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PAMJ One Health

Research

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Received: 02 Apr 2020 - **Accepted:** 26 Jul 2020 - **Published:** 14 Aug 2020

Keywords: HBA1c, fasting hyperglycemia, diabetes Mellitus type 2, uncontrolled diabetes, northwestern Tanzania, resource limited setting

Cite this article: Daniel Wilfred Gunda et al. Use of HBA1c and potentiality of gender, missed medication and fasting glucose in the prediction of poor glycemic control in resource-limited setting; a clinic-based case-control study. PAMJ - One Health. 2020;2(22). 10.11604/pamj-oh.2020.2.22.22624

Available online at: https://www.one-health.panafrican-med-journal.com/content/article/2/22/full

Use of HBA1c and potentiality of gender, missed medication and fasting glucose in the prediction of poor glycemic control in resource-limited setting; a clinic-based case-control study

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Abstract

Introduction: *diabetes mellitus (DM) type 2 is a rapidly growing health problem in the world especially in resource limited countries. Even with availability of affordable medication still a large proportion of patients don´t attain a well-controlled glycemic state thus putting them at high risk of morbidity and mortality due to irreversible complications. Availability of glycated hemoglobin test (HBA1c) for better monitoring of glycemic control is still a setback in most resource restricted setting including Tanzania. This study was designed to determine the magnitude of uncontrolled DM type 2 using HBA1c and assess the utility of different factors in sorting patients at high risk of having uncontrolled DM in a clinic based setting in north western Tanzania.* ***Methods:*** *this was a case control study involving diabetes type 2 patients at Bugando Medical Centre. A cross sectional measurement of glycated hemoglobin (HBA1c) and fasting glucose were done, medical history and adherence status to anti diabetes were assessed. Data analysis was done using STATA 13. Uncontrolled Diabetes was defined as an HBA1c of more than 7.0 and its correlates were assessed by logistic regression model. The predictive ability of independent variables was determined by calculating their sensitivity and specificity.* ***Results:*** *in total 229 patients were included in this study, where 114 (49.8%; 95%CI: 43.3-56.3) had uncontrolled DM2 by HBA1c. In this study uncontrolled DM was independently associated with female gender, (AOR: 2.1; 95%CI: 1.1-3.9; p=0.022), frequently missed medications (AOR: 1.1; 95%CI: 1.03-1.2; p=0.006), and higher fasting median blood glucose, (10.5 vs. 6.9; AOR: 7.3; IQR: 3.7-14.7; P<0.001). Fasting glucose had higher predictive values to uncontrolled DM2 (sensitivity: 79.0%; 95%CI: 70.3-86.0; specificity: 84.4%; 95%CI: 76.4-90.4, cut point: 8.5; area under ROC curve: 0.8584) as compared to gender and missed medications.* ***Conclusion:*** *uncontrolled DM type 2 is common in Notherwestern Tanzania, and is well predicted by fasting hyperglycemia. Fasting hyperglycemia can be used in selecting patients that could benefit from timely intensification of treatment where HBA1c is not available.*

Introduction

Diabetes mellitus (DM) is a rapidly growing global health problem which carries high morbidity and mortality, especially in low-income countries including Africa. In 2014 about 442 million adults had DM with a global prevalence of 8.5% as compared to 108million (4.7%) in 1980 [1]. By 2030, it is estimated that more than 400 million (85.0%) of DM patients will be living in developing countries [2,3]. In Sub Saharan Africa DM is about 12% of the general population where diabetes mellitus type two accounts for more than 90% of all diabetic cases [4]. In Tanzania, between 4.3-5.3% of the general population was estimated to have DM in 2016 [5,6]. The mortality due to DM is unacceptably high. For instance, in 2012 alone over 3.7 million people died due to DM and nearly a half, (43%) of these deaths occurred before the age of 70 mainly due to failure to achieve optimal glycemic control [7]. Uncontrolled DM increases the risk of recurrent infection which may significantly contribute to morbidity and mortality [8-10]. Several other irreversible diabetic mellitus related complications also contribute to high morbidity and mortality including coronary arterial diseases, cerebral vascular accident, chronic renal failure, diabetic foot diseases with leg amputation, vision loss and neuropathy among others [11,12]. Studies among patients with Diabetes type 2 indicate that poorly controlled DM is a very frequent problem where some studies have reported a prevalence of up to 86% of their participants [13-15]. The risk of uncontrolled DM is highest among young patients, those who are un-compliant to medications, those with longer diabetic periods, and among those with longer travel distances to the health facility among others [16-24]. The current study describes the magnitude and potential discriminators of uncontrolled DM using HBA1c among adult DM2 patients at Bugando. We believe this data is important in devising potential strategies to

achieve overall optimization of care of patients with DM 2 in diabetic care settings similar to ours.

Methods

This was a hospital-based case-control study, which was done between September 2018 and July 2019 as an elective research activity. The study was conducted at Bugando Medical Centre (BMC) in the northwestern part of Tanzania. The diabetes clinic exists as an integral part of internal medicine. Diabetic patients diagnosed within and those referred in from catchment hospitals are routinely monitored in this clinic on a monthly base. Patients who are found to have uncontrolled sugars, the potential triggers of uncontrolled diabetes are usually sought including un-compliance to medications and infections with subsequent adjustment of anti-diabetes doses. All adult diabetic type 2 patients on treatment were involved in this study. A minimum sample size of 185 was estimated from Kish and Lisle formula assuming 86% of the study participants had uncontrolled DM as found previously [25] with an allowable error of 0.05 at 95% Confidence Interval (CI). Patients were invited to participate in the study and the informed consent was obtained. Information regarding demographic data, type of medications and doses, missed medications, clinic attendance status and duration of DM were recorded and then all patients had a test for fasting blood glucose (FBG) and glycated adult hemoglobin (HBA1c).

Data were computerized using Epi data version 3.1 and STATA version 13 (Stata Corp LP, college station, TX) was used for data analysis. Continuous variables were expressed as medians with interquartile range (IQR) while categorical variables were expressed as proportions with percentages. Uncontrolled DM was defined as an HBA1c level of more than 7% as described previously [26] and was expressed as a percentage with 95% Confidence Interval(CI). The odds ratio (OR) with 95%CI of potential explanatory factors were calculated using univariate followed by multivariate logistic regression to assess the extent of association between different variables and the outcome of interest. In the first model, the factors were considered for inclusion into the final model if $p< 0.2$. The level of independent association was set at $p<0.05$ in the final model and the goodness of fit of the final logistic model was subsequently assessed. Based on previous knowledge and our own experience, Sociodemographic information, medical compliance, medication type, and fasting glucose were included in the logistic model [16-24]. The sensitivity and specificity of the final explanatory factors were determined to assess its utility in predicting uncontrolled DM in this subgroup of patients. To obtain the best cut point for continuous variables, a Receiver operating characteristic (ROC) curve was used.

Ethical clearance: the permission to conduct and publish the results from this research was sought from the Catholic University of Health and Allied Sciences (CUHAS)/ Bugando Medical Center joint ethical committee. Patients who didn´t consent were not reprimanded of their access to DM care. The patient´s files were handled by the researchers alone and the patients´ identifiers including names and registration numbers were not included in the final analysis to further maintain confidentiality.

Results

General study characteristics: a total of 229 patients were enrolled in this study. The majority, 125 (54.6%) were female participants with a median age of 59 (IQR: 53-67) years. The median duration of DM2 was 2 (IQR: 2-4) years with a median fasting glucose of 8 (IQR: 6.7-10.7) mmol/dL. About a third, 143(62.5%) of participants had fasting glucose higher than 7.1mmol/dL on the day of enrolment with a median number of missed drugs of 2 (IQR: 0-6) days (Table 1).

Prevalence and associated factors of uncontrolled DM2 among 229 participants: in the current study, 114 (49.8%; 95%CI: 43.3-56.3) participants met HBA1c criteria for uncontrolled diabetes (Table 1).

The odds of having uncontrolled DM by HBA1c were independently increased among female patients, (AOR: 2.1; 95%CI: 1.1-3.9; p=0.022), frequently missed medications (AOR: 1.1; 95%CI: 1.03-1.2; p=0.006), and with higher median fasting blood glucose, (10.5 vs. 6.9; AOR: 7.3; IQR: 3.7-14.7; P<0.001). The difference in the distribution of other factors was not different statistically (Table 2) and the assessment of the goodness of fit of the final model demonstrated no gross lack of fitness (Hosmer-Lemeshow chi2 (8): 8.31; Prob > chi2: 0.4041, area under ROC curve: 0.8086) (Figure 1). The assessment of the prediction ability indicated that elevated fasting blood glucose of more than 8.5mmol/dL had the highest sensitivity (79.0%; 95%CI: 70.3-86.0) and specificity (84.4%; 95%CI: 76.4-90.4) with an area under ROC curve of 0.8584 as compared to female gender and missed medications (Table 3).

Discussion

The objective of this study was to determine the prevalence and associated factors of uncontrolled DM type 2 by using HBA1c levels and assess the predictive ability of the independent factors. In this study, 114 (49.8%) of the studied participants were found to have uncontrolled DM which was more likely to occur among female participants, with frequently missed medications and higher median fasting blood glucose. Median fasting glucose of more than 8.5 demonstrated both high sensitivity and specificity in predicting uncontrolled DM 2 as determined by HBA1c. The prevalence of uncontrolled DM2 in this study is similar to the prevalence of 43.0% from the USA [24] and 55.3% from Trinidad [27]. However, our finding is higher than a prevalence of 16.7% reported from Israel [28] and 38.9% reported from Pakistan [14]. Higher prevalence of uncontrolled DM2was reported in Hawaii, (68.5% vs. 49.8%) [16], urban part of Dar es salaam (69.7% vs. 49.8%) [20], Ethiopia, (80.0% vs. 49.8%) [22] and Ghana (86.0% vs. 49.8%) [25]. Even with these differences in the prevalence, these findings suggest that uncontrolled DM2 is a wide spread problem which might be even higher among resource-limited countries. Prior studies had suggested that persistent hyperglycemia among diabetic patients increases the independent risk of both micro and macro vascular complications [29]. The findings in the current study suggests that about 50.0% of our participants had persistent hyperglycemia for over 3 months, putting them at highest risk of morbidity due irreversible chronic diabetic complications [30]. Thus deliberate planning of immediate intensive glycemic control in this subgroup of patients is important in scaling down the unfavorable outcome following poor glycemic control [31].

To identify patients at risk of poor glycemic control several factors were assessed for their independent association with uncontrolled diabetes mellitus. Several other previous studies have reported similar findings that female gender is associated with poor glycemic control including reports by Nuez *et al*. from USA [32] and Apparico *et al*. from Trinidad [27]. Similar to our current study missing drugs were also significantly associated with uncontrolled DM in a study by Tubiana-Rufi *et al*. in France [18], in Ethiopia [19] and urban Dar es salaam [20]. In agreement with our study also, a positive correlation between higher fasting blood glucose and higher glycated HBA has been reported in several other studies among adult patients with diabetes mellitus type 2 [33-35]. Since HBA1c measurements are not routinely done in our setting similar to most resource-limited settings [36], a simple, and rapid practically cheap tool is important in facilitating isolation of patients at high risk of having uncontrolled DM type 2. In our study fasting blood sugar was found to have highest sensitivity and specificity in predicting persistent hyperglycemia by HBA1c. Similar findings were reported in another study where it was found that persistent fasting hyperglycemia also predicts better uncontrolled diabetes (area under ROC curve: 0. 92) [37] suggesting that among those on medications, fasting hyperglycemia could potentially discriminate patients with uncontrolled diabetes mellitus. With a linear correlation

between fasting hyperglycemia and HBA1c among DM type 2 patients, Al-Lawati *et al*. indicated that fasting hyperglycemia had a sensitivity and specificity of up to 70.7% and 82.7% respectively in predicting uncontrolled DM type 2 (AUROC curve: 0.80; 95%CI: 0.79-82) similar to our study [38]. These findings suggest that in setting where HBA1c is not readily obtainable for routine use fasting blood sugars levels may be used to identify patients who are likely to have uncontrolled type 2 diabetes and plan on strengthening of treatment to mitigate morbidity from long- term DM complications.

Conclusion

The current study is liable to some limitations; including the fact that this is a single-center study, its results may not be generalizable. Since this was a cross sectional study patients follow up was not done. However, even with these limitations, the findings from this study are still important, especially in resource-limited settings where HBA1c is not readily done. The current results suggest that fasting hyperglycemia is potentially useful in selecting patients at high risk of having uncontrolled DM2 and thus can be planed for intensified glycemic control. Longitudinal studies to further assess the performance of fasting glucose with larger sample sizes are warranted.

What is known about this topic

- *Diabetes mellitus type 2 in a rapidly growing problem in resource limited setting;*
- *Poor glycemic control dramatically increases the morbidity and mortality in DM 2 patients;*
- *HBA1c is feasibly used in resource rich countries for long term of monitoring of glycemic control.*

What this study adds

- *Uncontrolled DM 2 is a common encounter in resource limited countries as well;*
- *Fasting blood glucose can reliably select patients with poor long term glycemic control who would benefit from immediate initiation intensified glycemic in setting where HBA1c is not readily obtainable.*

Competing interests

The authors declare no competing interests.

Authors' contributions

DWG&EKM: participated in designing of the study; HAB; acquired the data; DWG& BRK: did data analysis and interpretation; DWG: did manuscript drafting. All the authors significantly reviewed the manuscript for its intellectual content and agreed on the final version.

Acknowledgments

The authors would like to acknowledge the great support given by the department of medical records and the diabetes team at BMC during the enrolment and retrieval of patients´ information.

Tables and figure

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Table 1: general study characteristics among 229 DM type 2 participants

Variable	**Frequency**	**Percentage (%) or Median(IQR)**
Sex		
Female	125	54.6
Male	104	45.4
Age (years)		
Physical address	229	59 [53-67]
Within Mwanza	115	50.2
Outside Mwanza	114	49.8
DM duration (years)	229	2 [2-4]
Hypertension		
Yes	138	60.3
No	91	39.7
Anti DM drugs		
Oral alone	215	93.89
Insulin	14	6.11
Blood pressure (mmHg)		
Systolic	229	130 [123-145]
Diastolic	229	85 [77-93]
Number of co-medications	229	2 [1-3]
Fasting blood glucose (mmol/dL)	229	8[6.7-10.7]
Fasting sugar>7.1mmol/dL		
Yes	143	62.5
No	86	37.5
Missed anti-DM	229	2 [0-6]
Glycated HB (HBA1c)		
Median	229	7 [6.0-8.6]
>7.0%	114	49.8
<7.0%	115	50.2

DM: diabetes mellitus; HB: Hemoglobin; HBA1c: Glycated HB; IQR: interquartile range

Table 2: associated factors of uncontrolled DM 2 among 229 study participants						
Variable	**Uncontrolled DM2 (HBA1c>7.0)**		**Un adjusted**		**Adjusted**	
	No (115)	Yes (114)	95%CI	p-value	95%CI	p-value
Sex						
Male	60 (52.2)	44 (38.6)	1.0			
Female	55 (47.8)	70 (61.4)	1.7 (1.0-2.9)	0.040	2.1 (1.1-3.9)	0.022
Age (years)	60 (53-67)	59 (51-67)	1.0 (0.9-1.1)	0.575		
Years of DM	3 (2-4)	2 (1-4)	1.0 0.9-1.1)	0.502		
Address						
Within Mwanza	59 (51.3)	58 (50.9)	1.0			
Outside Mwanza	56 (48.7)	56 (49.1)	0.9 (0.54-1.5)	0.741		
DM drugs						
Metformin	105 (91.3)	108 (94.7)	1.7 (0.6-4.8)	0.313		
Glibenclamide	24 (20.9)	37 (32.5)	1.8 (1.0-3.3)	0.049	1.3 (0.5-3.3)	0.471
Glimeperide	11 (9.6)	17 (14.9)	1.6 (0.7-3.7)	0.220	1.2 (0.3-3.7)	0.728
Insulin	7 (6.1)	7 (6.1)	1.0 (0.3-2.9)	0.987		
Days missed	1.5 (0-4)	2.5 (1-8)	1.1 (1.0-1.2)	0.001	1.1 (1.03-1.2)	0.006
Medications #	2 (1-3)	2(1-3)	1.2 (0.9-1.6)	0.136	1.4 (0.7-2.5)	0.264
Hypertension						
No	39 (33.9)	52 (45.6)	1.0			
Yes	76 (66.1)	62 (54.4)	0.6 (0.3-1.0)	0.071	0.4 (0.2-1.2)	0.105
Systolic BP	130[123-142]	130 [123-145]	1.0 (0.9-1.01)	0.433		
Diastolic BP	86 [79-95]	82 [75-92]	1.0 (0.9-1.01)	0.396		
Fasting Glucose	6.9 (6.2-7.8)	10.5 (8.9-12.9)	8.5 (4.5-16.1)	<0.001	7.3 (3.7-14.7)	<0.001
BP: blood pressure**; CI:** confidence interval**; DM:** diabetes mellitus; **DM2:** diabetes mellitus type 2; HB: Hemoglobin; HBA1c: Glycated HB						

Table 3: prediction of Uncontrolled DM by gender, missed drug and fasting glucose						
Variable	**Cut point**	**ROC curve***	**Sensitivity**	**95%CI**	**Specificity**	**95%CI**
Female gender	NA	NA	61.40	51.8-70.3	52.1	42.6-61.5
Missed drugs	3	0.6046	50.0	40.5-59.5	60.9	51.2-69.8
Fasting glucose	8.5	8	79.0	70.3-86.0	84.4	76.4-90.4
CI: confidence interval; DM: diabetes mellitus; NA; not applicable; ROC: receiver operating characteristic curve						

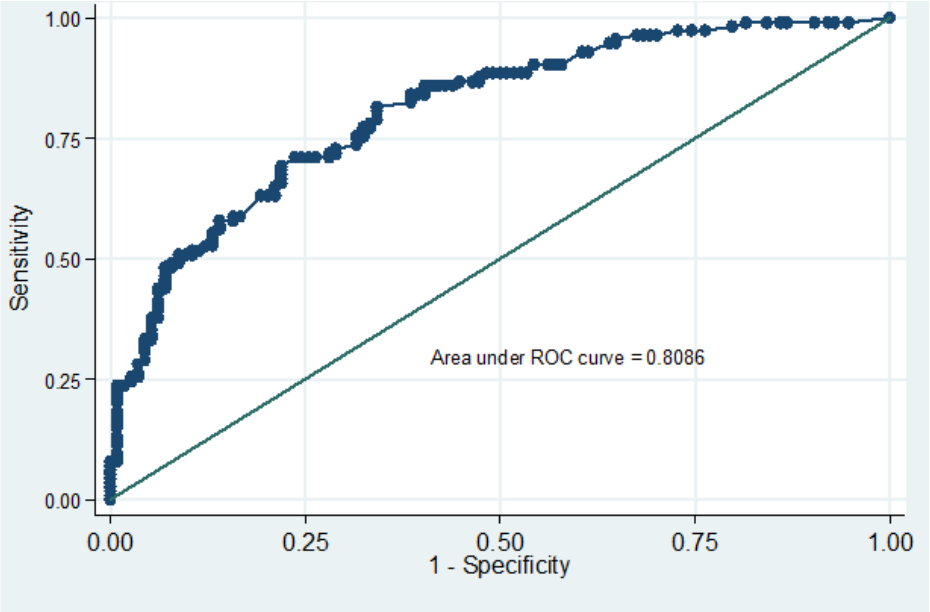

Figure 1: assessment of the goodness of fit for the final logistic model