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Research Article

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

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Introduction: The prevalence of diabetes in Sudan is increasing, but suitable risk assessment and screening tools to identify at-risk individuals are lacking. Objective: To evaluate the Diabetes Risk Score (DRS) tool for detecting undiagnosed type 2 diabetes mellitus.

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 DRS questionnaire. Random blood glucose and glycosylated hemoglobin (HbA1c) were tested. Descriptive statistics and sensitivity analyses were used to test the applicability of the DRS in Sudan. Results: The prevalence of undiagnosed Type 2 diabetes was found to be 14%. Regarding blood tests, random blood glucose 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 to have 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 Type 2 diabetes was 0.751 (95% confidence interval: 0.662-0.840).

Conclusion: The DRS tool was found to be applicable with reference to the HbA1c test for predicting undiagnosed Type 2 diabetes.

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Introduction

Diabetes mellitus (DM) is a serious chronic disease that has emerged as a worldwide public health problem. It is considered one of the four priority non-communicable diseases (NCDs) requiring global action. The incidence and prevalence of diabetes have been steadily increasing ^[11]. Notably, the Middle East and North Africa (MENA) region has the second-highest rate of diabetes among all International Diabetes Federation (IDF) regions. The prevalence of diabetes in this region is 9.2%, but nearly half of the cases (49%) are undiagnosed. The IDF has announced that the number of people with diabetes worldwide will reach 693 million by 2045 ^[21].

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, and the prevalence of diabetes among Sudanese adults is 10.9% ^[4].

A recent study found that the incidence rates of type 1 diabetes mellitus in Khartoum State among children under the age of five and those aged 16 to 19 were 8.4 and 7.7/100,000, respectively.

The overall prevalence of diabetes was 6.0% in 2016 according to the STEPwise Surveillance (STEPS) 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 overall prevalence of diabetes, 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 $\frac{[8]}{[8]}$. In settings with poor resources, selective multistage screening is encouraged by the World Health Organization (WHO). The implementation of the Package of Essential Non-communicable Disease Interventions (PEN) at the primary care level includes recommendations for the screening of individuals older than 40 years, as well as younger individuals who have risk factors [9].

Screening for type 2 DM (T2DM) involves a combination of risk assessment and biochemical tests to confirm the diagnosis of new cases. Screening tests

are combined to improve performance and give more accurate results. Screening tests for T2DM can be applied separately (a questionnaire followed by blood glucose measurement if a high-risk score is reached) or simultaneously ^[10]. Screening tests are usually followed by diagnostic tests (fasting blood glucose and/or oral glucose tolerance tests) using standard criteria to make a definitive diagnosis.

Several potential approaches are available to screen for diabetes ^[10]. The entire population may be screened, or selective or targeted screening can be performed for subgroups who have already been identified as having relatively high risk concerning age, body weight, ethnic origin, etc. Opportunistic screening may also be carried out at a time when people meet health care professionals for reasons other than diabetes.

Sudan still has weaknesses regarding early detection and prevention strategies. The strategy that is currently being implemented relies on diagnostic criteria for diabetes and laboratory confirmation through healthcare providers according to the Sudan DM Guidelines of 2011, which were developed by the Federal Ministry of Health Sudan (FMoH) and the NCD 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. Thus, the objectives of this study were to evaluate the Diabetes Risk Score (DRS) tool for detecting T2DM among undiagnosed individuals in a Sudanese setting based on its sensitivity and receiver operating characteristic curve.

Materials and Methods

Study Design

This analytical, cross-sectional, health-facility-based study was performed at referral primary health care centers (RPHCCs) selected from localities in Khartoum State.

Study population and sampling procedures

A total of 632 primary health care centers are available to provide preventive and curative health services for the population of Khartoum ^[11]. The first-stage study population was chosen from 74 RPHCCs that have a high attendance rate and provide an advanced package of services. Participants were eligible for inclusion criteria if they were adults aged 18 years or older and were not known to have diabetes or previously diagnosed with diabetes (participants must not have received a previous diagnosis of diabetes mellitus from a healthcare provider). The exclusion criteria were pregnancy (a female individual who has confirmed pregnancy through a positive pregnancy test result), the use of metformin or other glucose-modifying medications (an individual who is currently prescribed and actively taking Metformin or another glucosemodifying drug for the management of diabetes mellitus or other metabolic conditions), and critical illness (individuals who exhibit clinical signs and symptoms indicative of severe illness, typically requiring urgent medical intervention or hospitalization).

Sample size

Three-stage random cluster sampling was adopted. The first stage was the division of Khartoum State into seven localities, and the second stage was the selection of targeted RPHCCs these localities. The third stage was the selection of targeted attendees from each health center. The sample size was calculated as follows:

$$n=z^2pq/d^2*de\!f\!f$$

Where:

- n = the desired sample size
- z = the confidence coefficient, 1.96
- p = 10.9% (the proportion of unknown diabetics derived from the prevalence of diabetes in Sudan according to IDF 2018)
- p = 100-10.9 = 89.1
- q = 1-p = 1-0.89 = 0.11
- d = desired margin of error, 0.05
- deff = design effect, 1.5

The sample size was calculated as 226 participants, which was divided proportionally among the 7 localities. The total number of selected health centers in all of Khartoum State was 10. The study used probability proportional to size to calculate the number of attendees in each RPHCC. Finally, the selection of the sample unit (attendees) was done using systematic random sampling during the sample collection at each selected RPHCC.

Data Collection Procedures

Data were gathered through face-to-face interviews, measurements of weight, height, and waist circumference, and blood spot samples. An adapted DRS questionnaire was used, which consisted of the 12 original questions about the main risk factors for T2DM extracted from the CANRISK tool ^[12] in addition to three added questions to reflect cultural and nutritional habits that are believed to influence the risk of Type 2 diabetes among the Sudanese population. Diabetes risk scores were considered as the outcome variable. Based on the original score applied in First Nations and Métis communities in Canada, the participants were divided according to diabetes risk scores into low, moderate, and high-risk groups for those with scores of less than 21, 21 to 32, and 33 or more, respectively ^[12].

To measure the sensitivity and specificity in regard to HbA1c readings, DRS scores were also categorized using binary outcomes: scores less than 33 were considered as negative DRS, while scores of 33 or more were considered as positive DRS. The height in centimeters and weight in kilograms were used to calculate the body mass index (BMI) to assess general obesity, while the waist circumference was used for central obesity. Height, weight, BMI, and waist circumference were all considered measurable independent variables [13].

A random blood glucose test was performed through a capillary blood sample using a glucometer (FreeStyle Lite, Abbott Diabetes Care Inc., Alameda, CA) and pinprick lancets. The cutoff point was set as 140 mg/dl to distinguish between high and low readings. Due to its availability at the facility-based level and reasonable cost, the test was used as a proxy indicator for blood glucose levels in the study. The most recent HbA1c test was used to determine the average blood glucose levels over the previous three months with a point-of-care device (Clover A1C- HbA1c Analyzer®).

According to the American Diabetes Association, the following HbA1c cut-off points were established ^[14]. The risk of developing DM or a prediabetes when the HbA1c result was less than 5.7%, moderate risk was indicated by a result between 5.7% and 6.4%, and high risk was indicated by a result of more than 6.4%. The HBA1c test result was also used as a binary outcome as follows: HbA1c of 6.4% or more considered positive for T2DM, and HbA1c less than 6.4% was considered negative for T2DM.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) version 25 for Windows was used for analyses. Data were coded, entered, cleaned, and categorized according to the category of risk scores on the questionnaire. Descriptive analysis was performed for the dependent and independent variables of the study population

using percentages, tables, and figures. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and ROC curves were generated using cross-tabulation of the outcome (DRS) with the reference test (HbA1c).

Ethical consideration

The Sudan Medical Specialization Board and the Major Research Committee of the Khartoum State Ministry of Health provided official ethics approval. Written consent was obtained from the participants after explaining the purposes and objectives of the research. The blood test used was noninvasive and required a minimum-risk procedure with a 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. For those who were determined to have Type 2 diabetes, a referral note was given 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, resulting in a response rate of 94.7% (5.3% did not consent to participate in HbA1c testing). The participants were 22.9% males and 77.1% females. Regarding sociodemographic characteristics, 77.6% of the study population were married, and most (40.7%) were originally from the central region. The age group of 38-47 years had the highest percentage of participants (37.9%), while the age group of 58-67 years had the lowest percentage (9.3%). The respondents' occupation, household size, length of time living in Khartoum, and income are 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%)
Between 3 & 5	66 (30.8%)
More than 5 members	113 (52.8%)
Occupation	
Employed	110 (51.4%)
Not employed	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%)

Characteristics	n (%) (N=214)
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

The participants' medical histories indicated various conditions. There were 71 participants (31.2%) who had a history of high blood pressure or taking medication

for hypertension, while 41.1% (88) of the participants had a family history of diabetes, and 13.6% (29) had a history of high glucose levels at some point in time Table 2.

Characteristics of participants		Frequency	Percentage
History of kirk DD or modiration	No	143	66.8 %
History of high BP or medication	Yes	71	31.2%
Family History of DM	No	126	58.9%
Family History of DM	Yes	88	41.1%
History of high glucose level ever before	No	185	86.4%
History of high glucose level ever before	Yes	29	13.6%

Table 2. Medical history among attendees of Referral Primary Health Care Centers at Khartoum State, Sudan, n=214

Regarding BMI, 34.6% ^[74] were within the normal BMI range, while 29.4% were overweight, and 36% were obese. Furthermore, 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. Among men ^[27], 55%

had a regular waist circumference (less than 94 cm), while 24.6% had a waist circumference between 94 and 102 cm, and approximately 20.4% ^[11] had a waist circumference of 102 cm or higher. Only 9% of the study population were smokers, and 76% were physically inactive Table 3.

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 <u>for Women</u> N=165	
Less than 80 cm	45 (27.3%)
80-88 cm	43 (26.1%)
88 cm and more	77 (46.7%)
Waist circumferenc <u>for Men</u> 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	
Yes	52 (24%)
No	162 (76%) [ok1]

Table 3. Anthropometric Measurements eating habits, smoking and physical activity among attendees of ReferralPrimary Health Care Centers at Khartoum State at Khartoum State.

Concerning RBG, the majority of the participants (93%) had normal values (cutoff: < 140 mg/dl). 86% were

negative for diabetes according to the HbA1c result (cutoff: < 6.4%). Regarding DRS, 59.8% were considered negative (cutoff: < 33) Table 4.

Categorical and b	inary outcome variables w Health (vith their corre Care Centers at	- 0	•	attendees of F	Referral Primary
Finding	Categorical outcome	Frequency	Percent	Binary outcome	Frequency	Percent
Random blood	≤140g/dl	199	93.0 %	Negative (≤140g/dl)	199	93.0 %
glucose	>140g/dl	15	7.0 %	Positive (>140g/dl)	15	7.0 %
	<5.7	166	77.6 %		107	
HbA1c	5.8 - 6.4	18	8.4 %	Negative (<6.4%)	184	86 %
	≥6.4	30	14.0 %	Positive (≥6.4%)	30	14.0 %
	less than 21	70	32.7 %	Nagative (.22)	128	59.8 %
DRS	21 - 33	58	27.1 %	Negative (<33)	128	J9.8 %
	33 and more	86	40.2 %	Positive (≥33)	86	40.2 % [ok1] [ok2]

Table 4. Binary outcome variables with their corresponding cutoff values among attendees of Referral Primary HealthCare Centers at Khartoum State.

[†] e Abbreviations RBG, Random blood glucose, HbA1c, hemoglobin A1c, DRS, Diabetes Risk Score [‡] N = 214

HBA1c tests were used a reference test in this study. 30 participants were considered diabetic by both tests (14.0%) Table 5.

	Н	bA1c	
Diabetes Risk Score	Positive (≥6.4%)	Negative (<6.4%)	Total
High Score(33 and more)	25	61	86
Low score (less than 33)	5	123	128
Total	30	184	214

Table 5. Cross-tabulation for DRS with HbA1c (Sensitivity Analysis) among attendees of Referral Primary Health CareCenters at Khartoum State.

[†] Percentage according to the number of patients

 $^{\ddagger}N = 214$

- [§] Sensitivity = 25/30*100 = 83.33%
- ¶ Specificity = 123/184*100 = 66.85%

The sensitivity and specificity of the DRS in relation to the reference test were 83.33% and 66.8%, respectively. The total PPV was 29.07%, and the NPV was 96.09%. The area under the curve (AUC) for the DRS was 0.751 (95% confidence interval (CI): 0.662–0.840) (Figure 1).

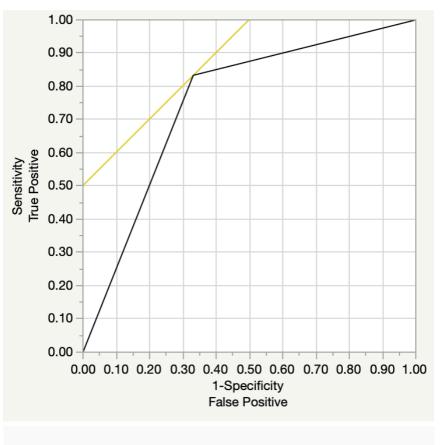


Figure 1. It shows the Area under the Curve for the Diabetes Risk Score (sensitivity against 1-specificity) among attendees of the Referral Primary Health Care Centers at Khartoum State, Sudan. The AUC for the Diabetes Risk Score = 0.751 (95% CI: 0.662-0.840)

Discussion

This study evaluated the DRS as a screening tool by predicting the prevalence of undiagnosed diabetes, which was measured as 14%. This finding is consistent with the prevalence of diabetes in the MENA region (9.2%) ^[2]. The result is supported by IDF 2019 statistics for Sudan ^[4], as well as the Khartoum State STEPS 2016 survey (11.6% with a CI of 9.1–14.1%) ^[5]. The prevalence of newly diagnosed participants was 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. In comparison, according to the findings of a Saudi study, women had higher scores than men in both moderate and high-risk categories ^[15], although none of the models from Gulf regions addressed gender ^[16]. The DRS has been widely implemented as a low-cost and

valid screening tool in many countries to detect those who are at risk of developing T2DM. This risk prediction model enables early detection, prevention, and intervention $\frac{[12]}{2}$.

The majority of participants (72.4%) were 18 to 44 years old, which is similar to the CANRISK study performed with a South Asian population. Regardless of the model, the odds of dysglycemia increased with age, and there were significantly higher odds in the older age groups. Both results demonstrate a significant relationship between age and the risk of diabetes ^[12]. Regarding BMI, the majority of the participants were overweight or obese with rates of 29.4% and 36%, respectively. According to the DRS, 40.2% had a high-risk DRS (\geq 33), while 59.8% had a low-risk DRS (< 33). This 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 Eastern Mediterranean region, many similarities related to the DRS have been reported. Studies performed in Saudi Arabia, Kuwait, United Arab Emirates, and Oman reported sensitivities and specificities of 76.6% and 52.1%, respectively ^{[16][17]} ^{[18][19]}. In 2015, there were approximately 1.5 million new diabetes cases among adults according to the 2017 National Diabetes Statistics Report of the Centers for Disease Control. Adults aged 45 to 64 years were the most prevalent age group for diabetes diagnoses ^[20].

The AUC result shows that 95% of DRSs were acceptable and had good predictability for preventing undiagnosed diabetes. Thus, the DRS could be used at the community level. This finding is similar to that of a Canadian study, in which the AUC was 0.80 for South Asians with a slight reduction to a 0.75 among First Nations/Métis populations [12]. The accuracy of the DRS in this study is consistent with the previous observations of the CANRISK and FINDRISC surveys, in which the DRS performed reasonably well in identifying patients with elevated blood glucose levels, with AUC curves ranging from 0.69 to 0.85% [21]. The PPV and NPV results are similar to the result of a Métis population, in which the PPV was 30%, and the NPV was 90% with a cutoff point of 33. In the Canadian South Asian population study, the PPV was 28%, and the NPV was 93% [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 participants was considerable. Less than half of the participants had high DRS results.

The sensitivity, specificity, and AUC of the DRS tool showed that it is an accurate method that is 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 tool for diabetes screening in 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. This study comprises a representative sample of primary health care centers from Khartoum State's major geographical regions. In part to the limitations of the cross-sectional investigation, we were unable to assess DRS' effectiveness in predicting T2DM events. Therefore, conduct a follow-up investigation to assess the predictive validity of the DRS. Another drawback is that the population demographics were tilted toward females, which may have significantly undermined the risk score's performance in the male gender. Also, more research is needed to examine a larger Sudanese population to test variables related to Sudanese culture and the risks of developing diabetes, which may limit the applications of the DRS at a larger population scale.

Appendix

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18 Histor	y of high BP or medication	0No 1Yes	0
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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.

Notes

Third, due to the nature of the cross-sectional study, we were unable to evaluate the performance of DRS in predicting DM and preDM events. We will try to conduct a follow-up study and assess the predictive validity of NCDRS further.

Validation of the risk score in the same population and the use of a larger sample size would have further enhanced the generalizability of our results.

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.

Funding

No funding to declare.

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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