15] The lack of improvement in metabolic indices with either blood or urine glucose monitoring in comparison with the absence of any testing may be attributed to the inability to initiate a prompt intervention, because insulin therapy based on premeal or bedtime blood or urine glucose readings was not an option used by these subjects. Alternatively, abrupt dietary change, i.e., starvation or skipping a meal may improve glycemic control transiently, but the practice is not likely to be healthy in the long term. Moreover, instant lowering or omitting the dose of the oral agents in the presence of lower preprandial sugar level may not be possible. Finally, day-to-day glycemic control in subjects with type 2 DM treated with oral agents is devoid of extreme excursions noted in subjects treated with multiple injections, especially those with type 2 DM.[1,2] Thus, the variations between daily blood sugar determinations after an overnight fast and at premeal and bedtime are markedly less pronounced as compared with subjects with type 1 and type 2 DM using multiple insulin injections. In fact, authors of one study recommended HbA_{1C} determinations once a year in subjects with type 2 DM when desirable glycemic control was attained by oral agents and/or diet and exercise.[16] However, this recommendation appears rather extreme, especially if the optimal goal for HbA_{1C} 6.5% is to be attained and maintained, because the natural course of the disease is progressive, with gradual reduction in β-cell function inducing lapse of glycemic control also described as onset of secondary failure.[17,18] Therefore,

in the final analysis, daily HBG monitoring prior to all meals and at bedtime is not likely to be cost-effective in management of type 2 DM with oral agents and/or diet.[15–20] We recommend that HbA_{1C} be monitored at intervals of 3 months in all subjects, irrespective of therapeutic strategies and type of diabetes and the four times daily HBG monitoring be reserved only for subjects using multiple insulin injections. In subjects using oral agents, HBG monitoring should be conducted once or twice a week as well as in times of stress or if symptoms of hypoglycemia ensue, because both these circumstances require prompt attention by the patients themselves or their health care provider. However, if subjects desire daily monitoring of blood glucose, costs could be reduced by using visual strips alone or by substituting it with urine glucose testing.[21]

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