

Self-monitoring of blood glucose improved glycemic control and the 10-year coronary heart disease risk profile of female type 2 diabetes patients in Trinidad and Tobago

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Abstract

Background and Aim: The risk of death from coronary heart disease (CHD) in women with diabetes is more than three times that of non-diabetic women. We assessed the difference in CHD risk levels of Afro-Caribbean diabetic women provided with facilities for self-monitoring of blood glucose and their counterparts without such facilities

Materials and Methods: Forty-nine patients who never used gluco-meters were studied as intervention (23) and control (26) groups. The intervention group was trained on self-monitoring of blood glucose. At baseline, BP, anthropometric indices, and fasting blood glucose of all patients were measured. Subsequently, the intervention patients were provided with gluco-meters, testing strips, and advised to self-monitor fasting and postprandial blood glucose every other day for 6 months. CHD risk was determined with the United Kingdom Prospective Diabetes Study risk engine calculator.

Results: The age, duration of diagnosis of diabetes, BP, and anthropometric indices were similar in the two groups (all, $P > 0.05$). The majority of the patients were unemployed or retired with only primary education. After 3 months, the HbA_{1c} levels of the control patients did not change ($8.3 \pm 0.4\%$ vs. $7.8 \pm 0.4\%$, $P > 0.05$) whereas the HbA_{1c} levels of the intervention patients reduced significantly from the baseline at 3 ($9.2 \pm 0.4\%$ vs. $7.4 \pm 0.3\%$, $P < 0.001$) and 6 ($9.2 \pm 0.4\%$ vs. $7.3 \pm 0.3\%$, $P < 0.001$) months. The 10-year CHD risk level of the intervention group was remarkably reduced from the baseline level after 6 months ($7.4 \pm 1.3\%$ vs. $4.5 \pm 0.9\%$) of the study.

Conclusion: Provision of facilities for self-monitoring of blood glucose in Afro-Caribbean women with type 2 diabetes improves both their glycemic control and CHD risk profile.

Key words: Afro-Caribbean, coronary heart disease, glycemic control, type 2 diabetes

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Introduction

The risk of death from coronary heart disease (CHD) in women with diabetes is more than three times that of non-diabetic women.^[1,2] Diabetes mellitus removes the normal premenopausal gender-related differences in the prevalence of CHD.^[2-4] The disparity between CHD in premenopausal women and men of the same age has been shown to be

related to the beneficial effect of female sex hormones such as estrogen and progesterone.^[4-6] Thus, diabetic women on postmenopausal estrogen therapy have a reduced risk of CHD.^[6] The impact of diabetes on CHD mortality is greater for women especially those from a lower socioeconomic background.^[7] Diabetes, dyslipidemia, overweight, obesity,

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and poor glycemic control are recognized risk factors for CHD in women in different populations.^[11,8-14] Although cardiovascular disease is recognized as one of the leading causes of death in Trinidad and Tobago,^[15] only one research report has characterized the CHD risk profile of diabetic patients in Trinidad and Tobago in quantitative terms.^[16] A 10-year CHD risk can be estimated from the equations derived from the Framingham Heart Study^[17] or the United Kingdom Prospective Diabetes Study (UKPDS) risk engine.^[18] These two tools are comparable in estimating CHD risk levels.^[19] However, UKPDS risk engine is more useful for type 2 diabetic patients because it incorporates diabetes-specific attributes such as glycated hemoglobin A_{1c} levels, an index of long-term glycemic control, in its calculation.^[18] Interestingly, glycated hemoglobin A_{1c} reports on type 2 diabetic patients in this population showed poor glycemic control and were associated with increased cardiovascular risk.^[11-14] Thus, in an attempt to determine the impact of glycemia on the CHD risk profile of female diabetic patients in this population, the study aimed to use the UKPDS risk engine to characterize the difference in CHD risk profiles of female patients provided with facilities for self-monitoring of blood glucose and their counterparts without such facilities.

Materials and Methods

Recruitment strategy

The female patients studied are a subgroup of type 2 diabetic patients who previously participated in a project for self-monitoring of blood glucose. The patients were attending primary care clinics in Tobago and were not using glucometers at home to monitor their blood glucose level. They were considered as type 2 diabetics if they had been managed on oral hypoglycemic medication and/or diet/exercise since diagnosis (except on occasions when patients took insulin to control hyperglycemia). The patients received information leaflets, and additionally, posters were strategically posted on the clinic bill-boards explaining the objectives and protocol of the research study. Furthermore, on clinic days, a member of the research group addressed the patients explaining the rationale for the study and subsequently the names and other information of volunteers were documented. The volunteers were later informed of the scheduled study dates.

Intervention and control groups

There were 23 female patients in the intervention group and 26 patients in the control group. The intervention group was given gluco-meters and testing strips that could last for 3 months (90 days). Furthermore, members of the intervention group (gluco-meters users) was trained on how to use the gluco-meters (Easi-Check, TaiDoc Technology Corporation, San-Chung, Taipei, Taiwan, People's Republic of China) and in data documentation using a study calendar folder that contained information on (i) dates and days of

the 3-month duration, (ii) fasting and postprandial blood glucose values, (iii) date and time of blood glucose testing, (iv) food eaten before measuring postprandial glucose levels, and (v) any action taken after seeing the blood glucose values. The intervention patients were further advised to measure their blood glucose levels and document the same every other day (i.e., 45 times) for the first 3 months (90 days) and return to the clinic for another 3-month supply and evaluation (measurements of fasting glucose, blood pressure and anthropometric indices). During the follow-up, the intervention patients were called on the telephone at least once every week to generally ascertain if they had any problems with the gluco-meters and testing strips. Two patients who reported problems with their meters or testing strips received replacements. The members of the control group were advised not to use gluco-meters at home for monitoring their blood glucose levels. They were requested to return to the clinic after 3 months for evaluation (measurements of fasting glucose, blood pressure and anthropometric indices). The control group patients were never placed on weekly follow-up (for the 3 months of their study duration) until the time they were reminded of the next study date and time.

Study protocol

Informed consent was obtained from all the patients who participated in the study. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in an *a priori* approval by our institutional ethics review committee. All patients were studied at one clinic (Roxborough Lifestyle Disease Clinic) in the morning (after 12 to 14 h of overnight fasting) for baseline, 3-month, and 6-month (intervention patients only) study visits. During the first visit, the bio-data of all the patients were obtained and a short questionnaire was administered to ascertain information on the previous medical history, diabetes duration and management, and education and occupation. The blood pressures of the patients were taken by one nurse using a semi-automated sphygmomanometer with standard adult cuff size (Diammap, Pro-Care Auscultator 300, General Electric, USA). Waist and hip circumferences were measured using a tape measure – waist (cm), at the level of the umbilicus with the patient standing and breathing normally, and hip circumferences (cm), at the level of the largest projection of the buttocks. Weight (kg) was determined using a standard hospital balance, and height (m), with metal rule. Patients wore light clothing, with no shoes. Then, a fasting blood sample was collected from each patient. Blood samples were collected for HbA_{1c} and lipid measurements. This protocol was used during subsequent visits at 3 and 6 months (intervention group only).

Biochemical analysis

Serum total-cholesterol and high-density lipoprotein were measured in multichannel auto-analyzers using dry slide

kits (Johnson and Johnson Vitros 250, Ortho-Clinical Diagnostics Inc., Rochester, NY, USA) while HbA_{1c} was determined using the boronate affinity assay (Axis-Shield PoC AS, N-0504, Oslo, Norway).

Calculation of the absolute CHD risk - UKPDS risk engine-based clinical and biochemical characteristics

The criteria for risk assessment using the UKPDS risk engine^[18] included the following: records of sex (male or female), age (> 20 years), ethnicity (Afro-Caribbean, Asia-Indian, or White), smoking (nonsmoker, current smoker, or ex-smoker), diabetes duration (any positive integer, or 0 for newly diagnosed diabetes), systolic blood pressure (between 60 and 250 mmHg), total cholesterol (between 1 and 15 mmol/L), HDL-cholesterol (between 0 mmol/L and the "total cholesterol" value), glycated hemoglobin (between 2% and 20%), and presence or absence of atrial fibrillation. Based on the above criteria, the absolute 10-year CHD risk was calculated using UKPDS risk engine software obtained from the official UKPDS website <http://www.dtu.ox.ac.uk/ukpds/publications.html>.

Statistics and calculations

The results are expressed as mean ± SE. The Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) software was used in all analyses. Differences between intervention and control patients at baseline and 3-month or 6-month visit parameters were performed using Student's *t*-test while the chi-square test was employed for categorical parameters. One-way ANOVA was employed to determine differences in baseline, 3-month, and 6-month CHD risk levels in the intervention group. A *P*-value < 0.05 was considered statistically significant on two-tailed testing for all analyses.

Results

The clinical characteristics of the female patients studied are shown in Table 1. The lifestyle background, diabetes duration, anthropometry, and blood pressure levels of the two groups of patients were similar (*P* > 0.05). Of the 23 patients randomized to the intervention group, 83% and 70% returned for 3- and 6-month evaluations, respectively [Table 2]. Similarly, out of 26 patients in the control group, 73% returned for 3-month evaluation. Table 2 shows the baseline and subsequent changes in the parameters used in the calculation of the 10-year CHD risk levels. Although the mean baseline total-cholesterol of the control group was significantly higher than that of the intervention group (*P* < 0.05), HDL-cholesterol levels of the latter group of patients increased significantly from the baseline value at 3 (1.1 ± 0.1 mmol/L vs. 1.4 ± 0.1 mmol/L, *P* < 0.05) and 6 months (1.1 ± 0.1 mmol/L vs. 1.4 ± 0.1 mmol/L, *P* < 0.05, Table 2) of the study. Furthermore, the glycated hemoglobin

A_{1c} levels of the intervention group reduced significantly from the baseline value at 3 (9.2 ± 0.4% vs. 7.4 ± 0.3%, *P* < 0.001) and 6 months (9.2 ± 0.4% vs. 7.3 ± 0.3%, *P* < 0.001, Table 2) of the study. Figure 1 shows the CHD risk profile of the two groups of patients at baseline and after 3 months. There was no difference in the CHD risk levels of the two groups at baseline. However, in contrast with the control group, the risk level of the intervention group was insignificantly reduced by nearly one-half after 3 months (7.4 ± 1.3% vs. 4.3 ± 0.7%, *P* > 0.05, Figure 1). Again, in absolute terms, the 10-year CHD risk levels of the intervention group was reduced from the baseline level, albeit insignificantly, after 6 months (7.4 ± 1.3% vs. 4.5 ± 0.9%, *P* > 0.05, Figure 2) of the intervention.

Discussion

We studied the difference in CHD risk levels in female type 2 diabetic patients who were provided with facilities for self-monitoring of blood glucose and those who were not provided with any such facility for a period of 6 months. Analysis of our data showed that patients provided with facilities for self-monitoring of blood glucose had a remarkable reduction in 10-year CHD risk compared with their counterparts without access to such facilities. The implications of these findings are further discussed in relation to health care delivery in a developing country.

The finding that facilitated self-monitoring of blood glucose among female patients resulted in a remarkable reduction in the 10-year CHD risk level is of interest particularly as the patients studied were from primary care settings. Worldwide, the primary focus in the management of diabetes is glycemic control, and, to date, glycated hemoglobin A_{1c} measurement still remains the acceptable standard for assessing long-term glycemic control.^[20,21] Indeed, both the Diabetes Control

Table 1: Baseline clinical characteristics of the intervention and control patient

Parameters	Intervention patients (N = 23)	Control patients (N = 26)
Number of retired or unemployed	11	14
Primary school education only	19	23
Number of smokers	1	0
Number of alcohol users	4	7
Age (years)	58.3 ± 2.2	58.3 ± 2.6
Diabetes duration (years)	6.6 ± 1.2	7.2 ± 1.7
Systolic blood pressure (mmHg)	154.7 ± 5.6	143.5 ± 5.8
Diastolic blood pressure (mmHg)	80.1 ± 2.7	76.0 ± 2.4
Weight (kg)	84.3 ± 4.3	84.8 ± 4.3
Height (wm)	1.63 ± 0.01	1.62 ± 0.02
Body mass index (kg/m ²)	31.8 ± 1.5	32.0 ± 1.5
Waist circumference (cm)	104.5 ± 2.9	103.8 ± 3.1
Hip circumference (cm)	111.9 ± 2.6	111.6 ± 2.6

Table 2: Baseline and subsequent changes in the parameters used in predicting 10-year coronary heart disease risk

Parameters	Intervention patients (N = 23)		Control patients (N = 26)		
	Baseline (N = 23)	After 3 months (N = 19)	After 6 months (N = 16)	Baseline (N = 26)	After 3 months (N = 19)
Systolic blood pressure (mmHg)	154.7 ± 5.6	148.5 ± 6.0	144.0 ± 7.6	143.5 ± 5.8	139.2 ± 5.1
Glycated hemoglobin A _{1c} (%)	9.2 ± 0.4	7.4 ± 0.3	7.3 ± 0.3 ^{**}	8.3 ± 0.4	7.8 ± 0.4
Total cholesterol (mmol/L)	4.7 ± 0.2	5.0 ± 0.2	5.4 ± 0.2	5.3 ± 0.2 [†]	5.0 ± 0.2
HDL-cholesterol (mmol/L)	1.1 ± 0.1	1.4 ± 0.1	1.4 ± 0.1 [†]	1.3 ± 0.1	1.2 ± 0.1

*P < 0.05 for differences from the baseline values, **P < 0.001, †P < 0.05 for the difference between the baseline of the intervention and control patients.

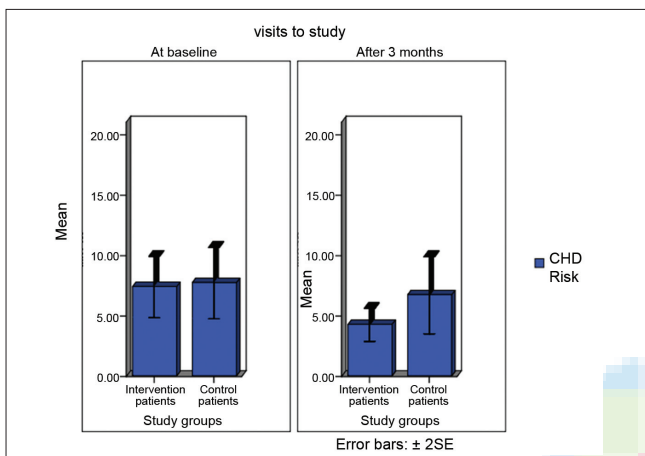


Figure 1: Baseline and 3-month coronary heart disease risk profile of the intervention and control groups of patients

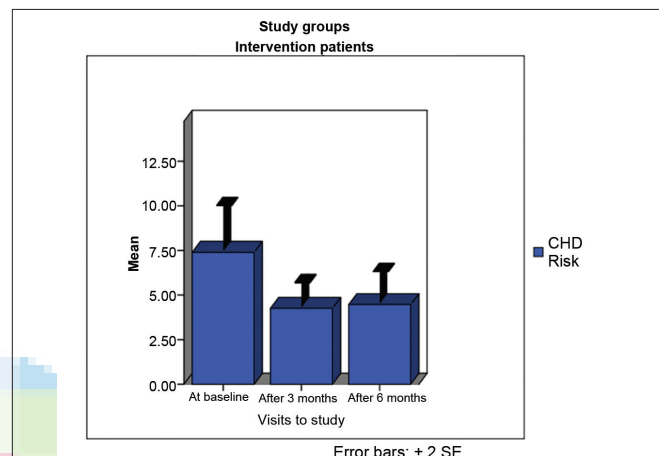


Figure 2: Improvements in coronary heart disease (CHD) risk profile of the intervention group during the 6-month study period

and Complication Trial Research Study (DCCT) and the United Kingdom Prospective Diabetes Study Group (UKPDS) showed that a significant reduction in HbA_{1c} levels has a parallel reduction in the risk of micro- and macrovascular complications.^[22-24] Thus, the HbA_{1c} parameter was included in the UKPDS risk engine calculator for estimating 10-year CHD risk levels in type 2 diabetic patients.^[18] Previous studies from other developing countries^[25,26] and our laboratory^[27,11-14] have reported a poor glycemic control among type 2 diabetic patients. Similarly, a report from the United States has identified ethnic-related difficulties in glycemic control among type 2 diabetic patients of African origin.^[28,29] Although our previous report from this multiethnic population showed that patients of Indian origin had worse glycemic control than their counterparts of African origin,^[14,16] one important observation in the current report is that the provision of facilities for self-monitoring of blood glucose improved both the glycemic control and 10-year CHD risk level in Afro-Caribbean patients studied.

It should, however, be noted that the risk of CHD is relatively low in the African or Afro-Caribbean population.^[9,16] Indeed, the mean 10-year CHD risk score in this study is less than the 15% score the National Institute for Clinical Excellence (NICE) advocated for initiating statin

treatment in the UK population.^[30] However, the current study has interestingly demonstrated that the level of CHD risk in Afro-Caribbean women could be reduced further if the patients are empowered through self-monitoring of blood glucose. Given that there is paucity of diabetes health educators and patients' poor application of diabetes education acquired in many developing countries,^[31,32] providing patients with training and equipment for self-monitoring is potentially beneficial for both diabetes control and CHD prevention as demonstrated here. Although the debate on the cost-effectiveness aspect of self-monitoring of blood glucose is still continuing,^[33] the importance of the current findings is that the study was conducted in patients from a low socioeconomic background in primary settings in a developing country. A previous study in another population showed that the impact of diabetes on CHD mortality is greater in women of lower socioeconomic background.^[7] The patients in this study fit this profile and should benefit from the provision of facilities for self-monitoring of blood glucose.

While we acknowledge that the patients studied here showed enough motivation to self-monitor their blood glucose levels, which proved to be beneficial, it is likely that the sustainability of self-monitoring of blood glucose

in the general population would require a high degree of supervision. Furthermore, the study serves as a preliminary report on a relatively small sample size and short-term follow-up period. The contributions of proper adherence to medication and lifestyle changes were not factored in the favorable outcome reported. These are limitations to the study and warrant a large sample size study with longer term duration for a confirmation of the observations reported here. That notwithstanding, in our experience, though anecdotal, most patients in the primary care settings do not have the sophistication and leverage to depart from instructions handed down to them by their primary health care team. Therefore, we conclude that the provision of facilities for self-monitoring of blood glucose improves both the glycemic control and CHD risk profile of Afro-Caribbean type 2 diabetic women in the primary care settings. Female type 2 diabetics of African origin will benefit from the inclusion of gluco-meters and testing strips in their health care package.

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