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Original Article

Cardiovascular risk prediction model for Omanis with type 2 diabetes

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ABSTRACT

Aim: To date, no cardiovascular risk assessment tool has been developed specifically for any Arabian population including Omanis. This study aims to develop a suitable cardiovascular risk prediction model in the form of a statistical equation, for Omanis with type 2 diabetes.

Materials and methods: A sample of 2039 patients with type 2 diabetes selected from primary care settings in the Aldakhiliyah Province of Oman were involved in a retrospective cohort study. All patients were free of cardiovascular disease at baseline (in 2009–2010) and were followed up until: 1) their first cardiovascular event occurred; 2) the patient died, or 3) the end of the data collection in December 2015.

Results: Among the total sample, 192 cardiovascular disease events were recorded within a mean follow-up period of 5.3-year. The 5-year probability of a cardiovascular event was given as $1 - 0.9991^{Exp \sum XiBi}$, where $Exp \sum XiBi$ (hazard ratio) = $Exp (0.038 \text{ age} + 0.052 \text{ DM duration} + 0.102 \text{ HbA1c} + 0.201 \text{ total cholesterol} + 0.912 \text{ albuminuria} [1 \text{ if present}] + 0.166 \text{ hypertension} [1 \text{ if present}] + 0.005 \text{ BMI})$.

Conclusion: The first cardiovascular risk prediction tool in the Arab world was developed in this study. It may be used to estimate the 5-year cardiovascular risk among Omanis with type 2 diabetes in order to plan patient management and preventive measures. However, further validation studies are required to determine the accuracy of the model.

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1. Introduction

Cardiovascular disease (CVD) in the form of coronary heart disease (CHD), stroke and peripheral arterial disease (PAD) represents the leading cause of morbidity and mortality among patients with type 2 diabetes mellitus (DM) [1]. Diabetics are thought to have a two-to-four-fold increase in the risk of developing CHD compared to non-diabetics [2]. In addition, it is estimated that 50% of diabetic patients die prematurely of a cardiovascular cause [1].

Various professional guidelines for the management of type 2 diabetes have advocated the use of CVD risk assessment tools to estimate CVD risk in type 2 diabetics using traditional CVD

predictors such as hypertension (HTN), dyslipidemia, high glycosylated hemoglobin (HbA1c), albuminuria, obesity, smoking, and family history of CVD [3,4]. CVD risk estimation is important to plan for the initiation of preventive and therapeutic measures including anti-lipid, anti-hypertensive and anti-platelet therapies, as well as appropriate health education [3,4]. Some examples of such tools which are usually presented as statistical equations or risk charts include: the Action in Diabetes and Vascular Disease: Preterax and Diamicon-MR Controlled Evaluation (ADVANCE) study model; the Australian Fremantle Diabetes Study model; the Chinese Total CHD Risk Score; the U.S. Atherosclerosis Risk in Communities (ARIC) model; the U.K. Prospective Diabetes Study (UKPDS) risk engine for diabetes patients, and the World Health Organization (WHO)/International Society of Hypertension (ISH) risk prediction charts [5–10].

In Oman, as in other Arabian countries, type 2 diabetes has become a great public health burden [11,12]. However, very limited literature is available related to CVD occurrence and its risk factors among type 2 diabetics in this region. In addition, most of the available data are descriptive in nature. As such, a previous study found that 54.1% of Omani patients presenting for coronary artery

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bypass surgery were diabetic [13], and local statistical reports have shown that more than 50% of amputations in Oman were due to DM [14]. In addition, a high prevalence of common CVD risk factors was observed among Omani diabetics [12].

With regards to CVD risk assessment tools, no CVD risk assessment model has yet been developed for any of the Arabian populations including Omanis. Despite the availability of the international risk assessment tools, they are not considered optimal for Omani and Arabian diabetics. This is mainly due to the differences in lifestyle patterns, socio-demographic characteristics and patterns of CVD risk factors in these populations, as addressed in a recent review [15]. To fill this gap, the present study aims to develop a risk assessment tool in the form of a statistical equation suitable for estimating the 5-year CVD risk among Omanis with type 2 diabetes.

2. Subjects, materials and methods

2.1. Study design and subjects

This retrospective cohort study was conducted between September 2015 and July 2016. Omanis with type 2 diabetes residing in the Aldakhiyah Governorate (Province) of Oman were considered to be the reference population. Diabetes care services in this region are delivered through the National Diabetes Control Programme via four polyclinics and 21 health centres. All patients are assessed for the main risk factors and complications of DM at the initial DM diagnosis and are then reassessed at least once a year. A diabetes diagnosis in these institutions is made according to WHO criteria. Standardised assessment forms and management procedures are implemented following the diabetes care manual [16,17]. In these institutions, patient DM diagnoses, associated health assessments and data recording are performed by diabetologists and trained general physicians, as well as trained nursing staff. All patient-related data are maintained in computerised files and in diabetes registers. Three polyclinics (Nizwa, Bahla and Izki Polyclinics) and one large health centre (Manah Health Centre) were selected as the study institutions. The year 2009–2010 was considered to constitute the baseline.

All Omanis with type 2 diabetes who were recorded in the diabetes registry of the four selected institutions; free of CVD at the baseline; and showed regular followed ups were included in the sampling frame. Exclusions included patients with no annual assessment on the key factors and CVD outcomes at the baseline, and those who developed non-ischemic heart diseases or who underwent limb amputations for non-ischemic causes during the follow-up period. Patients with end-stage kidney disease and liver cirrhosis were also excluded. After applying these inclusion/

exclusion criteria, a total of 2039 patients were eligible and were included in the study. These patients were then followed-up until their first CVD event occurred, they died or until the end of the data collection period in December 2015.

2.2. Data collection and definitions

A well-designed data collection sheet was used to collect all related data including demographic data, data related to CVD risk factors at baseline and the CVD outcome. These data were retrieved by trained staff from the diabetes registers and from patient computerised files in the selected institutions. The following baseline factors were considered in this study: gender, age, diabetes duration, body mass index (BMI), HbA1c, HTN, blood pressure (BP) control, total cholesterol level, low density lipoprotein (LDL) level, high density lipoprotein (HDL) level, triglycerides (TG) level, dyslipidemia, albuminuria, smoking status and first-degree family history of CVD.

A CVD outcome was diagnosed by specialized physicians based on the clinical presentation and confirmed using diagnostic tests. A CVD outcome was defined as the first fatal or non-fatal CHD, stroke or PAD event. CHD diagnosis was confirmed by electrocardiograms (ECG) and a serum troponin test. However, in some instances an ECG stress test (Treadmill test) and coronary angiography were required to confirm the diagnosis. In addition, a computed tomography (CT) scan was used to confirm a stroke event, while one of the following criteria was used to diagnose PAD: intermittent claudication confirmed by angiography; clinical diagnosis of gangrene; or limb amputation due to an ischemic cause. To ensure that the included participants were free from CVD at the beginning of the study, the same diagnostic criteria were applied at the baseline.

CVD Outcomes were tracked from baseline until December 2015 (i.e. a maximum follow-up period of 7 years) by reviewing the clinical notes and diagnosis for each patient and for all visits during the follow-up period. In addition, as the CVD outcomes included fatal events, death certificates were checked to confirm the causes of death. Table 1 presents the definitions of CVD outcomes and key risk factors.

2.3. Data analysis

Data were analysed using SPSS software, Version 22.0. Categorical variables were presented in total counts and percentages while continuous variables were expressed in means and standard deviations (SDs). Chi-squared tests and independent T-tests were used to assess differences between proportions and differences between means respectively, in relation to different

Table 1
Definitions of cardiovascular outcome and main risk factors.

Variable	Definition and cut-off points
CVD outcome	The first fatal or non-fatal CVD recorded events from the following list: - Confirmed physician diagnosis of CHD in form of: stable angina, unstable angina, or acute myocardial infarction. - Confirmed physician diagnosis of ischemic or haemorrhagic stroke. - Confirmed physician diagnosis of PAD (ischemic limb, gangrene or amputation).
HTN	Physician diagnosis of HTN (systolic blood pressure (SBP) \geq 140 mmHg or diastolic blood pressure (DBP) \geq 90 mmHg confirmed in BP chart readings after excluding other causes).
Uncontrolled blood pressure	SPB \geq 140 mmHg or DBP \geq 90 mmHg
Albuminuria (micro or macro)	Persistent albumin/creatinine ratio of \geq 2.5 in males and \geq 3.5 in females, confirmed at least twice within three months or more, after excluding other possible causes.
Dyslipidaemia	At least one of the following: Total cholesterol \geq 5.2 mmol/l; LDL \geq 2.6 mmol/l; HDL \leq 0.9 mmol/l for males and \leq 1.3 for females or TG \geq 1.7 mmol/l.

Abbreviations: CVD, cardiovascular disease; CHD, coronary heart disease; PAD, peripheral arterial disease; HTN, hypertension; SPB, systolic blood pressure; DBP, diastolic blood pressure; LDL, low density lipoprotein; HDL, high density lipoprotein; TG, triglycerides.

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