Original

Association of Self-Monitoring of Blood Glucose with Glycaemic Control among Patients with Type 2 Diabetes Mellitus in a Tertiary Hospital in Nigeria

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Abstract

Background: The effects of Self-Monitoring of Blood Glucose (SMBG) on glycaemic control in patients with type 2 diabetics using oral hypoglycaemic agents are conflicting and inconclusive. This study examined the association between SMBG and glycaemic control among adult patients with type 2 diabetes.

Method: Hospital-based cross-sectional analytical study for 6 months at Bowen University Teaching Hospital (BUTH), Ogbomoso, Nigeria using a systematic random Sampling technique. A structured questionnaire was administered to collect demographic data, average monthly income, DM history, and SMBG practice information from the participants. Data was analysed using the statistical package for social sciences (SPSS) version 22 by IBM Corporation, Armonk, New York. SMBG was determined based on participants' responses to the self-administered questionnaire. Chi-square was used to determine the association between SMBG practice and the glycaemic control since both variables were categorical.

Result: Out of the 310 participants who received the questionnaires, 301 completed them and had the results of their glycosylated hemoglobin test, resulting in a 97% response rate. Less than half of the study participants (48.2%) practiced SMBG. Patients with tertiary education (65.1%) compared to no formal education (33.3%), primary (42.9%), and secondary (51.6%) - were more likely to perform SMBG (P = 0.000). SMBG had no statistically significant association with the level of glycaemic control.

Conclusion: Finding shows that SMB practice had no statistically significant association with the level of glycaemic control among adult DM patients. Conduct of randomised controlled study comparing the effects of structured and unstructured SMBG regimens is recommended

Keywords: Diabetes mellitus, self-monitoring of blood glucose, SMBG, glycosylated haemoglobin, glycaemic control.

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Introduction

Diabetes mellitus (DM) is a chronic, costly, and debilitating cosmopolitan disease killing one person in every five seconds (6.7 million deaths in 2021),[1] making it the ninth leading cause of mortality globally with rising trends of prevalence in lower-income countries.[2] It currently affects an estimated 537 million adults aged 20-79 years worldwide (representing 10.5% of the world's population in this age group) and the figure is projected to rise to 783 million by 2045.[1] More than 75% of those adults with diabetes reside in low- and middle-income countries and the total number of people with diabetes in Africa is projected to increase by 129% by 2045.[1] Diabetes-related health expenditure currently constitutes 11.5% of total global health expenditure (966 billion dollars).[1] Diabetes mellitus is therefore, a significant and growing public health problem globally and in low- and middle-income countries in particular because of its increasing prevalence, association with cardiovascular disease, and mortality.[3] Diabetes mellitus has been defined as a group of progressive metabolic disorders characterized by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action, or both.[4]

For many people with diabetes, glucose monitoring is key for the achievement of glycaemic targets.[4] Currently available methods for health providers and patients to assess the effectiveness of glycaemic control include glycosylated haemoglobin (HbA1c), Self-Monitoring of Blood Glucose (SMBG), Continuous glucose monitoring (CGM), and Flash glucose monitoring.[5] Self-monitoring of Blood Glucose (SMBG) is defined as the collection by diabetic patients of detailed information about their blood glucose levels at many time points during the day on a day-to-day basis to aid adjustments in therapy and lifestyle activities and ultimately improve glycaemic control and prevent diabetes-related complications.[6] Several studies have demonstrated the efficacy of SMBG in the management of diabetic patients, especially in patients with type 1 diabetes mellitus and insulin-treated type 2 diabetic patients. This brought about the recommendations of SMBG for all type 1 and type 2 diabetic patients being treated with insulin by the American Diabetes Association and the International Diabetes Federation.[4,7] However, the results of studies to evaluate the effects of SMBG on glycaemic control, especially in patients with type 2 diabetics using oral hypoglycaemic agents are conflicting and inconclusive. The role of SMBG for such patients has, therefore, remained elusive.

Furthermore, the pattern of SMBG utilization in Nigeria is quite unpredictable and there is no local recommendation guiding the practice of SMBG in Nigeria. The practice of self-glucose monitoring among DM patients in Nigeria, according to a study, ranges from 3.4% amongst patients in rural settings to 73% in urban settings.[8] A recent study in Port Harcourt revealed that 27% of patients with diabetes practised SMBG whereas 96% were aware of the practice.[9]

Similarly, there is paucity of studies in Africa, including Nigeria, on the impact of SMBG on glycaemic control among type 2 DM patients and the findings of the few local studies available are contradictory. Whereas it was reported in a Sudanese cross-sectional study that SMBG had no positive impact on glycaemic control in type 2 DM patients.[10] Another study carried out in South Africa reported the beneficial effects of SMBG practice on glycaemic control especially when the practice is integrated with patient education.[11]

It is against this backdrop that we set out to provide insight into blood glucose monitoring practice among adult diabetic patients to assess its possible impact on overall glycaemic control and to make appropriate recommendations regarding its use by patients for improved glycaemic control. Study examined the pattern of practice of SMBG and determine its association with glycaemic control among adult patients with type 2 diabetes mellitus accessing care at Bowen University Teaching Hospital (BUTH), Ogbomoso, Nigeria to make appropriate recommendations regarding its use for better glycaemic control.

Method

Study Area

We carried out the study at the adult DM clinics of both the General Out-Patient Department (GOPD) and Endocrinology clinic of Bowen University Teaching Hospital (BUTH), a teaching hospital in Ogbomoso, Nigeria serving many rural environs. BUTH, formerly called Baptist Medical Centre, was founded on 18 March, 1907 as a mission hospital, but on December 1st, 2009, it was upgraded to a teaching hospital. It is a four hundred (400) bed-teaching hospital that provides primary, secondary, and tertiary health care services for the five local governments in Ogbomoso and its

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environment. The hospital caters for over 50,000 out-patients and 10,000 in-patients per year. Diabetes care is an integral part of the clinical services offered at Bowen University Teaching Hospital (BUTH) in Ogbomoso, at both the General Out-Patient Department (GOPD) and the Endocrinology clinic. SMBG is an important part of diabetes therapy at BUTH, particularly for patients on insulin or with unstable blood glucose levels. Patients are trained to use glucometers and record readings, allowing for real-time treatment modifications and promoting good self-management of diabetes.

Study Design and Sampling Technique

We performed a hospital-based cross-sectional analytical study using a systematic random Sampling method. The data collection lasted six months (between November, 2019 and May, 2020.).

Study Population

The study population consisted of adult patients with type 2 diabetes mellitus (DM) attending both the General Out-Patient Department (GOPD) and the Endocrinology clinic at Bowen University Teaching Hospital (BUTH) in Ogbomoso, Nigeria.

Sampling Methodology

A systematic sampling method was employed to select participants for the study. The sampling frame consisted of all adult patients with type 2 DM who attended the diabetes clinics over six months. Patients were selected at regular intervals from the clinic register until the desired sample size was reached.

Operationalization of SMBG

Self-Monitoring of Blood Glucose (SMBG) was operationalized based on patients' self-reports in the study questionnaire. Participants were asked whether they monitor their blood glucose levels using a glucometer. Based on their responses, participants were categorized into two groups: those who practice SMBG and those who do not.

Inclusion Criteria

We recruited consenting eligible patients aged 40 years and above who were first diagnosed of DM after the age of 40 years and must have been on DM treatment for at least 6 months.

Exclusion Criteria

Patients with gestational diabetes who require a different glycaemic target and diabetic patients on hospital admission (outside the study outpatient setting) were excluded from the study.

Sample Size Determination

The study sample size was determined using the formula:

$N = Z^2PQ/D^2$ [12]

Where:

N - The desired sample size.

Q - The proportion of the population not involved in the study i.e., 1-P

P -The proportion in the target population estimated to have a particular characteristic.

Z - The critical value for a two-tail test is usually set at 1.96 which corresponds to a 95% confidence level.

D - The absolute accuracy required is usually set as 0.05.

Using the prevalence of SMBG practice of 40% among diabetes patients in southwest Nigeria,[13] P is 0.4, Q=1-0.4.

N= 368.79 approximated to 369.

However, a total of 1,200 adult patients with type 2 DM attended the DM clinics (both GOPD and Endocrinology clinics) in the previous year from the hospital medical records department. Since the study population is < 10,000, the sample size was adjusted using the formula:

$$nf = \frac{n}{1 + \frac{n-1}{N}}$$ [12]

Where: n_f = desired sample size when the population is less than 10,000

n = desired sample size when the population is greater than 10,000

N = estimate of the population size = 1,200

Therefore, $n_f \approx 282$

An allowance of 10% (10/100 × 282 =28.2) was given for the poorly completed questionnaires and missing test results. This was added to the desired sample size to give a total of 310

I.e (282 + 28.2) = 310

The initial sample size was calculated to be 369 based on a 40% prevalence of SMBG practice among patients with diabetes. After adjusting for a smaller population size (1,200), the sample size was reduced to 282. Adding a 10% allowance for incompletely filled questionnaires, the final sample size was set at 310.

Our target populations were adult outpatients previously diagnosed with DM receiving care at the BUTH.

Type 2 DM was defined as DM first diagnosed in an adult patient after the age of 40 years. Participants with HbA1c of < 7% were classified as having good glycaemic control while poor control was considered as having HbA1c of ≥ 7%. Monthly income was grouped into three; Low-income class (<50,000 Naira), middle class (50,000-99,999 Naira), and high-income class (>100,000 Naira).[14]

Data collection

All eligible patients were ushered into the appropriate consultation office one at a time. The nature of the research programme and what was expected of each of the participants were explained to their full understanding. Signed consent was obtained from each participant. Confidentiality was assured and ensured. A structured questionnaire, previously pretested over one month among 30 adult diabetic patients at the General Out-patient Department of Ladoke Akintola University of Technology Teaching Hospital, Ogbomoso, was administered using the interviewer-administered method to collect demographic data, average monthly income, DM history, and SMBG practice information of the participants. In the study, the exposure variable, Self-Monitoring of Blood Glucose (SMBG), was determined based on participants' responses to the self-administered questionnaire. A venous blood sample of about 2ml was collected by the researcher at the adult DM clinics into a lithium heparin vacutainer tube, well mixed, and stored at room temperature before analysis in the laboratory (samples were not stored longer than 8 hours). The glycosylated haemoglobin was assessed using the DCCT-aligned HBA1CNow®+ Analyser (manufactured by Polymer Technology Systems, Inc. Indianapolis, USA). The accuracy of the HBA1CNow®+ system, when compared with the National Glycohaemoglobin Standardization Program (NGSP) certified method (Tosoh HBA1C 2.2 Plus), was 99.7% using a venous sample.

Data Analysis

Data were entered into a computer and analysed using the statistical package for social sciences (SPSS) version 22 by IBM Corporation, Armonk, New York. Percentages were used to determine the pattern of SMBG practice and the analyses were presented using frequency tables and charts. Descriptive statistics such as the mean, standard deviation, range, minimum and maximum were used to describe the level of glycaemic control while the Chi-square test was used to compare categorical variables such as the association between SMBG and the glycaemic control. For all statistical tests, the confidence interval was set at 95%. Statistical tests were considered significant if the p-value was less than 0.05. Microsoft Excel was used to draw charts.

Results

A total of 301 participants completed the questionnaires and had their glycosylated haemoglobin test results out of the 310 questionnaires administered, giving a response rate of 97%. The gender, age distribution, income categories, and educational levels of the respondents are shown in Table 1. The table also shows that majority of the study participants (75.1%) were using oral drug alone to control their diabetes mellitus and only 3% of the participants were using insulin alone to control their blood glucose. The table also shows that 69.4% of the study participants had HbA1c <7%, indicating good control while 30.6% of the study participants had HbA1c ≥7%, indicating poor control.

Table 1: Socio-demographic and clinical characteristics of the respondents

Variable		Freq (N=301)	Percent
Sex	Male	100	33.2
	Female	201	66.8
Age (Years)	41-60yrs	140	46.5
	61-80yrs	147	48.8
	81-100yrs	14	4.7
Income	< 50,000(Low)	230	76.4
	50,000-99,999(Middle)	71	23.6
	=>100,000(High)	0	0.00
Level of Education	No formal education	84	27.9
	Primary	70	23.3
	Secondary	64	21.3
	Tertiary	83	27.6
Modalities of DM Treatment	Insulin alone	9	3.0
	Drugs alone	226	75.1
	Insulin and drugs combined	66	21.9
HbA1c Category	Good control	209	69.4
	Poor control	92	30.6

**Good control: HbA1c <7%, Poor control: HbA1c ≥7%*

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Table 2 shows the pattern of SMBG practice among the respondents. Less than half of the study participants (48.2%) practiced SMBG. It also shows that the majority of the study participants did not alter their diabetes treatment based on the blood glucose obtained from SMBG. In this study, weekly blood glucose checks accounted for 25.50% of responses, and SMBG was performed irregularly by 4.1% of respondents, as shown in Table 2.

Table 2: SMB Practice Pattern among the Respondents

Practice of SMBG Variables		Freq	(%)
Do you practice SMBG	Yes	145	48.2
	No	156	51.8
Upon practice of SMBG, do you adjust treatment with SMBG results	Yes	24	16.3
	No	121	83.7
Frequency of blood glucose check among those who practice SMBG	Alternate daily	28	19.3
	Daily	27	18.6
	Fortnightly	26	17.9
	Monthly	16	11.0
	No regular pattern	6	4.1
	Weekly	37	25.5

According to Table 3, patients' education level, DM duration, and DM treatment modalities were the factors significantly associated with SMBG practice. Patients with higher levels of education-tertiary (65.1%) compared to no formal education (33.3%), primary (42.9%), and secondary (51.6%) - were more likely to perform SMBG (P = 0.000). Similarly, patients with DM duration of more than five years and those on Insulin therapy (taken alone or in combination with oral antidiabetic drugs) were more likely to perform SMBG (P = 0.010 and P = 0.000, respectively).

Table 3: Association between SMBG Practice and Sociodemographic Variables

VARIABLES		**SMBG PRACTICE**		**P-Value**
		Yes	**No**	
Age (years)	41 - 60	66 (47.1%)	74 (52.9%)	0.840
	61 - 80	73 (49.7%)	74 (50.3%)	
	81 – 100	6 (42.9%)	8 (57.1%)	
Sex	Male	52 (52.0%)	48 (48.0%)	0.349
	Female	93 (46.3%)	108 (53.7%)	
Marital Status	Single	1 (50.0%)	1 (50.0%)	0.526
	Married	99 (48.3%)	106 (51.7%)	
	Divorced/Separated	2 (100.0%)	0 (0.0%)	
	Widowed	43 (46.7%)	49 (53.3%)	
Level of Education	No formal education	28 (33.3%)	56 (66.7%)	*0.000
	Primary	30 (42.9%)	40 (57.1%)	
	Secondary	33 (51.6%)	31(48.4%)	
	Tertiary	54 (65.1%)	29 (34.9%)	
DM Duration	< 5 Years	54 (40.0%)	81 (60.0%)	*0.010
	≥ 5 Years	91 (54.8%)	75 (45.2%)	
DM treatment	Insulin alone	6 (66.7%)	3 (33.3%)	*0.000
	Drugs alone	88 (38.9%)	138 (61.1%)	
	Insulin and drugs combined	51 (77.3%)	15 (22.7%)	

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Table 4 shows the association between SMBG practice and glycaemic control among the study participants. From this analysis, SMBG had no statistically significant association with the level of glycaemic control.

Table 4: Association between SMBG practice and the level of Glycaemic control

SMBG Practice	**Glycosylated Haemoglobin (%)**			
	Good (<7) n=206 N(%)	Poor (=>7) n=95 N(%)	X^2	P-Value
Practice SMBG	105(72.4%)	40(27.6%)	2.047	**0.096**
No SMBG Practice	101(64. 7%)	55(35.3%)		

Discussion

This descriptive cross-sectional study examined the practice of SMBG among adult patients with type 2 diabetes. We also determined the association between SMBG and glycaemic control. We observed that more than half of our study participants did not practice SMBG. In addition, we discovered that the mean HbA1c among our study participants showed good control, and this was quite impressive. We, however, found out that the SMBG practice did not have any statistically significant association with the overall glycaemic control assessed using HbA1c.

It was discovered that only 48.2% (less than half) of the study participants practised SMBG. A similar finding has earlier been reported by a study in Port Harcourt, Nigeria where it was observed that 27% of patients with diabetes practised SMBG whereas 96% were already aware of SMBG existence.[9] This suggests that factors other than mere SMBG knowledge influence its practice among patients with diabetes mellitus. Another study in Nigeria reported that practice of self-glucose monitoring among DM patients in Nigeria ranges from 3.4% amongst patients in rural settings to 73% in urban settings.[8] This is still in agreement with this study finding because Ogbomoso is a sprawling semi-urban community.

In this study, 25.50% of respondents who performed SMBG checked their blood sugar once a week and 4.1% didn't perform SMBG regularly. According to the recommendation of a with SMBG. According to our study, those who had completed their tertiary education, had a long history of DM, and were using insulin to manage their DM were more likely to practice SMBG. We discovered that patients' age, gender, and marital status were not associated with the practice of SMBG. Similarly, Yacoub et al. also discovered a relationship between practicing SMBG and increased educational attainment. It is conceivable that people with greater education are more inspired and capable of performing SMBG.[16] Moreover, several studies have also demonstrated a strong association between SMBG and the use of insulin.[17,18]

We observed that 69.4 % of the study participants had HbA1c <7%, indicating good control according in line with < 7% recommended by the American Diabetes Association (ADA)[4] while 30.6% of the study participants had HbA1c ≥7%, indicating poor control. This finding is similar to the report of a recent review of literature that revealed that the percentage of people with diabetes who attained the ADA treatment target of < 7% has increased from 50.9% in 1988–1994 to 58.8% in 2005–2010.[19] This is quite significant because the Diabetes Control and Complications Trial (DCCT)[20] showed definitively that better glycaemic control is associated with 50–76% reductions in rates of development and progression of microvascular (retinopathy, neuropathy, and diabetic kidney disease) complications. The finding contrasts with the report of a review on glycaemic control among patients in Nigerian hospitals that revealed that the mean glycosylated haemoglobin ranged from 7.9% to 8.3% with most patients (63% to 68%) having poor glycaemic control.[21]

Remarkably, we observed that there was no statistically significant association between SMBG practice and glycaemic control among our study participants. This finding is similar to the results of randomised control trials such as the DiGEM, the Carolina study, and the ESMON study, where SMBG did not show any benefit in improving the overall glycaemic control.[22,23] It would be noted from all the above studies that SMBG had no positive impact on the glycaemic control of adult patients with diabetes mellitus. However, close observation of all the above studies would reveal that the

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studies did not use structured SMBG and only assessed HbA1c as a treatment endpoint. This is also the case in our study where the majority of those that performed SMBG (83.7%) did not use the result to adjust treatment.

In contrast to our study finding, epidemiological studies such as the ROSSO study and the Kaiser Permanente study in addition to the well-designed randomized controlled trial such as the ROSES trial, the STeP trial, and the St. Carlos trial have shown a beneficial effect of SMBG in the mean reduction of glycosylated haemoglobin.[24-26] It would be observed that most of the studies mentioned above which showed the benefits of SMBG used a structured testing regimen. SMBG is described as structured when blood glucose data are gathered according to a defined regimen, interpreted, and then utilized to make appropriate pharmacologic and/or lifestyle adjustments.[27]

This implies that performing SMBG alone does not lower blood glucose levels.[28] To be useful, the information must be integrated into clinical and self-management plans.[4] Therefore, when prescribing self-monitoring of blood glucose, it is important to ensure that patients receive ongoing instructions and regular evaluation of technique, results, and their ability to use data from self-monitoring of blood glucose to adjust therapy.

An inevitable limitation of our study was its inherent weakness of not being able to establish causation between variables as a result of its cross-sectional design nature. However, results from this study were similar to findings from many other studies, giving it further credence. Another challenge is that the glycosylated haemoglobin (HbA1c) used in this study as the primary tool to assess the effectiveness of glycaemic control could be affected by the packed cell volume and genotype of the participants. However, our study participants did not have clinical signs and symptoms suggestive of anaemia and/or haemoglobinopathy, since the study was done in outpatient settings among apparently healthy-looking patients.

Implications of the findings of this study

The lack of a significant association shows that SMBG may not directly improve glycemic control. This suggests that simply monitoring blood glucose levels without commensurate changes in behavior, treatment, or lifestyle may be insufficient to improve diabetes outcomes. The lack of a significant relationship between SMBG and glycemic control may also indicate that other factors, such as medication adherence, nutrition, physical activity, stress management, and patient motivation, play a more important role in obtaining adequate glycemic control. It calls into question the value of SMBG as a stand-alone intervention in diabetes management.

Strengths and Limitations of the Study

With a 97% response rate, the study reduced the impact of non-response bias. The high participation rate improves the findings' reliability and represents the research population more accurately. Diabetes mellitus is a major public health concern worldwide, and studying the association between SMBG and glycemic control in Nigeria provides useful information that can help design diabetes care and treatment policies in the region.

The cross-sectional study nature of this study limits our ability to establish causation between SMBG and glycemic outcomes. The information on SMBG practices was gathered using self-administered questionnaires, which may have resulted in recall bias or inaccurate reporting of SMBG frequency and practices by individuals.

Conclusion

In conclusion, our study has shown that SMBG practice had no statistically significant association with the level of glycaemic control among adult patients with type 2 DM. We attributed this to the fact our study did not use a structured SMBG regimen. We, therefore, recommend further studies of randomized controlled nature to compare the effects of structured and unstructured SMBG regimens on glycaemic control among adults with type 2 diabetes.

What is already known on this topic

SMBG is beneficial in the management of diabetic patients, especially in patients with type 1 diabetes mellitus and insulin-treated type 2 diabetic patients.
It is believed that better glycaemic control is associated with 50–76% reductions in rates of development and progression of microvascular complications.

What this study adds

We have shown that SMBG practice had no statistically significant impact on the level of glycaemic control among adult patients with type 2 DM.

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We also discovered that more than half of our study participants did not practice SMBG.

Declarations

Authors' Contribution: Olumide Thomas Adeleke conceived and designed the study, approved the design and implementation, coordinated and supervised data collection, drafted the initial Article and critically reviewed and revised the draft.
Isaac O. Amole approved the design and implementation of the study, coordinated, supervised data collection and critically reviewed and revised the draft.
Adewumi O. Durodola approved the design and implementation of the study, coordinated, supervised data collection and critically reviewed and revised the draft.
Olufemi Timothy Awotunde approved the design and implementation of the study and critically reviewed and revised the draft.
Stephen Adesope Adesina approved the design and implementation of the study and critically reviewed and revised the draft.
Adepeju O. Adegoke approved the design and implementation of the study and critically reviewed and revised the draft.
Olubukola. Ayodele Ala approved the design and implementation of the study and critically reviewed and revised the draft.
Oludamola Victoria Adeleke coordinated, supervised data collection and critically reviewed and revised the draft.
Akintayo David OlaOlorun approved the design and implementation of the study and critically reviewed and revised the draft.

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