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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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Abstract

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 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 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 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 ^[1]. 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 ^[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, and the prevalence of diabetes among Sudanese adults is 10.9% ^[4]. 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 ^[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 lacks 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.

Methodology

Study Settings

This analytical, cross-sectional, health-facility-based study was performed at referral primary health care centers (RPHCCs) selected from localities in Khartoum State. 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. The exclusion criteria were pregnancy, the use of metformin or other glucose-modifying medications, and critical illness.

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:

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

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 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 pin-prick 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 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.

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

Characteristics	n (%) (N=214)
Sex	

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%)
Income equal to expenditure	64 (29.9%)
Income less than expenditure	143 (66.8%)

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.

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

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

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.

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

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	
Yes	52 (24%)
No	162 (76%)[ok1]

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.

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

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

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] ^[ok2]

† 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.

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

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

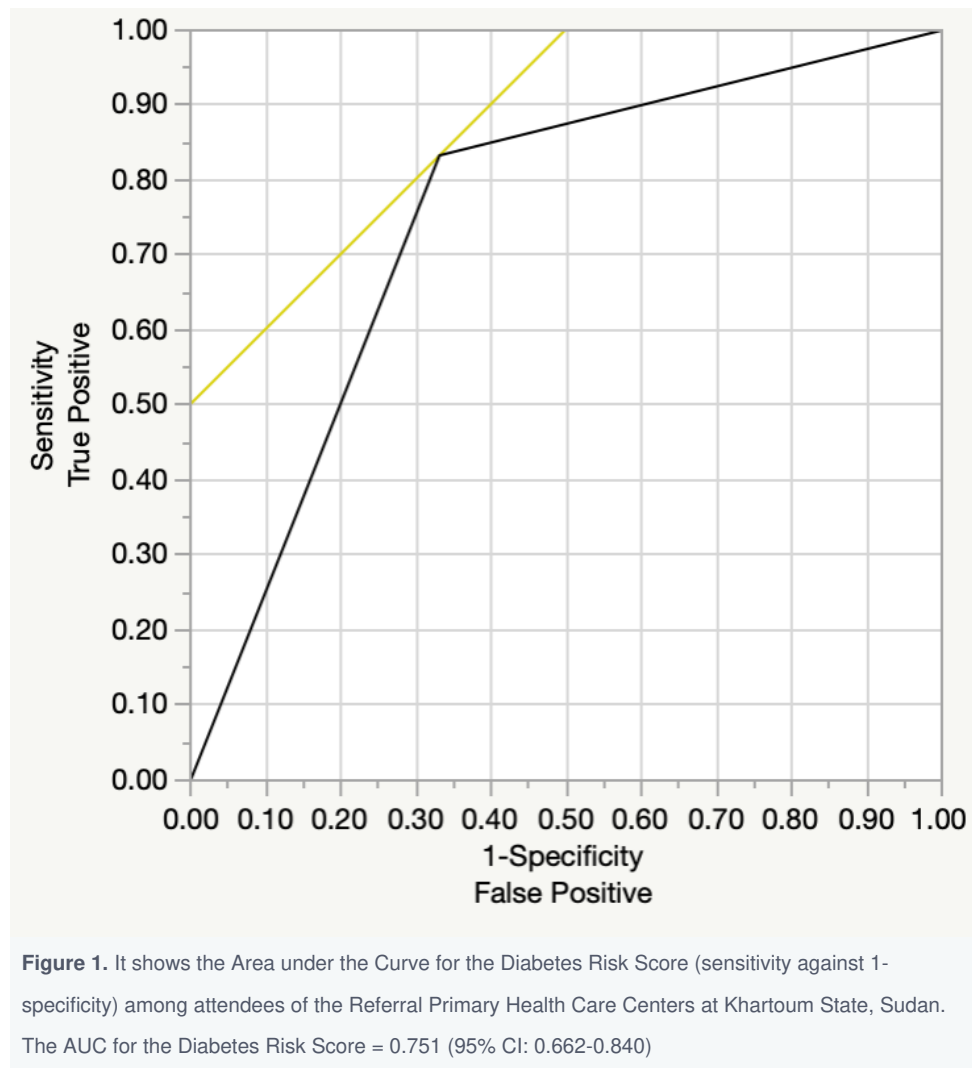
† Percentage according to the number of patients

‡ N = 214

§ Sensitivity = $25/30 * 100 = 83.33\%$

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

The sensitivity and specificity of 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).



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 [12].

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 (≥ 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. However, 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

Diabetes Risk Score Questionnaire for undiagnosed Diabetic client attending Referral Primary Health Care Centers at Khartoum State			
Do you have Diabetes: 1- Yes 2- No Serial Number: Health Center: Locality:			
Target population: Adult 18 and above, Not Known Diabetic, who is attending Family Medicine Or General Clinics at Referral Primary Health Care Centre (RPHCC) at Khartoum State.			
No	Questions	Answers	Scores for individual questions
Answer the questions and Choose the corresponding score for each question in Pink, then Add the total scores at the end			
1	Place of origin	0-Central Region 1-..... North 2-South 3-.....East 4-..... West	Origin of participants mother and father: If the origin South Asia.....11 If the origin Africa.....5 If the origin of Arab, Turk.....3 If the origin of white0
2	Duration of residency in Khartoum in years		
3	Occupation	0-Employed 1-Not Employed	If yes, Specify:
4	Marital status	0-.....Married 1-..... Not married	
5	Education	0- University and above 1- Secondary or Primary 2- Illiterate	0.....0 1..... 2 2..... 6
6	Age Years	Less than 44.....0 45-54.....6 55-64.....14 65 and more..... 15
7	Sex	0- Female 1- Male	0.....0 1.....6
8	Head of the Family financially	
9	No of Family member	
10	Family income .to. Expenditure	Less /Equal/ More	
11	Currently smoking (Cigarette/Tumbak /Shishah)	0-No..... If No, ever smoke: 0- Yes 1- No	0.....0 1.....1
12	Do you usually do Physical Activity 30 minutes/day	0- Yes If Yes, what kind:..... 1- No	0.....0 1.....1
13	Usually how many days/week you eat Vegetables	0-..More than two times per week. 1- Less than twice per week	0.....0 1.....1
14		0-More than two per week.....	0.....0
	Usually how many days/week you eat fruits	1- Less than twice per week	1.....1
15	Usually how many days/week you eat: Kiswa-Asida / Gurrasa / Bread Baladi with Raddah / Bread Afrangi / Rice	0-.....More than two times per week 1-Less than twice per week	

16	Family History of DM (Mother, Father, Sisters, Brothers & Kids)	0-..... No 1- Yes	0.....0 1.....6		
17	History of high glucose level	0-..... No 1- Yes	0.....0 1.....14		
18	History of high BP or medication	0-..... No 1- Yes	0.....0 1.....4		
19	<u>Ladies:</u> History of large baby 4.1 kg	0- No 1- Yes	0.....0 1.....1		
20	BMI	Height Cm Weight..... Kg	Less than 25.....0 25-29.....6 30 and more14		
21	Waist Circumference Cm	WOMEN	MEN		
		Less than 80.....0 80-88.....4 88 and more.....6	Less than 94.....0 94-102.....4 102 and more.....6		
Total Score for question (1,5,6,7,11,12,13,14,16,17.18,19,20,21)		21 and less Low Risk	21-33 Moderate	33and more High Risk
Test	HbA1c%	5.7and less Normal	5.7-6.4 Pre-diabetes	6.4 & more Diabetes

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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