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Original Article

Validation of the cardiovascular risk model developed for Omanis with type 2 diabetes

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ABSTRACT

Aim: The first cardiovascular risk prediction model in the Arab world was recently developed for Omanis with type 2 diabetes mellitus. This study aims to validate the newly developed model.

Materials and methods: A retrospective cohort study design was applied in this study. The model was validated in two samples; the model derivation sample and a separate validation sample, consisting of 1314 and 405 diabetics respectively. All patients were free of cardiovascular disease at the baseline (2009–2010) and were followed up until: the first cardiovascular event occurred; the patient died; or up to December 2015. All data were retrieved from the patients' medical records in a primary care setting.

Results: In both the derivation and validation samples, the model showed good discrimination, with an area under the receiver operating curve of 0.73 (95% CI: 0.69–0.77) and 0.70 (95% CI: 0.59–0.75) respectively. Calibration of the model was satisfactory and the actual difference between the mean predicted and observed risk in different risk groups ranged from 0.7%–3.1% and 0.1%–4.2% in the derivation and validation samples respectively.

Conclusion: The recently developed cardiovascular disease risk assessment model for Omanis with type 2 diabetes achieved adequate overall validity. The model showed good discrimination and acceptable calibration; it therefore has the potential to be used in local clinical settings. However, further validation and comparison studies are needed to judge the generalizability and superiority of the model over other tools currently used in Oman.

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1. Introduction

Risk assessment tools in general are mathematical models or charts used to estimate the risk of a condition/outcome event for an individual. They are usually based on the predictive information available for various risk factors of a specified outcome. In these models, the standardised coefficient of each included risk factor indicates its relative contribution to the overall risk of a given health condition [1–3].

In the context of cardiovascular disease (CVD) prevention and management, such models are usually used to estimate an individual's CVD risk, which can then be used to assess the prognosis and support the choice of preventive and therapeutic strategies for individuals at risk. Once an individual's CVD risk is

predicted with some degree of certainty, management can be tailored accordingly, such as when to intensify a preventive intervention, when dietary advice needs to be specific, when advice on physical activity needs to be intensified and individualized and when specific drugs need to be prescribed to control CVD risk factors [4].

The use of CVD risk assessment models among type 2 diabetics using traditional CVD risk factors such as hypertension (HTN), dyslipidemia, high glycosylated hemoglobin (HbA1c), albuminuria, obesity, smoking status, and family history of CVD has been emphasized in several professional guidelines [5,6]. A few examples of such global tools include: the U.K Prospective Diabetes Study risk engine for diabetes patients; the Action in Diabetes and Vascular Disease: Preterax and Diamicron-MR Controlled Evaluation study model; the Australian Fremantle Diabetes Study model; the U.S Atherosclerosis Risk in Communities model; the World Health Organization/International Society of Hypertension charts and the Chinese Total Coronary Heart Disease Risk Score [7–12].

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As the above global models are not optimal for populations with different lifestyles and ethnicities [13], the first CVD risk assessment model in the Arab world was recently developed in the form of a mathematical equation using seven common traditional CVD risk factors for Omanis with type 2 diabetes mellitus (DM) [14]. The estimated 5-year CVD probability according to this model is expressed as $1 - 0.9991^{Exp \sum XiBi}$, where $Exp \sum XiBi = Exp (0.038 \text{ age [years]} + 0.052 \text{ DM duration [years]} + 0.102 \text{ HbA1c [\%]} + 0.201 \text{ total cholesterol [mmol/l]} + 0.912 \text{ albuminuria [coded 1 if present]} + 0.166 \text{ HTN [coded 1 if present]} + 0.005 \text{ BMI [kg/m}^2\text{]})$. In addition, the CVD outcome considered in this model includes coronary heart disease (CHD), stroke and peripheral arterial disease (PAD), enabling treating physicians to estimate overall CVD risk. However, this model has not yet been validated. In order to extend the use of this recently developed model as a feasible CVD risk assessment tool in clinical practice and to ascertain the suitability of the model, this study aimed to validate this CVD model developed for Omanis with type 2 DM.

2. Subjects, materials and methods

2.1. Study design and participants

The performance of the model was evaluated with two samples: the model derivation sample and another independent sample (validation sample). The derivation sample was selected from four primary care institutions in the Aldakhilyah Governorate (Province) of Oman, and was used to develop the model; while the validation sample was taken from other two primary care institutions in the same Province. A retrospective cohort study design was utilized for both the internal and external validation of the model. The derivation sample included 1314 Omani type 2 diabetic patients from three polyclinics (Nizwa, Bahla, and Izki Polyclinics) and one large health center (Manah Health Centre). The reference population and the health care settings from which the derivation and validation samples were taken have been described elsewhere [14]. The validation sample consisted of 405 patients chosen from one polyclinic (Samail Polyclinic) and one health centre (Burkat Almoz Health Center). The year 2009–2010 was considered to constitute the baseline for this study.

The same sampling methods, inclusion/exclusion criteria and variable/outcome definitions that were used for the derivation sample were also applied to the validation sample [14]. In brief, all Omanis with type 2 diabetes who were recorded in the diabetes registry of the selected institutions and were free of CVD at baseline were included in the study. The included patients were followed up until either their first CVD outcome occurred they patient died or until the end of the data collection period in December 2015. The exclusion criteria were defined as follows: patients with incomplete data related to key CVD factors and

outcomes at baseline and those who developed heart diseases or underwent limb amputations due to non-ischaemic causes during the follow-up period. In addition, patients with end-stage renal disease and liver cirrhosis were also excluded.

2.2. Data collection

In both samples, data on demographic characteristics, key risk factors at baseline and CVD outcomes were gathered by trained staff using a well-designed data collection sheet. The data were retrieved from the diabetes registers and patients' computerized files at the selected institutions. All definitions of variables in the present study were consistent with those used in the previous model derivation study

The CVD outcomes included fatal and non-fatal CHD, stroke and PAD events. These outcomes were recorded from baseline (2009–2010) until December 2015 (a maximum follow-up period of 7 years), by reviewing clinical diagnoses and physician's clinical notes documented at all patients' visits during this period. Descriptions of the CVD diagnostic criteria and risk factor definitions have been presented elsewhere [14]. In brief, CHD was diagnosed based on clinical presentation and confirmed by electrocardiography, a troponin test, a treadmill test and/or coronary angiography. A stroke event was confirmed by a computed tomography scan and PAD was confirmed by either a clinical diagnosis of gangrene, a limb amputation due to an ischaemic cause or intermittent claudication confirmed by angiography. In addition, causes of death were also determined from death certificates.

In terms of CVD risk factors, albuminuria was defined as an albumin/creatinine ratio of ≥ 2.5 for males and ≥ 3.5 for females confirmed at least twice within three months or longer, after excluding other possible causes. A HTN diagnosis was defined as multiple readings of systolic blood pressure of ≥ 140 mmHg or diastolic blood pressure of ≥ 90 mmHg, after excluding other causes of elevated blood pressure [15,16]. In addition, total serum cholesterol and HbA1c were measured using standardised laboratory equipment. All laboratory measurements and definitions were consistent with those used in the model derivation study [14].

2.3. Data analysis

Data analysis was performed using SPSS software, Version 22.0. Continuous variables were expressed in means and standard deviations (SDs), while categorical variables were presented in total counts and percentages. The general performance of the model in the derivation sample was assessed using the -2 log likelihood statistic and by comparing the overall mean predicted CVD risk to overall mean observed risk. The ability of the model to discriminate CVD risk in both samples was assessed by calculating

Table 1
Baseline predictors and cardiovascular outcome among the derivation and validation samples.

Characteristic	Derivation sample (n = 1314) % or mean \pm SD	Validation sample (n = 405) % or mean \pm SD	P value
Sex (female)	64.1%	64.0	.96
Age (years)	55.3 \pm 11.0	52.3 \pm 11.4	<.001
DM duration (years)	6.6 \pm 4.0	5.3 \pm 4.1	<.001
Total cholesterol (mmol/l)	4.9 \pm 1.1	5.2 \pm 1.2	<.001
HbA1c (%)	7.9 \pm 2.2	8.1 \pm 2.2	.03
BMI (kg/m ²)	29.1 \pm 5.3	28.3 \pm 5.0	.01
Albuminuria (present)	18.6%	22.2%	.10
HTN (present)	58.6%	50.9%	.01
CVD outcome (present)	9.6%	12.8%	.06

Abbreviations: SD, standard deviation; DM, diabetes mellitus; HbA1c, glycosylated haemoglobin; BMI, body mass index; HTN, hypertension; CVD, cardiovascular disease.

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