Research Article

Evaluation of Diabetes Risk Score Tool for Detecting Undiagnosed Type 2 Diabetes Mellitus in Attendees of Referral Clinics at Primary Health Care Centers, Sudan

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Introduction: The prevalence of diabetes in Sudan is increasing; however, suitable risk assessment and screening tools to identify at-risk individuals are lacking.

Objective: To evaluate the Diabetes Risk Score (DRS) tool for detecting Type 2 Diabetes Mellitus among undiagnosed individuals.

Methods: In this cross-sectional study, 214 individuals were recruited from Primary Health Care Referral Centers in Khartoum State. Attendees were interviewed to fill out the Diabetes Risk Score (DRS) questionnaire. Random blood glucose and glycosylated hemoglobin (HbA1c) were tested. Descriptive statistics and sensitivity analysis were performed to test the applicability of the DRS in Sudan.

Results: The prevalence of undiagnosed diabetes was found to be 14%. Regarding blood tests, Random blood glucose (RBG) was normal in 93% of the participants (cutoff ≤140 mg/dl). The HbA1c result was normal in 86% of the participants (cutoff < 6.4%). The DRS was high in 40.2% (cutoff ≥33), while 59.8% were considered moderate to low risk. The DRS had a sensitivity of 83.33% and a specificity of 66.85%. The positive and negative predictive values were 29.07% and 96.09%, respectively. The Area Under the Curve (AUC) for detecting undiagnosed diabetes was 0.751 (95% CI: 0.662-0.840).

Conclusion: The DRS tool was found to be applicable with reference to the HbA1c test for predicting undiagnosed diabetic patients.

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Introduction

Diabetes mellitus (DM) is a serious chronic disease that has emerged as a worldwide public health problem and is considered one of the four priority non -communicable diseases (NCDs) requiring global action. The incidence and prevalence of diabetes have been steadily increasing [1]. The prevalence of diabetes in the Middle East and North Africa (MENA) region, which notably possesses the second-highest percentage of all International Diabetes Federation (IDF) regions, measures 9.2%, nearly half the MENA region (49%) is undiagnosed. Moreover, the IDF announced that the number of people with diabetes worldwide will reach 693 million by 2045[2].

According to the Central Intelligence Agency (CIA), the total estimated population of Sudan is 43,087,468. Khartoum state has three major cities with a combined population of 7,380,479. [3].According to IDF 2019 statistics, Sudan is one of the 19 territories of the IDF-MENA region, with the diabetes prevalence in Sudanese adults reaching 10.9%[4]. The overall prevalence of diabetes was 6.0%, according to a fact sheet from the STEPwise Surveillance (STEPS), a 2016 survey of non-communicable diseases. In Khartoum state, the prevalence was 11.6%[5]. A cross-sectional survey in Gadarif state measured the prevalence of newly diagnosed diabetes as 10.0%[6]. Diabetes prevalence was significantly higher in urban areas than in rural areas. The prevalence of undiagnosed diabetes in North Africa is high compared to the total diabetes prevalence, ranging from 18% to 75%[7]. Several studies have recommended active screening for individuals older than 45 years, as well as those with hypertension or unexplained weight loss[8]. In poor resource settings, selective multistage screening was encouraged by the World Health Organization (WHO). The implementation of the Package of Essential Non-communicable Disease Interventions (PEN) at the primary care level recommends the screening of individuals older than 40 or younger with risk factors[9].

Screening for T2DM is the combination of risk assessment and biochemical tests for confirmation of a diagnosis of a new case. Screening tests, either questionnaires or biochemical tests, done combined to improve performance and gives a more accurate result. Screening in T2DM can be done using the following tests in order (i.e. assessing risk by questionnaire followed by blood glucose measurement if

the high-risk score is reached) or simultaneously (i.e. measurement of blood glucose and HbA1c at the same time) [10]. Screening tests are usually followed by diagnostic tests FBG and/or an OGTT using standard criteria to make the definitive diagnosis.

Several potential approaches are available to screen for diabetes [10]:

- Screening the entire population
- Selective or targeted screening performed in a subgroup of subjects who have already been identified as being at relatively high risk concerning age, body weight, ethnic origin, etc.
- Opportunistic screening carried out at a time when people are seen, by health care professionals, for a reason other than the disorder in question

Sudan still lacks early detection and prevention strategies, with the implemented strategy relying on diagnostic criteria for diabetes and laboratory confirmation through healthcare providers, according to the Sudan Diabetes Mellitus guidelines 2011, developed by the Federal Ministry of Health Sudan (FMoH) and the Non-communicable Diseases (NCDs) Directorate. There are numerous advantages to implementing a simple and non-invasive screening tool for the early detection of borderline and undiscovered diabetic cases. Such simple interventions could reduce healthcare expenditures by either reversing the occurrence of the disease or delaying the appearance of disease complications.

Study objectives

To evaluate the DRS tool for detecting Type 2DM among undiagnosed individuals in a Sudanese setting using the sensitivity study and ROC curve.

Methodology

Study Settings

This study was an analytical, cross-sectional, health facility-based study at Referral Primary Health Care Centers (RPHCCs) selected from Khartoum state localities. Khartoum's population is around 7,380,479. A total of 632 Primary Health Care Centers are available to provide preventive and curative health services for the Khartoum population [11]. Due to their high attendance rate, 74 RPHCCs provided an advanced package of services from which the first-stage study population was chosen.

Inclusion Criteria:

1. Participants were not known to have diabetes or were previously diagnosed with diabetes.
2. Adults aged 18 and up were eligible to participate.
3. Males and females.

Exclusion Criteria:

1. Pregnant women.
2. Patients who use metformin and other glucose-modifying medications.
3. Critically ill patients.

Sample size

Three-stage cluster random sampling frame was adopted. The first stage was the distribution of Khartoum State into seven localities. The second stage was the selection of targeted RPHCC from different localities. The third stage was the selection of targeted attendees from each health center.

Sample size was calculated using the following formula:

$$n = z^2 pq/d^2 * deff$$

Where:

- n=desired sample size
- z=confidence coefficient, 1.96
- p= proportion of unknown diabetic,

Derived from the prevalence of diabetic in Sudan according to the IDF 2018, 10.9

- p=100-10.9=89.1
- q=1-p=1-0.89=0.11
- d=desired margin error,0.05
- deff =design effect,1.5
- n=$(1.6)^2$*0.89*0.11/$(0.05)^2$ *1.5=225.8=226

The distribution of sample size (226) was done proportional to the 7 localities. The total number of the selected health centers in all Khartoum State was 10. The study used Probability Proportional to Size (PPS) to calculate the number of attendees in each RPHCC. Finally, the selection of the sample unit

(Attendees) used Systematic Random Sample (SRS) during the sample collection inside each selected RPHCC.

Data Collection Procedures

Data were gathered through face-to-face interviews, weight, height, waist circumference measurements, and blood spot samples. An adapted DRS questionnaire was used, consisting of the twelve original questions for the main risk factors for T2DM extracted from the CANRISK tool [12] in addition to three added questions to reflect the culture and nutritional habits that are believed to influence the risk of diabetes among the Sudanese population. According to the original score conducted in First Nations and Métis in Canada, the dependent or outcome variable, the diabetes risk score, was divided into low-, moderate-, or high-risk groups (less than 21, 21 to 32, and 33 and more, respectively) [12]. For measuring sensitivity and specificity in regards to HbA1c readings, DRS scores were recategorized to binary outcomes - less than 33 as "negative DRS," or 33 and more as "positive DRS.". Anthropometric measurements such as height "in centimeters," weight "in kilograms," and waist circumference "in centimeters" were used to calculate BMI for general obesity and waist circumference for central obesity. Height, weight, BMI calculation, and waist circumference were all measurable independent variables[13]. A random blood glucose test was performed to measure the current random blood glucose value through a capillary blood sample using a glucometer (FreeStyle Lite, Abbott Diabetes Care Inc., Alameda, CA) and pen-prick lancets. The cut-off point measurement was set at 140 mg/dl to distinguish between high and low readings. Due to its availability at the facility-based level and reasonable price, the test was used as a proxy indicator for blood glucose levels in the study. The most recent HbA1c test was performed to measure the average blood glucose levels over the previous three months using a point-of-care device (Clover A1C- HbA1c Analyzer) ®. Waste was disposed of using lancets, alcohol swabs, and safety boxes. According to the American Diabetes Association, the following HbA1c cut-off points were established [14].

1. Low risk of developing DM when HbA1c result is less than 5.7%;
2. Moderate risk of developing DM or a prediabetes state when HbA1c is between 5.7% and 6.4%; and
3. High risk of developing DM or diabetes when the HbA1c result is more than 6.4%. When using the HBA1c test result as a binary outcome, the reclassification was as follows:
    1. HbA1c equal to or more than 6.4% was diagnosed as positive T2DM; and
    2. HbA1c less than 6.4% was considered negative for T2DM.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) software, version 25 for Windows, was used. Data were coded, entered, cleaned, and categorized according to the questionnaire risk score category. Descriptive analysis for the dependent and independent variables of the study population was performed using percentages, tables, and figures. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and receiver operating characteristic (ROC) curves were generated using cross-tabulation of the outcomes (DRS) with the reference test (HbA1c).

Ethical consideration

The Sudan Medical Specialization Board and the Khartoum State Ministry of Health's Major Research Committee provided official ethics approval. The researcher obtained written consent from the participants after explaining the research purposes and objectives. The blood test used was noninvasive and required a minimum-risk procedure with the pinprick technique. The participants were made aware of their right to leave the study at any moment without suffering any consequences. Data confidentiality was guaranteed, and only the principal investigator had access to personal information, which was kept private. A referral note was given to those who were determined to have diabetes to seek medical care and advice. General lifestyle advice was delivered to those who had low-risk scores.

Results

A total of 214 outpatient attendees were enrolled by a response rate of 94.7%, while 5.3% represent non-response rate who refused to consent and hence participate in HbA1c testing.

Among the tested participants, 22.9% and 77.1% were male and female, respectively.

Considering marital status, 77.6% of the study population were married. Concerning other sociodemographic characteristics, most of the respondents (40.7%) were originally from the central region. The age group [38-47] had the highest percentage of participants (37.9%), while the age group [58-67] had the lowest percentage (9.3%). The respondents' occupation, household size, length of time living in Khartoum, and income are all shown in (Table 1).

Characteristics	n (%) (N=214)
Sex	
Female	165 (77.1%)
Male	49 (22.9%)
Age groups in year	
18-27	32 (15.0%)
28-37	48 (22.4%)
38-47	81(37.9%)
48-57	27(12.6%)
58-67	20(9.3%)
<68	6(2.8%)
Place of origin	
Central Region	87 (40.7%)
North	46 (21.5%)
South	5 (2.3%)
East	6 (2.8%)
West	70 (32.7%)
Duration of residency in Khartoum state	
Less than 15 Years	30 (14%)
15- 30 Years	111 (51.9%)
31- 45 Years	40 (18.7%)
More than 45 Years	33 (15.4%)
Marital Status	
Married	166 (77.6%)
Unmarried	48 (22.4%)
No. of family members	
Less than 3 members	35 (16.4%)

Characteristics	n (%) (N=214)
Between 3 & 5	**66 (30.8%)**
More than 5 members	**113 (52.8%)**
Occupation	
Working	**110 (51.4%)**
Not working	**104 (48.6%)**
Level of Education	
University and above	**84 (39.3%)**
Secondary	**106 (49.5%)**
Primary or Illiterate	**24 (11.2%)**
Family Income to Expenditure	
Income more than expenditure	**7 (3.3%)**
Income equal to expenditure	**64 (29.9%)**
Income less than expenditure	**143 (66.8%)**

Table 1. Socio-demographic characteristics among attendees of Referral Primary Health Care Centers at Khartoum State.

Regarding body mass index among the targeted population, 34.6% [74] were within the normal BMI range, while 29.4% were overweight, and 36% were obese. According to the study, 27.3% of women had a normal waist circumference of less than 80 cm, 26.1% had a circumference between 80 and 88 cm, and 46.7% had a circumference of 88 cm or more.. Fifty-five percent of men [27] had a regular waist circumference (less than 94 cm), while 24.6% had a waist circumference between 94 and 102 cm. Approximately 20.4% [11] had a waist circumference of 102 cm or higher. The study showed that only 9% of the studied population consisted of smokers and that 76% of the population was physically inactive (Table 2).

Characteristics of participants	n (%)
BMI N=214	
Normal Weight (18-Less than 25)	74 (34.6%)
Overweight (25-Less than 30)	63 (29.4%)
Obesity (30 and above)	77 (36.0%)
Waist circumference for Women N=165	
Less than 80 cm	45 (27.3%)
80-88 cm	43 (26.1%)
88 cm and more	77 (46.7%)
Waist circumferenc for Men N=49	
Less than 94cm	27 (55.1%)
94-102 cm	12 (24.5%)
102 cm and more	10 (20.4%)
Vegetables consumption N=214	
More than two times per week	198 (92.5 %)
Less than twice per week	16 (7.5 %)
Fruits consumption N=214	
More than two times per week	73 (34.1 %)
Less than twice per week	141 (65.9 %)
Kisra-Asida-Gurrasa -Bread N=214	
More than two times per week	161 (73.8 %)
Less than twice per week	53 (26.2%)
Smoking N=214	
YES	19 (9%)
NO	195 (91%)
Physical Activity N=214	

Characteristics of participants	n (%)
Yes	**52 (24%)**
No	**162 (76%)**

Table 2. Anthropometric Measurements eating habits, smoking and physical activity among attendees of Referral Primary Health Care Centers at Khartoum State at Khartoum State.

Concerning the RBG, the majority of the participants (93%) had normal RBG (cutoff < 140 mg/dl). The participants who had HbA1c (cutoff (< 6.4%)), accounting for 86%, were negative for diabetes. Regarding the DRS, 59.8% were considered negative (cutoff < 33) (Table 3).

Finding	Categorical outcome	Frequency	Percent	Binary outcome	Frequency	Percent
Random blood glucose	≤140g/dl	199	93.0 %	Negative (≤140g/dl)	199	93.0 %
	>140g/dl	15	7.0 %	Positive (>140g/dl)	15	7.0 %
HbA1c	<5.7	166	77.6 %	Negative (<6.4%)	184	86 %
	5.8 - 6.4	18	8.4 %			
	≥6.4	30	14.0 %	Positive (≥6.4%)	30	14.0 %
DRS	less than 21	70	32.7 %	Negative (<33)	128	59.8 %
	21 - 33	58	27.1 %			
	33 and more	86	40.2 %	Positive (≥33)	86	40.2 % [ok1]

Table 3. Categorical and binary outcome variables with their corresponding cutoff values among attendees of Referral Primary Health Care Centers at Khartoum State, Sudan .

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† *e Abbreviations RBG, Random blood glucose, HbA1c, hemoglobin A1c, DRS, Diabetes Risk Score*

‡ *N = 214*

The reference test in this study is HBA1c. The participants who were considered diabetic by both tests numbered 30 (14.0%) (Table 4).

Diabetes Risk Score	HbA1c		Total
	Positive (≥6.4%)	Negative (<6.4%)	
High Score(33 and more)	25	61	86
Low score (less than 33)	5	123	128
Total	30	184	214

Table 4. Cross-tabulation for DRS with HbA1c (Sensitivity Analysis) among attendees of Referral Primary Health Care Centers at Khartoum State.

† *Percentage according to the number of patients*

‡ *N = 214*

§ *Sensitivity = 25/30*100 = 83.33%*

¶ *Specificity = 123/184*100 = 66.85%*

The sensitivity and specificity of DRS in relation to the gold standard test were 83.33% and 66.8%, respectively. The total positive predictive value (PPV) was 29.07%, and the corresponding negative predictive value (NPV) was 96.09%. The Area under the curve (AUC) for the Diabetes Risk Score was 0.751 (95% CI: 0.662-0.840) (Figure 1)

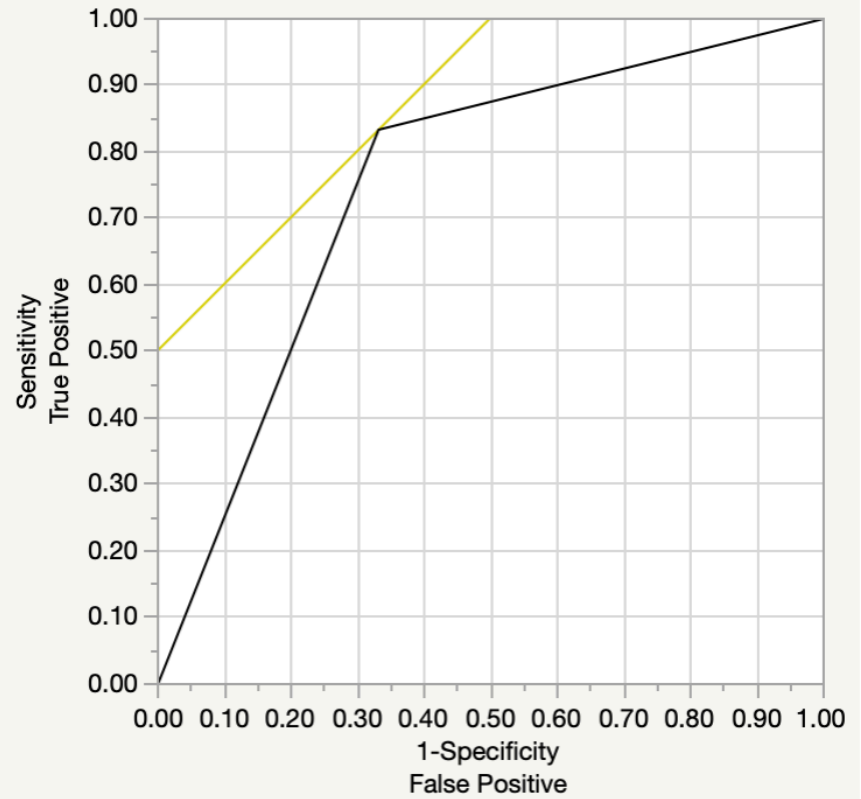

Figure 1. It shows the Area under the Curve for the Diabetes Risk Score (sensitivity against 1-specificity) among attendees of the Referral Primary Health Care Centers at Khartoum State, Sudan. The AUC for the Diabetes Risk Score = 0.751 (95% CI: 0.662-0.840)

Discussion

Our study evaluated the DRS as a screening tool by predicting the prevalence of undiagnosed diabetes, which is measured at 14%. This finding is consistent with the MENA diabetes prevalence (9.2%). [2] The result is nearly supported by IDF 2019 Sudan statistics [4], as well as the Khartoum State STEPS 2016 survey (11.6% with a confidence level of 9.1-14.1) [5]. The prevalence of newly diagnosed attendees is nearly identical to that of a recent study conducted in Gadarif state in 2019, which revealed a prevalence of 10.0%. Men had a significantly higher risk than women, which corresponds to the Saudi study's findings, in which women had higher scores than men in both moderate- and high-risk categories [15], although none of the models from the Gulf regions addressed gender [16]. The DRS has been widely implemented

as a low-cost, valid screening tool in many countries to detect those at risk for developing T2DM. This risk prediction model enables early detection, prevention, and intervention [12].

The study showed that the majority of participants (72.4%) were 18 to 44 years old, similar to the CANRISK study performed in the South Asian population. Regardless of the model, the odds of dysglycemia increased with age, and there were significantly higher odds in the elder age groups. Both results demonstrate a significant relationship between the age increment and the increased risk of diabetes [12]. Regarding BMI, the majority of the study sample was overweight or obese, with rates of 29.4% and 36%, respectively. According to the DRS, 40.2% were found to have a high-risk (≥ 33) DRS, while 59.8% were considered to have a low-risk DRS (< 33). Such a risk score is widely recommended for use in low-resource settings as one of the major approaches for screening programs [12].

The sensitivity and specificity of our DRS were 83.33% and 66.85%, respectively. In the EMRO region, there are many similarities in DRS test performance. Saudi Arabia's study, like the Kuwaiti, Emirati, and Omani studies, had a sensitivity and specificity of 76.6% and 52.1%, respectively[16][17][18][19]. According to the CDC's 2017 National Diabetes Statistics Report Trusted Source, there were approximately 1.5 million new total diabetes cases among adults in 2015. Adults aged 45 to 64 years old were the most diagnosed age group for diabetes [20].

With a 95% confidence level, the AUC was found to be 0.751 (95% CI: 0.662-0.840). This result shows that 95% of DRSs were acceptable and had good predictability for preventing undiagnosed diabetes. The DRS could go beyond that and be used at the community level. This finding is not dissimilar from that of the Canadian South Asian study, in which the AUC was 0.80 with a slight reduction to a 0.75 AUC among First Nations/Métis populations[12]. The accuracy of the DRS in the study is consistent with the previous observations of the CANRISK and FINDRISC surveys, in which the DRS performed reasonably well at identifying patients with elevated blood glucose levels, with AUC curves ranging from 0.69% to 0.85% [21].

The current study showed a PPV of 29 and an NPV of 96; these results are similar to the Métis result, in which the PPV was 30%, and the NPV was 90% at the original cutoff point of 33. The PPV was 28, and the NPV was 93 in the Canadian South Asian population study[12].

A considerable number of people in Khartoum city were at risk of developing T2DM. The questionnaire used is reliable, valuable, and easy to use as a screening tool. The prevalence of diabetes among undiagnosed attendees was considerable. Less than half of the attendees had high DRS results.

The sensitivity, specificity, and AUC of the study DRS tool showed that it is an accurate method suitable for application in the screening of diabetes in the health system in Sudan. The main recommendations of this study are to adopt the DRS tool as an easy, affordable, and accessible diabetes screening tool for populations at the primary healthcare level and to adopt further confirmation by blood tests for DRS in moderate- and high-risk populations to reduce the economic burden on the health system. However, more research is needed to examine a large sample of the Sudanese population to test the variables of Sudanese culture and its risks of developing diabetes, as this may limit its applications on a larger population scale.

Abbreviations

- AUC: Area under the Curve.
- BMI: Body Mass Index.
- CANRISK: Canadian Diabetes Risk Assessment Questionnaire.
- CBS: Community Based Screening.
- CDC: Centers for Disease Control and Prevention.
- CHAD: Community Health Awareness of Diabetes.
- DRS: Diabetes Risk Score.
- FBG: Fasting Blood Glucose.
- FINDRISC: Finnish Diabetes Risk Score.
- GLV: Green Leafy Vegetables.
- HbA1c: Glycosylated Hemoglobin A1C.
- HTN: Hypertension.
- IDF: International Diabetes Federation.
- MENA: Middle East and North Africa.
- NCDs: Non-Communicable Diseases NPV Negative Predictive Value.
- PPV: Positive Predictive Value OGTT Oral Glucose Tolerance Test.
- PPS: Probability Proportional Sampling.
- RAQ: Risk Assessment Questionnaires.
- RBG: Random Blood Glucose.
- ROC: Receiver Operating Characteristic.
- RPHC: Referral Primary Health Care Centers.

- SPSS: Statistical Package for Social Sciences.
- STEPS: STEPwise approach to Surveillance.
- T2DM: Type 2 Diabetes Mellitus.
- WC: Waist Circumference.
- WHO: World Health Organization.
- WHO/PEN: World Health Organization / Package of Essential Non-communicable Disease Interventions.

Statements and Declarations

Authors' contributions

- SF: principle investigator was actively involved in the planning, conducting, data collection and design of the study, also in writing the paper.
- AA: was involved in the data analysis.
- ME: was involved in data collection, interpretation of the data as well as writing the paper. Author Agreement
- OK: Actively involved in the planning, conception, design of the study, also revision the paper. All authors have approved the final manuscript.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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Ethical approval

"The Evaluation of Diabetes Risk Score Tool for Detecting Undiagnosed Type 2 Diabetes Mellitus in Attendees of Referral Clinics at Primary Health Care Centers, Sudan study was approved by the Sudan Medical Specialization Board, and the Khartoum State Ministry of Health's Major Research Committee provided official ethics approval.

Consent to participate

The researcher obtained written consent from the participants after explaining the research purposes and objectives.

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Declarations

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