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journal homepage: www.elsevier.com/locate/diabres

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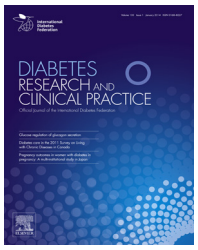

Do diabetes mellitus patients adhere to self-monitoring of blood glucose (SMBG) and is this associated with glycemic control? Experiences from a SMBG program in western Kenya

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ARTICLE INFO

Article history:
Received 13 July 2015
Received in revised form
21 October 2015
Accepted 18 November 2015
Available online 23 November 2015

Keywords:
Self-monitoring of blood glucose
DM
Adherence
Gglycemic control

ABSTRACT

Aims: Among diabetes mellitus (DM) patients with poor glycemic control enrolled into a self-monitoring of blood glucose (SMBG) program in Kenya, to assess the level of SMBG adherence, its associated factors and its relation to glycemic control (defined as HbA1c <7% and/or 2% absolute reduction relative to baseline).

Methods: In this retrospective cohort study, we used routinely collected data of patients enrolled during 2012–2013. We assessed adherence to SMBG by dividing the number of glucose tests performed by the number recommended. A level of ≥80% was considered 'good adherence'. Glycemic control was considered as absolute change from baseline of 2%.

Results: Of 164 patients (59% female; 76% rural), the proportions with good SMBG adherence were 34%, 17%, 15% and 10% during 0–6, 7–12, 13–18 and 19–24 months into the HGM program respectively. In multivariate analysis, male gender, urban place of residence and payment for glucostrips were associated with poor adherence during 0–12 months. The mean reduction in HbA1c compared to baseline was 1.2%, 1.1%, 0.8% and 0.7% at 6, 12, 18 and 24 months, respectively. We did not find any association between SMBG adherence and glycemic control.

Conclusions: Adherence to SMBG was sub-optimal, especially among those who had to pay for glucostrips. Patient education and provision of free glucostrips are recommended to improve adherence and glycemic control.

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http://dx.doi.org/10.1016/j.diabres.2015.11.006

1. Introduction

Globally, there were an estimated 387 million people living with DM (about half of them undiagnosed) and 4.9 million deaths in 2014 [1]. Nearly half of all DM deaths occurred in people aged less than 60 years globally, reaching 75% in less developed regions of sub-Saharan Africa. The number of DM patients is projected to increase to an astounding 592 million by 2035 [1]. In Kenya, the rising burden of DM remains largely neglected as the country is still struggling with infectious diseases. It is estimated that in 2014 775,210 DM cases were recorded in Kenya with 582,000 people with DM remaining undiagnosed [1]. Most of these patients present late and may not get the standard of care they need, leading to high morbidity and mortality.

A key component of DM management is self-monitoring of blood glucose (SMBG), which is proven to improve glycemic outcomes in patients with DM [2–4]. SMBG is tailored to meet the needs of the patient and varies depending on the treatment the patient is on [5]. Like in other interventions, patient adherence remains key to achieving good outcomes [6]. Adherence is defined by the World Health Organization as the extent to which a person's behavior – taking medication, following a diet and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider [7]. Adherence to SMBG therefore requires that patients test their blood sugar as advised by the healthcare provider, in terms of frequency and timing. The overall evidence about adherence to SMBG among DM patients is limited and most of the evidence comes from the United States of America, Europe or Asia [2,3,8,9]. We could not identify any published evidence on this issue from Africa.

At the Moi Teaching and Referral Hospital (MTRH) in Kenya, patients with DM who meet a certain criteria (Section 2.3) are enrolled into a home-based SMBG program, educated and provided with an electronic blood glucose meter to conduct intensive SMBG. Patients are contacted via telephone once a week and are expected to give the SMBG readings for that week. The SMBG readings are then used to guide a healthcare provider in adjusting their medication. However, it has been observed in the program that the glycemic control of some of the patients remains lower than expected and it is not clear whether this is related to patient's adherence to SMBG. Therefore we aimed to assess the adherence to SMBG in this group and its relation to glycemic control. The specific objectives were to (1) determine the adherence to SMBG at different time points into the program, (2) identify the demographic and clinical characteristics associated with non-adherence to SMBG and (3) assess whether adherence to SMBG is associated with glycemic control and hospital admissions and emergency room visits.

2. Methods

2.1. Study design

This is a retrospective cohort study using the routinely collected data of DM patients enrolled into the home based care program.

2.2. General setting

Kenya is located in East Africa with a population of 43.2 million as of 2012. The country is divided into 47 administrative counties. The health care delivery system in Kenya is divided into six levels. Level 6 represents the national referral hospitals which are currently two in the country, level 5 represents county referral hospitals, level 4 represents sub county referral hospitals and levels 3–1 represent the primary health care facilities. Currently DM management is mostly confined to level 4, 5 and 6 hospitals where comprehensive DM management teams and services are likely to be found. The current DM prevalence in the country is estimated at 3.6% [1] which may be an under representation due to lack of data collection tools to report on DM cases in the country as well as the fact that most DM patients remain undiagnosed.

The Moi Teaching and Referral Hospital, located in Eldoret town (310 km Northwest of Nairobi, the capital city of Kenya), is the second largest referral hospital in the country. The hospital serves a catchment population of 16.4 million people [10]. The hospital runs DM outpatient clinics and currently has about 3000 patients on care. The main occupation in the catchment population is farming with most people engaging in subsistence farming.

The Academic Model providing Access to Health Care (AMPATH) is a collaboration between Moi University College of Health Sciences (MUCHS), Moi Teaching and Referral Hospital (MTRH) and a consortium of North American academic medical centers led by Indiana University. AMPATH was first established as a response to the HIV pandemic but in collaboration with Ministry of health (MOH) has diversified to other chronic illnesses [11]. The chronic disease management (CDM) program of AMPATH oversees management of DM patients including those in the SMGB program in western Kenya.

2.3. Home glucose monitoring (HGM) SMBG program

As part of chronic disease management program, patients are enrolled into a home glucose monitoring program based on strict pre-defined criteria that includes all children, adolescents and adults with poor glycemic control. The program has two distinct arms. Arm 1 constitutes all children, adolescents and adults with very poorly controlled DM as assessed by an HbA1c above 13% and/or established DM complications. Arm 2 constitutes financially able adults who are mainly on Oral Glucose Lowering Agents (OGLAS) or on insulin. These patients are also poorly controlled but have HbA1c below 13% and meet a certain criteria for SMBG such as hypoglycemic episodes or an established DM complication. The patients in arm 1 receive free glucometers and glucostrips while those in Arm 2 receive a free glucometer but pay a subsidized fee of Kshs 500 ($5.90) which is much lower than the market price of Kshs 3000 ($37.50) for a box of 50 glucostrips. All the patients receive free DM diaries and have access to all the HGM services irrespective of the arm assigned.

Once enrolled, the patients are trained by a DM educator on SMBG, use of the DM diary and their medication. The diabetes clinic currently has one diabetes educator who serves all the clients. As a result of this, most patients receive one session of diabetes education which in most cases is individualized

without involving other family members. The issued glucometers are pre-programmed to keep records for up to a month to allow for validation of results. Patients are required to test their blood sugar as advised by the clinician and record it in the diabetes diaries provided to them. The testing schedule mostly depends on the type of medication the patient is on. Patients on oral glucose lowering agents (OGLAs) are expected to test their blood glucose at least 3 days per week, twice a day (pre-breakfast and/or pre-dinner or 2 h post meal). Patients on twice daily insulin injection are expected to test daily at least twice a day (pre-breakfast and pre-dinner) while those on basal bolus injections of insulin are required to test daily at least three times a day (pre-breakfast and pre-dinner and post-meal at any time).

The patients are contacted via telephone by HGM staff each week to enquire about the blood glucose readings of the previous week and their general well-being. During the call, patients are expected to read the blood glucose readings noted in their diaries. The readings are then entered into a database with each patient having a unique database number. On a weekly basis, a clinician reviews these readings and advises the adjustments to the doses of medication, if required. The patients are then called back and informed about the new insulin doses. Patients on oral medication are required to visit the hospital, in case it is warranted to change the medication based on physician's advice. Patients also get a HbA1c test every three months for those in Arm 1 and every six months for those in Arm 2 as they pay for it and may not afford to do it every 3 months. Patients are required to adhere to their normal clinic dates, and on these visits they bring in their diabetes diaries and glucometers which are used to validate the self-reported readings collected over telephone. A hospital-based patient file is maintained which contains information on their clinic visits, admissions, visits to the emergency room and laboratory results. All the services under the program are provided free of charge to the patients with the exceptions mentioned above.

2.4. Study population

All patients enrolled into the HGM between January 2012 and December 2013, and who were in the program for at least six months were included in the study.

2.5. Data variables and data extraction

Data variables included: age, gender, place of residence, type of medication, presence of co-morbidity such as Hypertension or any associated DM complication, duration of DM, payment for glucostrips, actual number of blood sugar tests done, expected number of blood sugar tests, HbA1c and hospital admissions and emergency visits. Data were retrieved from the HGM data base and patient record files. Data on SMBG, HbA1c and hospital admissions and emergency visits were censored on 30th June 2014.

2.6. Operational definition of adherence and glycemic control

Adherence to SMBG was calculated by dividing the actual number of SMBG readings received from the patient by the expected number of SMBG readings at 6, 12, 18 and 24 months. Adherence level of 80% or more was considered good adherence, and lower than this was regarded as poor adherence. We defined glycemic control as HbA1c <7% or an absolute reduction of 2% in HbA1c value from the baseline.

2.7. Data entry and analysis

Data was single entered and analyzed using EpiData software (version 3.1 for data entry and version 2.2.2.182 for analysis, EpiData association, Odense, Denmark). Adherence to SMBG at different time periods (months 0–6, 7–12, 13–18 and 19–24) was expressed as proportions. For the purpose of assessing factors associated with poor adherence, we restricted our analysis by calculating adherence for 0-12 months as the patients with follow up data for more than 12 months were few.

To assess possible association of demographic and other characteristics with poor adherence to SMBG, we calculated relative risks (RR) with 95% confidence intervals (CI). Those variables which were significant at p-value of less than 0.1 were included in a multivariate model. Adjusted relative risks were calculated using Poisson regression model with a robust variance estimator to assess the independent effect of factors on poor adherence to SMBG. We used STATA (version 12.1, TX, USA) for the multivariate analysis. p-Value of less than 0.05 was considered statistically significant for all analyses.

2.8. Ethics

Permission to carry out the study was obtained from MTRH. Ethics approval was obtained from the Institutional research and ethics committee (IREC) at MTRH and the Ethics Advisory Group of the International Union against Tuberculosis and Lung Disease, Paris, France. As this study was done using routinely maintained records, the need for individual informed consent from the patients was waived by the ethics committees.

3. Results

A total of 164 DM patients were included in the study. The median (interquartile range) age of the participants was 33 (21–55) years, 59% were female and 76% were from rural areas. The demographic and clinical characteristics of study participants are summarized in Table 1. Most of the patients were receiving insulin with 69.5% being on pre mixed insulin (70/30) and 4.3% on a basal bolus insulin regimen. The mean duration of DM since diagnosis was 5 years. About one-fourth of the patients had to pay for the glucostrips.

Adherence to SMBG at different time periods is described in the Fig. 1. At 0–6 months into the HGM program, 34% had good adherence to SMBG. The proportion with good adherence further decreased to 17%, 15% and 10% during 7–12 months, 13–18 months and 19–24 months, respectively.

Of all the 164 patients, there were 121 who had follow up data up to 12 months. Between 0 and 12 months, the proportion of patients with poor adherence was 78%. Factors associated with poor adherence during 0–12 months are

Table 1 – Demographic and clinical characteristics of DM patients enrolled into the home glucose monitoring program at MTRH, Eldoret Kenya, 2012–2013.

Characteristics	Number (%)
Total	164 (100)
Age groups	
<15 years	8 (4.9)
15–24 years	51 (31.1)
25–34 years	27 (16.5)
35–44	17 (10.4)
45–54	15 (9.1)
55–64	31 (18.9)
≥65	15 (9.1)
Gender	
Male	68 (41.5)
Female	96 (58.5)
Place of residence	
Rural	125 (76.2)
Urban	39 (23.8)
Type of DM[a] medication	
Only oral medication	11 (6.7)
Insulin alone/Insulin + oral medication	153 (93.3)
Co morbid condition	
Present	38 (23.2)
Absent	126 (76.8)
Payment for glucostrips	
Paying	34 (20.7)
Not paying	130 (79.3)
Duration of DM	
0–2 years	43 (26.2)
3–5 years	38 (23.2)
>5 years	79 (48.2)
Not recorded	4 (2.4)

[a] DM-Diabetes mellitus.

shown in Table 2. On bivariate analysis, age more than 30 years, male gender, urban place of residence and payment for glucostrips were associated with poor adherence. In multivariate analysis, male gender, urban place of residence and payment for glucostrips were identified as risk factors for poor adherence.

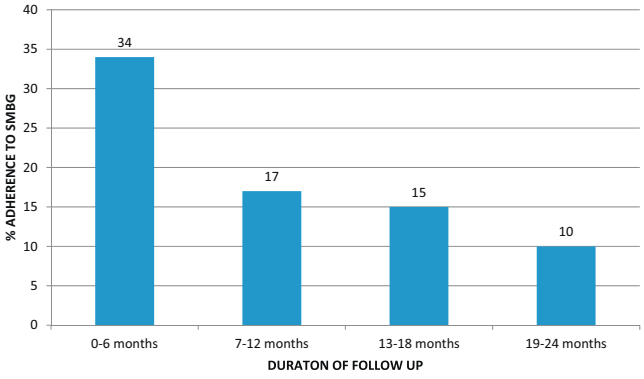

Fig. 1 – Adherence to self-monitoring of blood glucose and glycemic control among DM patients at different time periods after enrollment into self-monitoring program, Kenya, 2012–2013.

The trend in mean HbA1c is shown in Fig. 2. Improvement in glycemic control was highest in the first 6 months and decreased in subsequent months. The mean reduction in HbA1c compared to baseline was 1.2% (95% CI, 0.8–1.7), 1.1% (95% CI, 0.5–1.7), 0.8% (95% CI, 0.1–1.7) and 0.7% (95% CI, −0.7 to 2.0) at 6, 12, 18 and 24 months, respectively. At 12 months of follow up, 33% of patients achieved glycemic control.

There was no association between adherence to SMBG and glycemic control at 12 months among those adherent (accounting for 38%) and among the non-adherent (accounting for 40%; RR = 1.0, 95% CI 0.7–1.4, $p = 0.84$).

Of 121 patients who had a minimum follow up time of 12 months, 46 (38%) patients had at least one unscheduled visit (hospital admission or emergency room visit) to hospital related to DM. Poor adherence was not associated with unscheduled visits (RR = 1.23, 95% CI 0.69, 2.22, $p = 0.5$).

4. Discussion

Our study among DM individuals with poor glycemic control at enrollment in a home glucose monitoring program showed that adherence to SMBG was not optimal. More than 75% of DM patients were poorly adherent during 0–12 months after enrollment and this increased to 90% after 18 months. Being male, residing in urban area and paying for glucostrips were associated with poor adherence to SMBG. The mean HbA1c kept fluctuating through the program—reduced from baseline in the first 6 months then increased at 12 months, followed by a decline in the 18th month and a rise again in the 24th month. Despite this trend, the reduction in HbA1c from baseline was maintained and did not worsen to baseline level or more. Though there was reduction in HbA1c levels from the baseline after enrollment, adherence to SMBG was not associated with glycemic control.

Our study findings of poor adherence to SMBG confirm the results of previous studies on adherence from US, Europe and Asia [6,8]. A study done in Central Texas [4] using 80% cut off for defining adherence reported that only one third of DM patients were adherent to SMBG which was higher than the present study. However this study may not be comparable to other studies in developed countries as adherence is influenced by many factors like literacy level of patients, family support, presence of disease complications and support systems like provision of diabetes educator and reminders. All the above factors may be completely different in this study setting from the rest of the previous studies from developed and developing countries. Unlike the previous studies, only DM patients with poor glycemic control were enrolled in the present study and hence the level of adherence and glycemic control achieved is expected to be different.

Payment for glucostrips was associated with poor adherence in the present study. Though glucostrips were provided at subsidized cost, still for many patients this cost may be unaffordable due to other associated costs of DM management. The study from Central Texas reported similar findings that fewer environmental barriers including costs were significantly associated with good adherence. Another factor

Table 2 – Factors associated with poor adherence to self-monitoring of blood glucose among DM patients at 12 months after enrollment into the home glucose monitoring program at MTRH, Eldoret Kenya, 2012–2013 (N = 121).

Variables	Total	Poor adherence N (%)	RR (95% CI)	Adjusted RR (95%CI)
Age groups				
0–29 years	59	40 (68)	Ref	
≥30 years	62	54 (87)	1.3 (1.1,1.6)	1.1 (0.9, 1.4)
Sex				
Male	50	41 (82)	1.1 (0.9,1.3)	1.1 (1.1, 1.1)
Female	71	53 (75)	Ref	
Area of residence				
Urban	31	27 (87)	1.2 (1.0,1.4)	1.1 (1.1,1.1)
Rural	90	67 (74)	Ref	
Comorbidity				
Present	25	21 (84)	1.1 (0.9,1.4)	
Absent	96	73 (76)	Ref	
Duration of DM				
0–2 years	32	24 (75)	Ref	
3–5 years	31	21 (68)	0.9 (0.7,1.3)	
>5 years	56	47 (84)	1.1 (0.9,1.4)	
Medication type				
Insulin	114	88 (77)	0.9 (0.7,1.2)	
Oral medication	7	6 (86)	Ref	
Payment for glucostrips				
Paying	23	22 (96)	1.3 (1.1, 1.5)	1.3 (1.1,1.5)
Non paying	98	72 (74)	Ref	

RR—relative risk, CI—confidence interval.

associated with poor adherence was male gender. Similar finding was reported by the study from China, where females were more adherent to SMBG. Exact reasons for this difference are not known and role of behavioral characteristics can be explored by future qualitative studies.

Our study did not find any association between adherence to SMBG and glycemic control and this could be related to small sample size. The patients enrolled in the program are enrolled on criteria of being poorly controlled and this may have biased the assessment of glycemic control. These patients could also represent a pool of generally non adherent patients given the poor control present at enrollment which may also affect the level of adherence to SMBG observed. There are also other factors that could impact glycemic control other than adherence to SMBG which were not assessed in our paper such as medication adherence, adherence to lifestyle modification, type of medication and peer and family support.

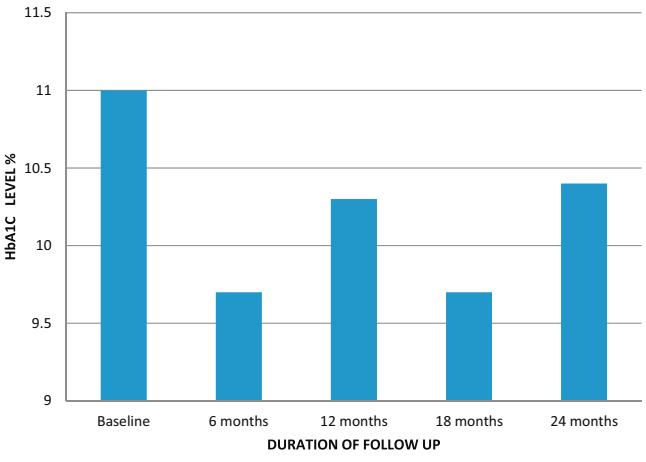

Fig. 2 – Trend in mean HbA1c level among DM patients at different time periods after enrollment into self-monitoring program, Kenya, 2012–2013.

However there was overall reduction in HbA1c levels in the first six months after enrollment into the program and this reduction was sustained thereafter. This is similar to findings in other studies where intensive SMBG was associated with improvements in HbA1c [2,8]. The trend in mean HbA1c observed is suggesting a pattern where patients improve their glycemic control which is followed by a period of poor DM practices possibly influenced by the apparent improvement. This is later followed by a period of good DM practices with resultant decline in HbA1c possibly due to panic induced by the worsened control. Many studies have reported the positive association between adherence and glycemic control [2]. The design of the program may not also facilitate attainment of glycemic control. This is due to the testing being done twice only which may not allow for adequate insulin dose adjustments. The type of insulin being used may have an implication on the level of glycemic control achieved. Majority of the patients are on premixed insulin due to its easy availability and low. This makes adjustment of insulin doses to cater for post meal hyperglycemia which compromises the level of glycemic control achievable.

The study findings have several implications. First, considering the overall low level of adherence to SMBG, routine counseling/DM education for this group needs to be improved. Structured educational materials on DM and SMBG targeting high risk groups like urban males can be developed and implemented. There is also a need to invest more in DM educators to facilitate provision of this essential service to the patients. Adherence to SMBG should be assessed at every hospital visit and the reasons for poor adherence should be sought. Diabetes educators and other health care providers

should be sensitized about the importance of adherence to SMBG and their counseling to DM patients should include sections on overcoming poor adherence to SMBG.

Second, provision of glucostrips at lower fees to patients in developing countries should be considered to facilitate SMBG in these patients. Third, considering the poor glycemic control at enrollment into the program, this select group of patients needs more comprehensive interventions (including advice for dietary changes and exercise) to improve glycemic control in addition to SMBG. The trend in mean HbA1c indicates that SMBG needs to be continuous to capture these trends and patient education needs to be sustained even when glycemic control is improving to avoid relapses to poor glycemic control. There should also effort to avail, at more affordable costs, basal bolus insulin regimens to DM patients in developing countries to allow control of post meal hyperglycemia which is the greatest contributor to glycemic control [12].

Future studies, if possible prospective, multicenter studies need to be planned with larger sample size, to assess other factors affecting SMBG and glycemic control. Qualitative studies are also recommended to understand the barriers to SMBG from patients' perspective.

Our study has several strengths. To the best of our knowledge, this is the first study from Africa on adherence to SMBG and its impact on glycemic control. Second, information on number of SMBG readings were validated with glucometer readings reducing the recall bias during self-reporting. Third, we used the HbA1c values for assessing glycemic control which is a robust measure. There were also a few limitations. We did not study environmental factors associated with adherence like family support, inconvenience and pain due to self-testing. This study was conducted at one referral hospital and generalizability of the study findings to other hospitals or other African countries may be limited. Finally, post hoc power calculation showed that we were grossly underpowered to detect association between SMBG adherence and glycemic control.

5. Conclusion

Adherence to SMBG was sub-optimal among DM patients enrolled in a home based glucose monitoring program and decreased with increase in duration of follow-up. Glycemic control was best at initial follow up and declined subsequently but never reverted to baseline. Patient and health provider education including provision of affordable glucostrips to all patients are needed to improve adherence. There is need to invest in more SMBG programs in developing countries to allow the improved monitoring and management of DM patients.

Funding

This work was made possible by the generous donation of Abbott foundation to the MTRH HGM program.

The Manuscript is written as part of the Operation Research program. The program was supported and funded by Bloomberg Philanthropies, The Union, MSF, The Department for International Development (DFID), UK and the World Health Organization. La Fondation Veuve Emile Metz-Tesch supported open access publications costs. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflict of interest

None declared.

Acknowledgement

This research was conducted through the Structured Operational Research and Training Initiative (SORT IT), a global partnership led by the Special Program for Research and Training in Tropical Diseases at the World Health Organization (WHO/TDR). The model is based on a course developed jointly by the International Union against Tuberculosis and Lung Disease (The Union) and Medécins sans Frontières (MSF). The specific SORT IT program which resulted in this publication was jointly developed and implemented by: The Center for Operational Research, The Union, Paris, France; The Operational Research Unit (LUXOR), Medécins Sans Frontières, Brussels Operational Center, Luxembourg; The Union, South-East Asia Regional Office, New Delhi, India and The Center for International Health, University of Bergen, Norway.

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