Gestational Diabetes Mellitus Risk score: A practical tool to predict Gestational Diabetes Mellitus risk in Tanzania

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Abstract

Background: Universal screening for hyperglycemia during pregnancy may be in-practical in resource constrained countries. Therefore, the aim of this study was to develop a simple, non-invasive practical tool to predict undiagnosed Gestational diabetes mellitus (GDM) in Tanzania.

Methods: We used cross-sectional data of 609 pregnant women, without known diabetes, collected in six health facilities from Dar es Salaam city (urban). Women underwent screening for GDM during ante-natal clinics visit. Smoking habit, alcohol consumption, pre-existing hypertension, birth weight of the previous child, high parity, gravida, previous caesarean section, age, MUAC ≥28 cm, previous stillbirth, haemoglobin level, gestational age (weeks), family history of type 2 diabetes, intake of sweetened drinks (soda), physical activity, vegetables and fruits consumption were considered as important predictors for GDM. Multivariate logistic regression modelling was used to create the prediction model, using a cut-off value of 2.5 to minimise the number of undiagnosed GDM (false negatives).

Results: Mid-upper arm circumference (MUAC) ≥28 cm, previous stillbirth, and family history of type 2 diabetes were identified as significant risk factors of GDM with a sensitivity, specificity, positive predictive value, and negative predictive value of 69%, 53%, 12% and 95%, respectively. Moreover, the inclusion of these three predictors resulted in an area under the curve (AUC) of 0.64 (0.56-0.72), indicating that the current tool correctly classifies 64% of high risk individuals.

Conclusion: The findings of this study indicate that MUAC, previous stillbirth, and family history of type 2 diabetes significantly predict GDM development in this Tanzanian population. However, the developed non-invasive practical tool to predict undiagnosed GDM only identified 6 out of 10 individuals at risk of developing GDM. Thus, further

development of the tool is warranted, for instance by testing the impact of other known risk factors such as maternal age, pre-pregnancy BMI, hypertension during or before pregnancy and pregnancy weight gain.

Introduction

During the last decade the prevalence of Gestational Diabetes Mellitus (GDM) considerably increased ranging from 1 to 20% of pregnancies, depending on the studied population, screening approaches applied, and diagnostic criteria [1-3]. In Tanzania, the overall prevalence of GDM is averaged to be about 6% with a higher prevalence of 8.4% in urban areas and lower prevalence of 1.0% in rural areas [2]. To date several risk factors for GDM are known, including mid-upper arm circumference (MUAC) ≥28 cm, family history of type 2 diabetes, previous stillbirth, anaemia, maternal age >25 years, BMI >25 [2, 4, 5]], sedentary lifestyle, lower maternal height, cigarette smoking, dietary factors such as sugar-sweetened beverages, high parity, ethnicity (e.g. Asian women tend to be more prone to develop GDM than blacks and whites)[6-8]blood groups, and +Rh factor [9].

Gestational diabetes is associated with a variety of adverse pregnancy outcomes such as macrosomia, dystocia, birth trauma, and metabolic complications in new borns [10, 11]. Next to that, patients with GDM are known to be at increased risk of developing overt diabetes mellitus (DM) postpartum [9].. Consequently, it is important to identify and manage GDM as early as possible. Currently, in Tanzania GDM is diagnosed from urine by measuring glucose level when mothers attend ante-natal clinic (ANC) regardless of gestational age. However, this is not a reliable method because it has less sensitivity compared to blood glucose test . Universal testing of blood glucose levels may be challenge due to limited resources and capacity in most health facilities in Tanzania [12, 13]. Therefore, it is essential to develop a simple practical non-invasive tool that is user-friendly at all levels.

Already several studies have been published on the use of risk scores in different settings and population groups, both for the detection of undiagnosed diabetes and for identification of those at future risk [10, 11, 14]. Most of these studies on diabetes risk score have been conducted in Whites and Asian populations and focussed on risk scores for type 2 diabetes mellitus (T2DM) [2, 12, 14]. It is unclear to what extent the findings obtained from the mentioned population can be applied to African settings. Van Leeuwen et al. developed a clinical prediction rule based on patients' characteristics, including family history of diabetes, ethnicity, history of GDM, and body mass index, to identify women at high and low risk for gestational diabetes mellitus early in pregnant Dutch women. The model detected 75% of women with GDM with a threshold value of 2% as the predicted probability above which diagnostic testing (OGTT) was performed [11]. Moreover, a study conducted in India

evaluating the use of an OGTT alone, or in combination with the Indian Diabetes Risk Score showed that use of the risk score followed by OGTT for those at high risk was more efficient and substantially cheaper than using an OGTT alone [15]. In Uganda, 251 pregnant women were screened at 26 to 36 gestational age and hyperglycemia first detected during pregnancy was about 32% and among them, 23.8% did not have any risk factor [16]. The authors reported that selective screening may miss up to about 24% of pregnant women with hyperglycemia [16]. However, there are limited studies on gestational diabetes risk scores; hence the aim of this study was to develop a simple, non-invasive practical tool to predict undiagnosed GDM in Tanzania.

Materials and Methods

Study setting

This study was conducted using cross-sectional data collected in Dar es Salaam city and Morogoro region from August 2011 to March 2012. Six health facilities in Dar es Salaam (urban) and two health facilities from Kilombero district in Morogoro region (rural) were chosen based on their high number of pregnant women attending ANC. As only 1% of 6% of the GDM mothers came from the rural area and 8% came from the urban area, only data from urban health facilities were used to develop the prediction model [2].

Study population, exclusion and inclusion criteria

Participants were recruited among pregnant women of African ethnicity who were aged ≥20 years, ≥20 gestational weeks, and attending antenatal clinic (ANC) during the survey period. Women with previously diagnosed diabetes were excluded. Other exclusion criteria included the presence of chronic disease(s), such as sickle-cell anaemia or cancer and having conditions that limit activities or normal dietary intake, such as bed-rest since conception. During the ANC visit participants were informed about the purpose of the study, procedure and the possible effects of Oral Glucose Tolerance Test (OGTT), emphasizing that participation was voluntary. In the urban area, 715 mothers were invited, 637 met the criteria for the examination and 599 completed the OGTT with a response rate of 89%. The study protocol was approved by Tanzania National Institute of Medical Research and the respective District Authorities. All participants consented to participate by signing consent forms and few who could not read or write provided oral consent. All information obtained from the participants was confidential and all who were identified with any condition requiring medical attention were referred to medical doctor in charge of the RCH clinic for further assessment and treatment

Data collection

Physical measurements

Height was measured without shoes and recorded to the nearest 0.1cm, using a height measuring board (Shorr productions, Maryland USA). Weight was measured to the nearest 0.1kg using Seca Electronic Scale (Seca, Hamburg, Germany). Mid-upper arm circumference (MUAC) was measured using a non-stretchable tape. Pre-gestational weight was assessed at the clinic retrospectively. However, most of the participants came late to the clinic (gestational age ranging from 20 to 38 weeks (mean±SD 28±4.7 weeks) and only a few participants were able to recall their pre-gestational weight. As MUAC is known to be relatively stable during the pregnancy and highly correlated with pre-pregnancy BMI [2, 17, 18], MUAC was used to classify women as normal (MUAC <28cm) and overweight (MUAC ≥28cm). This categorisation lies under the assumption that there was a negligible change of MUAC during pregnancy and that BMI = 0.1036*MUAC (mm) − 3.9 as suggested by Khadivzadeh [19]. Systolic and diastolic blood pressures (BP) were measured at the left mid-upper-arm, while the participant was sitting and relaxed for 10 minutes before the actual measurement, using a digital BP device (Microlife BPA100, Widnau, Switzerland). Blood pressure was measured twice with an interval of 5 to 10 minutes and the average was recorded in millimetre of mercury (mmHg). High blood pressure defined as systolic ≥140 mmHg and diastolic ≥90 mmHg). Therefore, participants being identified as having high blood pressure were referred to a doctor for further investigations and treatment.

Biochemical assessment

Participants were asked to collect urine on the spot in a disposable plastic container provided by the research staff. Urine samples were tested within an hour for glucose, ketones, leukocytes and protein using multi-six made with colour sensitive pads (urine strip 10 C, Dialeb GmbH, Australia). Overnight fasting blood samples were taken using finger prick with a sterile lancet after cleaning the site with antiseptic alcohol swaps after which blood glucose was measured using HemoCue Glucose B-201 from capillary whole blood. When fasting blood glucose concentrations exceeded the WHO limit for diabetes during the first visit (n=12), participants were asked to return for a second fasting glucose measurement three days later. Participants with normal glucose concentrations were sent for an OGTT test. Anhydrous glucose (75g) in 300ml of water was given and blood glucose was assessed after two hours. Participants were categorized using WHO diagnosis criteria [2], Participants' diagnosed with GDM were referred to the physician for further investigation, treatment and counselling. Haemoglobin level (Hb) was measured using HemoCueHb 201+ Haemoglobin photometer (HemoCue AB, Ängelholm, Sweden) and recorded to the nearest 0.1g/dl. Participants were classified as anaemic (<11g/dl) or normal (≥11g/dl) using Hb cut-off points suggested by WHO [20]. They were further classified as severe (<7g/dl), moderate (7-9.9 g/dl), mild (10-10.9 g/dl) and normal (≥11g/dl).

Socio-demographic data and physical activity

Demographic data and risk factors were obtained using pre-tested structured questionnaires [2]. , Physical activity was assessed retrospectively using the short form of the International Physical activity Questionnaire (IPAQ revised version 2002) that was translated into Swahili. Participants were asked to recall their activities from the day of the interview up to seven days backward. IPAQ is designed and validated for adults (15-69 years (IPAQ 2005)) and assesses specific types of activity like walking, moderate intensity activities and vigorous intensity activities [21]. Data were reported as metabolic equivalents (METS) according to IPAQ scoring protocol that categorised them as high, moderate and low METS [22] .

Statistical analysis

Participant characteristics are displayed as mean with SD, median with IQR, or frequencies with percentages. In order to develop the prediction model, we first examined crude associations between predictors - including smoking, alcohol, pre-existing hypertension, birth weight of the previous child, high parity, gravida, previous caesarean section, age, MUAC ≥28 cm, previous stillbirth, haemoglobin level, gestational age (weeks), family history of type 2 diabetes, intake of sweetened drinks (soda), physical activity, vegetables and fruits consumption and GDM, using chi-square tests and correlation coefficient for categorical variable and continuous variables, respectively. Potential predictors that were not correlated with GDM were not considered in subsequent analyses, which included smoking, alcohol consumption, pre-existing hypertension, birth weight of the previous child, previous caesarean section, gravida and high parity. Tolerance for all potential predictors was > 0.1 and Variance Inflation Factor (VIF) was <10, indicating that there was no multi-collinearity between the included variables.

Subsequently, binary multivariable logistic regression analysis with stepwise backward selection was used to develop a statistical prediction model for GDM resulting in univariate odds ratios (ORs), 95% Confidence intervals (95%CI) and p-values. In stepwise regression, a covariate was retained if statistical significance of 15% was reached. Traditionally, a significance level of 5% is used to consider the variable to be significant. However, we increased it to 15% to avoid the inaccurate exclusion of potential predictive variables [23, 24]. To create a risk score, regression coefficient of each significant variable in the multivariable logistic regression analysis was multiplied by 10 and rounded to the nearest integer [25, 26]. Then, the sum score was calculated for each participant by adding the score for each significant variable in the risk model. The total GDM risk score was calculated as the sum of all individual scores and ranges from 0 to 20. To assess the performance of the prediction model, the receiver operating characteristic (ROC) curve for GDM risk score was built by plotting the sensitivity on the y-axis and the false positive rate (1- specificity) on the x-axis. Moreover, the area under the curve (AUC) was used to measure the power to discriminate high-risk from low-risk individuals [14, 26]. The more accurate discriminating the test, the steeper the upward portion of the ROC curve, and the higher the area under

the curve (AUC). The optimal threshold was determined in achieving the highest sensitivity and specificity with the aim of minimising the number of false negatives. The sensitivity of the model was assessed with respect to the value of the presumed threshold value. The Statistical software program IBM SPSS version 21 was used for statistical analysis.

Results

Of the 609 participants in the studied population, 8.4% (n=51) had GDM. Moreover, this population had a mean±SD age of 27.5± 5.0 years gestational age of 28.1± 4.8weeks, MUAC of 27.3± 3.8 cm, fasting blood glucose level of 4.6± 1.0 mmol/L, and 2-h glucose (OGTT) of 6.1± 1.1 mmol/L. Most of these participants were moderately physically active (51.6%) and completed primary education (69%). Alcohol consumption (12.6%) and smoking (1.1%) during pregnancy was not common in these Tanzanian women (Table 1).

Table 1: Baseline characteristics of women included in this study

Characteristics	Mean± SD
Age (years)	27.5 ± 5.0
MUAC (cm)	27.3± 3.8
Haemoglobin level (g/dl)	10.1± 1.6
Gestational age (weeks)	28.1± 4.8
Fasting blood glucose (mmol/L)	4.6 ± 1.0
2-h glucose (OGTT) (mmol/L)	6.1 ± 1.1
	n (%)
Previous stillbirth, n yes (%)	93 (15.3)
Family history of type 2 diabetes, n yes (%)	88 (14.4)
Intake coffee, tea, other beverages, n yes (%)	520 (85.4)
Vegetable consumption, n yes (%)	212 (34.8)
Fruits consumption, n yes (%)	107 (17.6)
Alcohol consumption, n yes (%)	77 (12.6)
Smokers, n yes (%)	7 (1.1)
Marital status, n Married (%)	507 (83.3)
Single	61 (10.0)
Other (widowed, cohabiting & separated)	41 (6.7)
Level of physical activity	
Low	124 (20.4)
Moderate	314 (51.6)
High	171 (28.0)

Level of education

Informal	38 (6.2)
Primary	420 (69.0)
Secondary	131 (21.5)
Post-secondary	20 (3.3)
Source of income	
House works	293 (48.1)
Salary/wage	104 (17.1)
Petty business	209 (34.3)
Agriculture	3 (0.5)

Continuous variables are presented as mean ± SD and categorical variables as absolute numbers (%)

The results of the univariate logistic regression model are shown in table 2, including potential predictors for the GDM model and their OR (95% CI), coefficients (β) and p-value. MUAC≥28, previous stillbirth, family history of type 2 diabetes, haemoglobin level, and fruits and vegetable consumption, were associated with GDM with p=value 0.15.

Table 2: Potential predictors of GDM and their Odds ratios, coefficients and p-value.

	Univariate model: n=51 n of whom who had GDM		
	OR [a] (95% CI) [b]	β [c]	P [d]
Intercept			
Age (years)	1.01 (0.95-1.07)	0.01	0.78
MUAC≥28cm	1.78 (0.99-3.18)	0.58	0.051
Previous stillbirth	2.56 (1.34-4.90)	0.94	0.004
HB	0.80 (0.67-0.96)	-0.22	0.014
Gestational age (weeks)	0.98 (0.92-1.04)	-0.02	0.505
Family history of type 2 diabetes	2.20 (1.12-4.33)	0.79	0.022
Sweetened drinks (soda) consumption	0.78 (0.37-1.67)	-0.25	0.523
Vegetable consumption	1.75 (0.98-3.12)	0.56	0.058
Physical activity	1.00 (1.00-1.00)	0.00	0.573
Fruits consumption	1.69 (0.87-3.29)	0.52	0.124

[a] = Odds ratios, [b] = 95% confidence interval, [c] = log OR/ coefficient and [d] =Significance level.

Table 3 presents the results from a multivariate model, including the ORs, B's, and risk scores for the non-invasive characteristics MUAC≥28, previous stillbirth, and family history of type 2 diabetes. Fruits and vegetable consumption were removed from the model by backward elimination method.

Table 1 Risk variables factors in the multivariate logistic model

| Variables | Multivariate model (51 GDM cases) | | | Score (0-20) |
	OR [a] (95% CI) [b]	B [c]	P [d]	(β*10)
Intercept	0.056	-2.89	0	
MUAC ≥28cm	1.66 (0.92-2.99)	0.51	0.095	5
Previous still birth (yes)	2.42 (1.26-4.67)	0.89	0.008	9
Family history of type 2 diabetes (yes)	1.87(0.93-3.73)	0.62	0.077	6
Area under the ROC curve				0.64

[a=]Odds ratios, [b] = 95% confidence interval, [c] log OR/ coefficient and [d] = Significance level.

As higher risk scores - ranging from 0-20 points - indicate greater weight to a respective risk, previous stillbirth was identified as being a more important predictor for GDM than MUAC. The performance of the predictive risk score/tool is shown in figure 1. The area under the ROC curve (AUC) for the developed risk score is 0.640 (95% CI; 0.56 – 0.72; p 0.001), which indicates that the developed score is able to correctly classify 64% of high-risk individuals.

The GDM risk score value of 2.5 was selected as the cut-off point for increased risk of undiagnosed GDM, along with the sensitivity of 0.69 and specificity of 0.53, positive predictive value (PPV) of 12% and negative predictive value (NPV) of 95%. This cut-off value was chosen to maximise sensitivity and specificity, aiming to minimise the number of undiagnosed GDM (false negatives). Moreover, comparison of two threshold values in table 4 shows that 31% of mothers will remain undiagnosed with a cut-off value of 2.5.When changing the cut-off value to 5.5 this increases up to 55% of mothers remaining undiagnosed (false negatives), which even further increases as we change the cut-off value to 7.5 or 10.

Table 2: comparison of the threshold values for the risk of GDM

Threshold value	Sensitivity	Specificity	PPV [a]	NPV [b]	PLR [c]	NLR [d]

2.5	0.69	0.53	0.12	0.95	1.47	0.58
5.5	0.45	0.75	0.14	0.94	1.8	0.73
7.5	0.37	0.81	0.15	0.93	1.95	0.78
10.0	0.26	0.89	0.18	0.94	2.36	0.83

[a] = positive predictive value, [b] = negative predictive value, [c] = positive likelihood ratio, [d] = negative likelihood ratio.
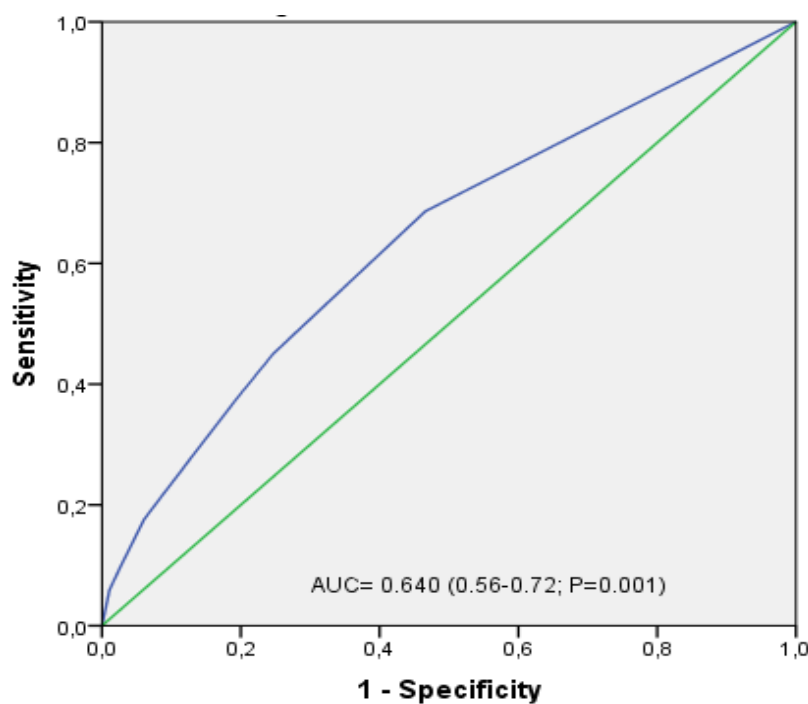

Figure 1 Shows the ROC curve for the GDM risk score in derivation population.

Discussion

A simple non-biochemical score could play an important role as the first step in the process of identifying individuals with an increased likelihood of having prevalent but undiagnosed diabetes [26], particularly in low-income countries. Therefore, the main goal of this study was to develop a simple, non-invasive, practical tool to predict undiagnosed GDM in Tanzanian women. A multivariate model was used to develop the tool, including MUAC, previous stillbirth, and family history of type 2 diabetes. With this model, 69% of the GDM cases presenting at various ANC's in Tanzania were identified. At the same time, we were able to identify 53% of the none-GDM cases presented in those ANC's. Moreover, with an

AUC of 0.64 (0.56-0.72) and a threshold value of 2.5, 6 out of every 10 high risks individuals could be correctly identified.

Our results are in line with the findings from van Leeuwen et.al who developed a clinical screening tool to identify women at high and low risk for GDM early in pregnant Dutch women. In their study, family history of diabetes, ethnicity, history of GDM, and body mass index were shown to be important predictors of GDM, which detected 75% of women with GDM with a threshold value of 2% as the predicted probability above which diagnostic testing (OGTT) was performed [11].Additionally, Naylor et.al developed a clinical scoring system based on age, BMI before pregnancy, and race from a prospective cohort study [7]. Their scoring system reduced the number a screening test performed by 34.6% and detected 81.2% to 82.6% of the women with GDM as compared with 78.3% classified during usual care implying that the use of women's clinical characteristics allows efficient selective screening for gestational diabetes. Furthermore, data of a Turkish retrospective case-control study showed that maternal age, BMI, first-degree relatives with a diagnosis of diabetes mellitus, prior macrosomic foetus, and adverse outcome during the previous pregnancies were the most important predictors of GDM which detected 85% of cases with GDM [7, 16, 27]. Unlike these other studies age of participants and gestational age were not significantly associated with GDM risk in our study. Probably this is because teenagers were excluded and we screened women regardless of gestational age ranging from 20 to 38 weeks. In Uganda, out of 80 (31.9%) pregnant women with hyperglycemia in pregnancy, 9 (23.8)% did not have any risk factor [16]{Caliskan, 2004 #4}.

Based on the above summarized literature it can be concluded that our GDM risk score did not perform as good as the risk score calculated in the study by van Leeuwen et.al [11]], and several of the other studies [16, 27]. This difference may be explained by the inclusion of different variables, for example, van Leeuwen et al included pre-gestational BMI in their model. Unfortunately, we were not able to test the impact of pre-gestational BMI as most participants did not remember their pre-gestational weight at the time they reported at the ANC (gestational age 8-32 weeks, with a mean of 20 weeks). However, we did include MUAC, which is easy to measure and has been shown to be a relatively stable measure during pregnancy and [19, 28]. In addition, van Leeuwen et al identified a history of GDM as a significant predictor of GDM. Unfortunately, history of GDM was not assessed in our study. Another reason for the difference between our score and the score developed by van Leeuwen et al could be that we studied an African population while Van Leeuwen studied a Western population. In addition, due to cross-sectional nature of the current study, it is possible that some women could have been diagnosed with GDM if further screening had been done between 24 and 28 weeks to those who were negative at earlier gestational age. For example, ~18% of our participants had gestational age < 24 weeks and ~84% of them

were negative. This may have resulted in misclassification of participants and consequently may affect the sensitivity of our study. Apart from pre-gestational BMI incorporated in a study by van Leeuwen et.al, the age of the participants, gestational age and pre-gestational BMI were also included into the model built by Naylor et.al and Caliskan et. al as significant risk factors in their population which were not risk factors in our study probably because we excluded teenagers {Caliskan, 2004 #4;Naylor, 1997 #19}. These could also explain the low performance of our model.

Thus, overall, these results may not seem that promising. However, it is important to note that those identified by the risk score (true positives) tend to be at higher risk of micro and macrovascular complications than those who are missed (false negatives) [15, 29]. Some of them might also be hyperglycemia detected first time during pregnancy. Although our screener is not very sensitive, we think it is an improvement of the current situation since it is important to identify more of the people at risk given the major possible complications. Nevertheless, it is important to understand the risks of adverse outcomes in the significant minority of individuals with undiagnosed GDM (false negatives), which would be 31% based on our analyses.

When interpreting our results, several aspects need to be considered. This is the first study to develop GDM risk score for GDM in Tanzania and in is among the few ones in Africa. Moreover, we feel that the sample size was adequate for the prediction model. As a rule of thumb, there should be 10 events per variable [24, 29]. In this study, we had 3 predictor variables in the final model, which requires at least 30 GDM cases where we had 51 GDM cases. Furthermore, due to the fact that we only used data from urban ANCs to develop our screening tool, we did not have to control for known urban/rural risk modifiers as education level and occupation level. However, there are also some limitations of this study. Misclassification of participants especially those who were screened at gestational age < 24 weeks and found negative. This might influence the sensitivity of our study. Moreover, some variables, including physical activity, and pre-gestational weight, were assessed retrospectively, which may have been a source of bias as well. Finally, due to practical reasons that are the aim to develop a non-invasive tool - haemoglobin level was excluded from the multivariate model, which reduced model performance. Lastly, there is a need to recalibrate the developed score before actual implementation. This can be done in a disease incidence and risk factor distribution of the target population where data from National database and hospital or general practitioners can be used [30]. Studies show that most of the original models perform better when recalibrated [30]. Brown et al. reported a rapid increase in the number of newly developed risk scores with similar variables but sometimes perform poorly upon external validation [10]. Therefore, we emphasize the need for recalibration, validation and applicability of those existing scores to other settings [10, 30]

Conclusion and recommendation for future research

The findings of this study indicate that MUAC, previous stillbirth and family history of type 2 diabetes are significant risks factors for the development of GDM in Tanzanian population. However, the developed score (AUC= 0.640 (0.56-0.72)) did not perform well in distinguishing those with GDM risk from those without GDM risk. Despite this, a simple, non-invasive practical tool, if well-developed, might be a useful tool to predict undiagnosed GDM especially in developing countries where there is a lack of protocol for GDM screening, qualified personnel, and screening tools specifically in Sub-Saharan Africa setting. We recommend further studies on improving the model, for example by including pre-gestational BMI and pregnancy weight gain. Therefore, recalibration, validation and applicability of the current score to another setting are vital in the future studies.

Conflict of interests

The authors have declared no conflict of interest.

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