Evaluation of capillary blood glucose versus a high-risk questionnaire for screening for undiagnosed diabetes mellitus in Eastern province, Saudi Arabia

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تقييم قياس غلوكوز الدم الشعري مقابل استبيان لِسُلَّم الاختطار المرتفع للسكري غير المشخص في المنطقة الشرقية للمملكة العربية السعودية

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الخلاصة: يقارن الباحثون في هذه الدراسة اختبارين لتحرِّي السكري غير المشخص عند تطبيقهما في حملة المسح الجموعي في المنطقة الشرقية للمملكة العربية السعودية في عامي 2004 و2005. وقد شمل التحرِّي 15 082 فرداً، كان 65.8٪ منهم إيجابيين وفقاً لاستبيان سُلَّم أحراز الاختطار الصادر عن الجمعية الأمريكية للسكري، وكان 71.3٪ منهم إيجابيين بكشف غلوكوز الدم الشعري باستخدام مقياس نقَّال لغلوكوز الدم. وقد تأكَّد تشخيص السكري من النمط الثاني لدى 20.3٪ من المشاركين بالدراسة، وتأكَّد تشخيص ما قبل السكري لدى 33.9٪ باستخدام اختبار سكر الدم الوريدي على الريق. وهكذا لم يكن أداء استبيان سُلَّم أحراز الاختطار يرقى إلى جودة اختبار غلوكوز الدم الشعري على الريق أو العشوائي. وقد كانت القيمة الفيصل المثلى لغلوكوز الدم الشعري على الريق 120 مغ/ دل، ولغلوكوز الدم الشعري العشوائي 160 مغ/ دل. وتبين أن قياس سكر الدم الشعري على الريق أكثر حساسيةً وأكثر نوعيةً وأكثر قدرةً على التمييز من قياس سكر الدم الشعري العشوائي لكشف السكري وما قبل السكري في هذه المجموعة السكانية السعودية.

ABSTRACT This study compared 2 screening tests for detecting undiagnosed diabetes mellitus when applied in a mass-screening campaign in the Eastern province of Saudi Arabia in 2004–05. Of 15 082 individuals screened, 65.8% were positive by the American Diabetes Association risk-score questionnaire and 71.3% by determination of capillary blood glucose (CBG) using a portable glucometer. Type 2 diabetes mellitus was confirmed in 20.3% of participants and pre-diabetes in 33.9% using fasting venous blood testing. The risk-score questionnaire did not perform well versus fasting and random CBG. Optimal cut-offs for fasting and random CBG were 120 mg/dL and 160 mg/dL respectively. Fasting CBG had higher sensitivity, specificity and discriminating ability than random CBG for detection of diabetes and pre-diabetes in this population.

Évaluation de la mesure de la glycémie capillaire comparée à l'administration d'un questionnaire de dépistage destiné aux personnes à haut risque de diabète jamais diagnostiqué auparavant dans la province orientale d'Arabie saoudite

RÉSUMÉ La présente étude a comparé deux méthodes de dépistage du diabète non diagnostiqué, utilisées pendant une campagne de dépistage de masse dans la province orientale d'Arabie saoudite entre 2004 et 2005. Parmi les 15 082 personnes dépistées, le diagnostic de diabète a été posé au moyen du questionnaire de risque de l'*American Diabetes Association* pour 65,8 %, et il a été effectué par détermination de la glycémie capillaire à l'aide d'un lecteur de glycémie portable pour 71,3 %. Le diabète de type 2 a été confirmé dans 20,3 % des cas et un état prédiabétique a été diagnostiqué chez 33,9 % des personnes dépistées au moyen d'une analyse de la glycémie à jeun par prélèvement veineux. Le questionnaire de risque était moins performant que l'analyse de la glycémie à jeun et l'analyse de la glycémie capillaire aléatoire. La valeur seuil optimale pour l'analyse de la glycémie à jeun était 120 mg/dl et celle de l'analyse capillaire aléatoire était 160 mg/dl. L'analyse de la glycémie à jeun avait une sensibilité plus élevée, une spécificité supérieure et une meilleure capacité de discrimination que l'analyse de la glycémie capillaire aléatoire pour le dépistage du diabète et des états prédiabétiques dans cette population.

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Introduction

The debate whether to screen for diabetes mellitus (DM) continues in the medical community among those who recommend [1] and those who discourage it [2]. Although it seems intuitive that early detection improves outcome, lack of direct evidence from randomized controlled studies of the effectiveness of screening for type 2 DM is the main barrier to its widescale application. Nonetheless, type 2 diabetes may remain undetected for several years [3], and by the time of clinical diagnosis many people have developed one or more micro- or macrovascular diabetic complications [4].

The American Diabetes Association (ADA) has recommended regular screening for type 2 diabetes at 3-year intervals, beginning at age 45 years (or less if there are other risk factors) [1]. However, mass screening was not recommended. To save community resources, the ADA suggested using a screening questionnaire—"take the test, know the score"—whereby only those with high risk-factor scores would be tested [5]. While different diabetes risk questionnaires have been developed and evaluated [6–10], their validity has been mainly assessed in Caucasian populations, which raises doubts over their validity in other populations. When diabetes risk scores have been applied to other ethnic groups, e.g. in Caribbean and South Asian people living in the United Kingdom (UK) [11], the results vary, and the need to validate screening tests in other populations has been emphasized.

The prevalence of DM is very high in the Saudi Arabian population [12], but the performance of screening tests has not yet been validated in this population. Capillary blood glucose (CBG) screening for type 2 DM, using a reflectance blood glucose meter, is less costly than other screening tests.

The aim of the present study was to compare 2 screening tests for detecting undiagnosed diabetes when applied in a Saudi population through a mass screening campaign in the Eastern province of Saudi Arabia. The study compared the performance of a diabetes risk-score questionnaire in a Saudi population with CBG testing by portable glucometer and determined which cut-off levels of random and fasting CBG yielded the best balance between sensitivity and specificity versus laboratory-confirmed fasting plasma glucose (FPG) testing.

Methods

Sample

This study was part of a larger screening campaign conducted in the Eastern province of Saudi Arabia between 28 August 2004 and 18 February 2005. The campaign and sampling has been described previously [13,14]. The target population was all Saudi residents of the Eastern province, aged 30 years and above, excluding pregnant women (650 000 subjects). They were invited to participate in a screening campaign for the early detection of DM and hypertension by attending one of the 300+ examination centres in the programme. A total of 15 082 individuals were included in the study reported here.

Individuals with undiagnosed diabetes who did screening of either fasting CBG or random CBG and underwent confirmatory testing were included in the study. Those with abnormal screening results for blood pressure and/or FPG, pregnant women and those who had self-reported previously diagnosed diabetes were excluded from this study.

Data collection

At the mass screening participants underwent measurements of weight and height and completed a structured questionnaire to collect data for the risk-score questionnaire. CBG screening for undiagnosed DM was done with a portable glucometer. Participants attended on another day for confirmatory testing for DM and pre-diabetes by fasting venous glucose blood levels after ≥ 8 hours fast.

The high-risk score questionnaire used in this study was the diabetes **risk** test recommended by the ADA [15] and studied by Rolka et al. [16]. The questionnaire provides a high-risk score based on age, body mass index (BMI), sedentary lifestyle, family history of DM and ever having delivered a macrosomic baby (> 4 kg). The maximum score was 22 and the cut-off score for a positive screening result was ≥ 10 points.

Capillary blood samples were taken and whole blood glucose concentration was measured using a uniform portable glucometer with the Medisafe Reader (Terumo Co.). During the field study, instruments were calibrated every morning. Supervision of the technicians carrying out the blood tests was ensured. Quality control supervised teams were distributed in every sector to assure the quality of performance and accuracy of the devices. Screening was considered positive if fasting CBG was ≥ 100 mg/dL or if random CBG was ≥ 140 mg/dL for those with undiagnosed diabetes.

Venous blood specimens were collected and FPG concentrations were determined using glucose oxidase methodology in the central laboratory of the Dammam area or in other government and private hospitals. Type 2 DM was diagnosed when FPG level was ≥ 126 mg/dL and pre-diabetes when FPG was 100–125 mg/dL. Normal FPG was < 100 mg/dL.

Laboratory personnel were blinded to the results of the screening test. Independent health team collected the questionnaires and the results of the screening tests, collated them with confirmatory FBS tests and delivered them to the main primary health directorate centre for data collection and entry.

Analysis

Different cut-off points of random CBG and fasting CBG and the risk-score questionnaire were evaluated separately

against the diagnostic standard for diabetes (FPG ≥ 126 mg/dL). Sensitivity, specificity, positive and negative predictive values, likelihood ratio of positive and negative tests, and 95% confidence interval (CI) for all those were calculated using standard methods [17]. To select the optimal cut-off point for a positive test, a receiver operating characteristics (ROC) curve was constructed by plotting sensitivity (true positive rate) against the false positive rate (1–specificity). The high-risk score questionnaire and fasting and random CBG were evaluated with respect to the area under the curve (AUC) in the ROC.

All analyses were performed using *SPSS* for Windows, version 16.

Results

A total of 15 082 individuals aged 30+ years were included in the study. DM was confirmed by FPG ≥ 126 mg/dL in 3052 (20.3%) and pre-diabetes in 5108 (33.9%) (Table 1). The characteristics of the study group of undiagnosed cases of DM according to socioeconomic status are shown in Table 2. The mean age was 46.5 (SD 11.6) years, 55.6% were women and 47.9% had a first-degree relative with diabetes.

A total of 9919 people (65.8%) had positive scores on the high-risk questionnaire (at the cut-off score of ≥ 10) (Table 1). The sensitivity of the test at this cut-off was 71%, while the specificity was 39% (Table 3). However, combining the risk score for the fasting CBG and random CBG increased the sensitivity to 83% and 75% and specificity to 86% and 77% respectively. Figure 1 shows the ROC curve for the high-risk questionnaire; the AUC was 0.55 (95% CI: 0.54–0.56).

In the biochemical screening tests, 10 761 (71.3%) participants were positive for either fasting CBG (at a cut-off of 100 mg/dL) or random CBG (at a cut-off of 140 mg/dL). Fasting CBG was done for 4961 (32.9%) participants, while random CBG was determined for 10 121 (67.1%). In Table 4 the diagnostic sensitivity, specificity and positive and negative predictive values of a positive test for both fasting and random CBS were compared with the FPG test at various cut-off points. Fasting CBG at 100 mg/dL had a sensitivity of 97% and specificity of 29%. When the cut-off point was increased to 140 mg/dL sensitivity dropped to 57% and specificity increased to 96%. Random CBG at 140 mg/dL had a sensitivity of 91% and specificity of 48%. When the cut-off point was increased to 200 mg/dL sensitivity dropped to 53% and specificity increased to 95%.

Table 1 Number of participants positive for type 2 diabetes mellitus by the risk-score questionnaire and capillary blood glucose screening (CBG) compared with laboratory-confirmed fasting plasma glucose (FPG) (*n* = 15 082)

Screening tool (cut-off)	No. positive	%
ADA risk score (≥ 10 points)	9 919	65.8
CBG (fasting ≥ 100 mg/dL or random ≥ 140 mg/dL)	10 761	71.3
FPG (≥ 126 mg/dL)	3 052	20.3
FPG (100–125 mg/dL)	5 108	33.9

ADA = American Diabetes Association.

The optimal cut-off point (highest sensitivity with comparable high specificity) for fasting CBG was 120 mg/dL (Table 4). Sensitivity was 81%, specificity 86%, positive predictive value 76% and negative predictive value 90%. The likelihood ratio of a positive test was 5.88 and the likelihood ratio of a negative test was 0.22.

For the random CBG, the optimal cut-off point was 160 mg/dL (Table 4). Sensitivity was 76%, specificity 77%, positive predictive value 58%, negative predictive value 89%. The likelihood of a positive test was 3.35 and likelihood ratio of a negative test was 0.31.

Figure 2 shows the ROC curve of the performance of fasting and random CBG. The AUC for random CBG (0.87) was lower than that for fasting CBG (0.82). If only those with positive high-risk scores were included, the AUC for fasting CBG increased to 0.87 and for random CBG dropped to 0.82 (Figure 3).

Table 5 shows the optimum cut-off point for both types of CBG screening tests according to sex. The optimum cut-off for random CBG screening was 165.5 mg/dL in men, with both a sensitivity and specificity of 77%, and the cut-off for optimum random CBG in women was 159.5 mg/dL, with lower sensitivity and specificity. The sensitivity and specificity for fasting CBG screening were higher in both men and women at cut-offs of 119.5 mg/dL and 121.5 mg/dL respectively.

Discussion

There is an increasing interest in using non-invasive tools such as risk-score questionnaires to detect high-risk groups suitable for screening. Finding a good high-risk score to detect undiagnosed DM, which at the same time is simple enough not jeopardize compliance is difficult. This may be due to the overlap in the characteristics of DM types 1 and 2 [18] so that individuals do not always fit the typical pattern of type 2 DM [9]. Several multivariate equation models have been constructed to predict undiagnosed DM, with variable rates of validity [6–10]. Spijkerman et al. found a different response to screening tools—the Cambridge risk score versus FPG and glycosylated haemoglobin (HbA_{1c})—among Caribbean and South Asian people living in the UK than the Caucasian population and recommended assessing the performance

Table 2 Characteristics of participants according to laboratory-confirmed fasting plasma glucose (FPG) results for diabetes mellitus (DM)

Variable	All[a] (*n* = 15 082)		FPG results			
			Type 2 DM[b] (*n* = 3052)		Pre-diabetes[c] (*n* = 5108)	
	No.	%	No.	%	No.	%
Age (years)						
30–40	4 603	30.5	725	23.8	1368	26.8
41–50	5 345	35.5	1104	36.2	1832	35.9
51–60	2 869	19.0	650	21.3	1093	21.4
> 60	2 254	15.0	570	18.7	813	15.9
Sex						
Male	6 673	44.4	1472	48.2	2121	41.5
Female	8 372	55.6	1580	51.8	2987	58.5
History						
Family history of DM	7 220	47.9	1587	52.1	2438	47.8
Family history of hypertension	6 606	43.9	1277	42.0	2239	47.8
History of gestational DM (women)	1 445	17.2	397	24.8	497	16.7
Marital status						
Single	429	2.9	77	2.5	126	2.5
Married	13 142	87.9	2652	87.8	4430	87.4
Widowed	1 142	7.6	243	8.0	425	8.4
Divorced	230	1.5	48	1.6	86	1.7
Occupation						
Self-employed	1 180	8.0	286	9.6	358	7.1
Housewife	7 103	48.0	1375	46.0	2578	51.5
Military	1 434	9.7	301	10.1	459	9.2
Professional	994	6.7	169	5.7	300	6.0
Technical	464	3.1	82	2.7	143	2.9
Non-technical	611	4.1	124	4.2	201	4.0
Administrative employee	1 709	11.6	332	11.1	522	10.4
Unemployed	1 288	8.7	318	10.6	448	8.9
Education						
Illiterate	5 824	39.3	1281	42.8	2162	43.1
Read & write	1 288	8.7	288	9.6	439	8.7
Primary	2 449	16.5	485	16.2	793	15.8
Intermediate	1 755	11.9	359	12.0	577	11.5
Secondary	2 029	13.7	352	11.8	604	12.0
University	1 373	9.3	206	6.9	425	8.5
Higher degree	83	0.6	19	0.6	22	0.4
Income (Saudi riyals)						
< 2000	4 051	30.0	873	32.2	1447	31.6
2000–< 5000	4 415	32.7	889	32.7	1465	32.0
5000–< 7000	2 365	17.5	461	17.0	835	18.2
> 7000	2 651	19.7	492	18.1	837	18.3

[a] *Total varies due to missing data.*
[b] *Fasting blood glucose ≥ 126 mg/dL;* [c] *Fasting blood glucose 100–125 mg/dL.*

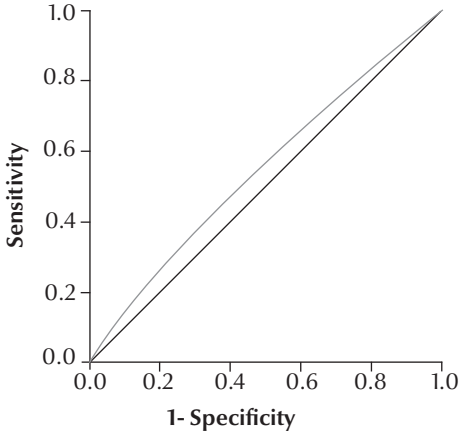

Figure 1 Receiver operator characteristics curve for the high-risk screening questionnaire (diagonal segments are produced by ties)

Table 3 Performance of the risk-score screening questionnaire and fasting and random capillary blood glucose (CBG) screening

Screening test and cut-off	Sensitivity		Specificity		Positive predictive value		Negative predictive value		Positive likelihood ratio		Negative likelihood ratio	
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
Risk score ≥ 10	71	69–73	39	38–40	34	33–35	75	74–76	1.16	1.13–1.20	0.75	0.70–0.80
Positive risk score + fasting CBG ≥ 120 mg/dL	83	80–851	86	84–88	78	75–81	89	87–91	5.80	5.10–6.70	0.20	0.17–0.24
Positive risk score + random CBG ≥ 160 mg/dL	75	73–78	77	75–78	60	58–63	87	85–88	3.22	2.99–3.46	0.32	0.29–0.35

CI = confidence interval.

of screening methods in different ethnic groups [11]. The high-risk questionnaire used for our Saudi population was that recommended by the ADA and studied by Rolka et al. [16].

In the current study, the high-risk score identified 71.3% of previously undiagnosed diabetics. However, the specificity of the high-risk score in our sample was low (39%), even lower than in a Caucasian population for whom it showed a sensitivity of 69%–75% and specificity of 49%–50% for the criteria of diagnosed DM, which may constrain its reliability for detecting undiagnosed DM [18]. This may be related to the unique cultural and ethnic characteristics of the Saudi population [11].

While it is desirable to have both high sensitivity and specificity in a screening test, this is rarely achievable in practice. Therefore there should be a trade-off between the two, according to the needs of the screening, taking into consideration the cost, convenience and reproducibility in mass screening. In screening there is usually a requirement to detect a higher number of cases, so a higher sensitivity is required in diagnosis, although there is no uniform agreement on the cut-off point. However, CBG testing by portable glucometer has the lowest cost, followed by laboratory-confirmed FPG and HbA_{1c} testing [1].

The sensitivity of fasting CBG and random CBG were higher in our study when the cut-off point was lowered but their specificity was very low. Increasing the cut-off point of fasting CBG from 100 mg/dL to 120 mg/dL and of random CBG from 140 mg/dL to 160 mg/dL optimized the balance of sensitivity and specificity. On the other hand, an argument could be made for lowering the cut-off points to 110 mg/dL and 150 mg/dL for fasting and random CBG respectively and consequently reduce the chances of missing cases of diabetes and pre-diabetes with reasonable specificity.

Zhang et al. studied the most efficient cut-off point for CBG to identify both pre-diabetes and undiagnosed diabetes in relation to both direct and indirect costs [19]. They chose a lower cut-off point (100 mg/dL) than in our study or Cervin et al.'s study [18], and found a sensitivity of 83% and specificity of 63%. Our study focused only on detecting undiagnosed DM. The main purpose, in addition to detection, was to follow patients through health care settings such as primary health care centres. So when focused on detecting undiagnosed DM the most efficient cut-off point for fasting CBG was higher, at 120 mg/dL.

To study whether to use a lower cut-off and have a lower specificity or a

Table 4 Sensitivity, specificity, and proportion of individuals who tested positive for pre-diabetes and undiagnosed diabetes by fasting and random capillary blood glucose (CBG) screening test at different cut-off points

Cut-off (mg/dL)	Sensitivity		Specificity		Positive predictive value		Negative predictive value		Positive likelihood ratio		Negative likelihood ratio	
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
Fasting												
100	97	96–98	29	27–31	42	40–44	95	93–97	1.37	1.33–1.41	0.09	0.07–0.13
110	91	89–93	67	65–69	59	56–61	93	92–95	2.72	2.55–2.90	0.14	0.11–0.16
120	81	79–83	86	85–88	76	73–78	90	88–91	5.88	5.25–6.58	0.22	0.19–0.25
130	70	67–73	93	92–94	85	82–87	86	84–87	10.55	8.92–12.48	0.32	0.29–0.35
140	57	54–60	96	95–97	88	85–90	81	79–83	13.98	11.25–17.36	0.45	0.42–0.48
Random												
140	91	90–92	48	47–50	42	40–43	93	92–94	1.76	1.70–1.81	0.18	0.16–0.21
150	84	83–86	65	64–66	50	48–51	91	90–92	2.41	2.30–2.51	0.24	0.22–0.27
160	76	74–78	77	76–79	58	56–60	89	88–90	3.35	3.16–3.55	0.31	0.29–0.34
170	69	70–71	86	85–87	66	64–68	87	86–88	4.77	4.43–5.14	0.36	0.34–0.39
180	63	61–65	90	89–91	72	70–74	86	85–87	6.35	5.79–6.95	0.41	0.39–0.44
190	57	55–60	93	92–94	77	75–79	84	83–85	8.29	7.43–9.26	0.46	0.43–0.48
200	53	51–55	95	94–96	81	79–84	83	82–84	10.75	9.43–12.24	0.50	0.47–0.52

CI = confidence interval.

higher cut-off and have lower sensitivity, we used ROC curves to determine whether to use fasting or random CBG. The AUC for fasting CBG was higher (0.87) than for random CBG (0.82). Rolka et al. reported similar findings: CBG screening in participants who had not eaten for ≥ 8 hours had a higher sensitivity and specificity in both sexes compared with random CBG [16].

It was clear from our data that the high-risk questionnaire performed poorly when carried out alone, with a sensitivity of 71% and specificity of 39%. Even when a positive high-risk score was used in conjunction with portable CBG screening, sensitivity increased from 71% to 83%. However, other predictors did not change or were negatively affected, and this may be due to the high percentage of the study population who were obese or overweight. Three-quarters of the population of Eastern province of Saudi Arabia are obese or overweight [20]. Besides, the age of the study participants was ≥ 30 years. So, based on those factors, the ability to discriminate between those who had and those who did not have the disease was low.

Our study had a number of strengths including the large size of the population

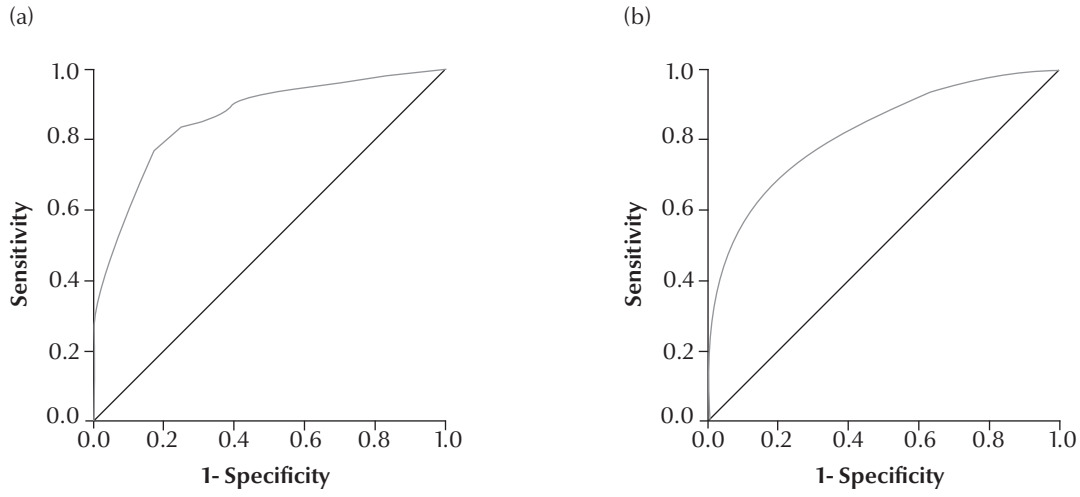

Figure 2 Receiver operator characteristics curve for (a) fasting capillary blood glucose screening test and (b) random capillary blood glucose screening test (diagonal segments are produced by ties)

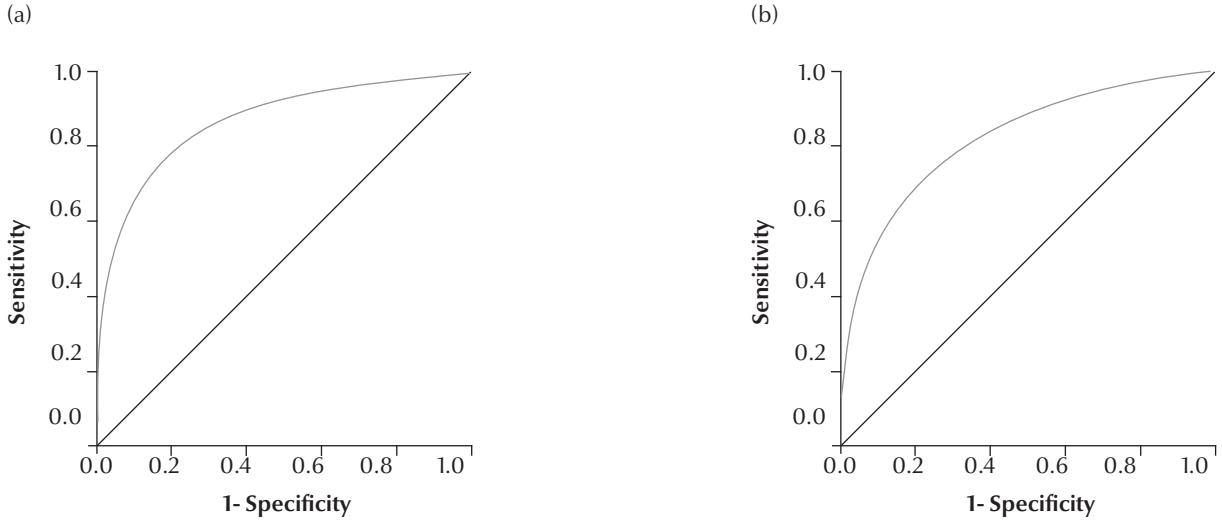

Figure 3 Receiver operator characteristics curve of (a) fasting capillary blood glucose screening test and (b) random capillary blood glucose screening test if administered after positive high-risk score (Diagonal segments are produced by ties)

Table 5 Optimal cut-off values of capillary blood glucose (CBG) screening test to predict diabetes mellitus according in males and female Saudi adults, Eastern province, 2004

Test/Sex	No. tested	AUC (95% CI)	Cut-off (mg/dL)	Sensitivity (%)	Specificity (%)
Random CBG					
Male	5104	0.85 (0.84–0.87)	165.5	77	77
Female	4991	0.79 (0.77–0.80)	159.5	70	71
Fasting CBG					
Male	1475	0.89 (0.87–0.91)	119.5	82	82
Female	3380	0.85 (0.83–0.87)	121.5	78	79

AUC = area under the curve; CI = confidence interval.

enrolled in the campaign, the diversity of subgroups, and the study design, in which the laboratory personnel carrying out the confirmatory FPG testing were not aware of the previous results of CBG screening. FPG was selected for this study as the diagnostic standard because it is a convenient test to ensure compliance of the participants, especially with large number of participants enrolled in this campaign.

Conclusions

The risk-score questionnaire did not perform well versus fasting and random CBG. The optimal cut-off points for fasting and random CBG were 120 mg/dL and 160 mg/dL respectively. Fasting CBG had higher sensitivity, specificity and discriminating ability than random CBG for detection of diabetes and pre-diabetes in this population.

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Diabetes in the Eastern Mediterranean Region

Diabetes mellitus is highly prevalent among both sexes in Member States of the WHO Eastern Mediterranean Region, ranging from 3.5% to 30.0% and it is highest among member countries of the Gulf Cooperation Council (GCC) at 11.5% to 30.0%. Many countries in the Region are now reporting the onset of type 2 diabetes mellitus at an increasingly young age. This is due to increasingly sedentary lifestyles, higher life expectancy and obesity. High blood pressure and cardiovascular diseases are also on the rise. In 2003, the 5 countries with the highest diabetes prevalence in the adult population were Nauru (30.2%), United Arab Emirates (20.1%), Qatar (16%), Bahrain (14.9%), and Kuwait (12.8%) (1). By 2025, the number of people with diabetes is expected to be more than double in Africa, the Eastern Mediterranean and South-East Asia regions.

Further information on the Regional prevalence of this condition can be found on the noncommunicable diseases website at http://www.emro.who.int/ncd/diabetes.htm/