REVIEW ARTICLE

Oman Medical Journal [2015], Vol. 30, No. 5: 315–319

Applicability of the Existing CVD Risk Assessment Tools to Type II Diabetics in Oman: A Review

Abdulhakeem Al-Rawahi[1*] and Patricia Lee[2]

[1]Research Department, Oman Medical Specialty Board, Muscat, Oman
[2]School of Public Health, Griffith University, Queensland, Australia

ARTICLE INFO

Article history:
Received: 29 June 2015
Accepted: 16 August 2015

Online:
DOI 10.5001/omj.2015.65

Keywords:
Cardiovascular Diseases; Type 2 Diabetes Mellitus; Risk Assessments; Arabs; Oman.

ABSTRACT

Patients with type II diabetes (T2DM) have an elevated risk for cardiovascular disease (CVD), and it is considered to be a leading cause of morbidity and premature mortality in these patients. Many traditional risk factors such as age, male sex, hypertension, dyslipidemia, glycemic control, diabetes duration, renal dysfunction, obesity, and smoking have been studied and identified as independent factors for CVD. Quantifying the risk of CVD among diabetics using the common risk factors in order to plan the treatment and preventive measures is important in the management of these patients as recommended by many clinical guidelines. Therefore, several risk assessment tools have been developed in different parts of the world for this purpose. These include the tools that have been developed for general populations and considered T2DM as a risk factor, and the tools that have been developed for T2DM populations specifically. However, due to the differences in sociodemographic factors and lifestyle patterns, as well as the differences in the distribution of various CVD risk factors in different diabetic populations, the external applicability of these tools on different populations is questionable. This review aims to address the applicability of the existing CVD risk models to the Omani diabetic population.

Type II diabetics have an elevated risk for cardiovascular disease (CVD), estimated as being two-to-six-fold higher compared to the general population.[1] CVD is also considered as a leading cause of morbidity and premature mortality in patients with type II diabetes.[2]

Many traditional risk factors such as age, male sex, hypertension, dyslipidemia, glycemic control, diabetes duration, renal dysfunction, obesity, smoking, and physical inactivity have been extensively studied and identified to be independent factors for CVD.[1,3]

Recently, other non-traditional predictors such as erectile dysfunction, unhealthy diet, social deprivation and other inflammatory, hematological, and thrombogenic markers have been studied and showed a positive relationship with CVD among diabetics.[3,4] However, traditional risk factors have been found to explain between 75%–90% of CVD events.[5,6] Also, there is no sufficient evidence that routine monitoring of these factors leads to better diagnostic and therapeutic results in diabetic patients.[3,7]

CVD risk assessment tools

Risk assessment tools, in general, are mathematical models or charts used to estimate the risk of an outcome event in an individual. They use the predictive information available for the various risk factors of the specified condition using mathematical models. Usually, such models are used for diagnostic and prognostic purposes. Diagnostic models estimate the current risk of a disease or health event and prognostic models estimate the future risk of a particular disease or health event within a given period.[8,9] CVD risk assessment tools estimate the CVD risk in an individual based on the information available mainly for the various traditional CVD risk factors.

Various professional guidelines for the management of type II diabetes mellitus (T2DM) recommend the use of CVD risk assessment tools to quantify the risk among patients with diabetes. This would also guide the initiation of appropriate preventive and treatment strategies, including antihypertensive, antiplatelet, and antilipid drugs.[10,11] Many different risk assessment tools were developed in different parts of the world in the

*Corresponding author: ✉abdulhakeem.r@omsb.org

Box 1: Common tools established to estimate CVD risk in the general population.

- Framingham Heart Study (FHS) model.
- New Prospective Cardiovascular Munster (PROCAM-2007) Study model.
- World Health Organization /International Society of Hypertension (WHO/ISH) charts.
- Chinese Adult Cardiovascular Disease risk tool.
- The risk score based on the Scottish Heart Extended Cohort (also known as Assessing Cardiovascular Risk Using SIGN Guidelines (ASSIGN)).
- Framingham General (FG) CVD risk profile for use in primary care.
- Japanese cardiovascular risk model.
- The two last versions of the Cardiovascular Disease Risk Score based on the British QRESEARCH database (QRISK2 and the new QRISK).

past decades to assess the CVD risk among patients with T2DM. These include the tools developed for general populations and considered T2DM as a risk factor, and the tools developed specifically for T2DM populations.

Tools for general populations, with diabetes as a risk factor

In general populations, many risk assessment tools have been developed that vary in their methodologies. Listed in Box 1 are the most common tools established to estimate the CVD risk in general populations that consider T2DM as a risk factor and use CVD as a general outcome or, at least, include coronary heart disease (CHD) in the outcome (as it is the most common among all CVD events) and were derived from large cohorts with both sexes.[12,13]

The FHS model and the PROCAM model are recommended and incorporated by some of the professional guidelines to estimate the CVD risk in patients with diabetes. The FHS model is recommended by the European Society of Cardiology and European Association for Study of Diabetes Guidelines and the Australian National Vascular Disease guidelines. The PROCAM model is recommended by the Canadian Diabetes Association guidelines.[13]

Notably, most of these tools were derived from studies among American or European populations. The age range for most of the study cohorts was 30–74 years. However, these tools differ in many ways, and they are presented in various forms, including risk charts and electronic risk calculators.[14] The sample sizes ranged from 1,756 patients to more than two million patients. They also differ in the endpoint outcomes used, which include CHD, CVD, and myocardial infarction. Some outcomes also include fatal events. Furthermore, these tools differ in their methodologies including characteristics of the study sample, study setting, follow-up time frame, statistical analysis, and the included predictors.[12–17] Most tools were derived from original longitudinal studies except the WHO/ISH charts, which were derived using databases related to the prevalence of the common risk factors of CVD and CVD event rates in the corresponding WHO regions. Most of these prediction models predicted the five- or 10-year risk using an average of eight predictors through cox regression, logistic regression, or Weibull proportional hazards modeling. Age, sex, systolic blood pressure, smoking, cholesterol measurements, and T2DM status were the most commonly used predictors.[12–17] Some tools included non-traditional predictors, but the value of adding them was thought to be small.[16,18] In addition, recommendations from the US Preventive Services Task Force concluded that the current evidence was insufficient to assess the usefulness of including the non-traditional risk factors in the risk assessment.[19]

Tools specific for type II diabetic populations

Many specific T2DM tools have emerged in recent years due to the suggestion that diabetes-specific risk tools perform better than those developed for the general population.[16,20] The most common ones established to estimate CVD risk in the T2DM population that take CVD as a general outcome or include CHD in the outcome and were derived from large cohorts with both sexes are given in Box 2.[13,15,16] Generally, the UKPDS risk engine

Box 2: Common tools established to estimate CVD risk in the type II diabetic population.

- Action in Diabetes and Vascular Disease, the Preterax and Diamicron-MR Controlled Evaluation (ADVANCE) study model.
- New Zealand Diabetes Cohort Study (DCS) model.
- Australian Fremantle Diabetes Study (FDS) model.
- Swedish National Diabetes Register (SNDR) equation.
- Chinese Total CHD risk score.
- Scottish Diabetes Audit and Research in Tayside, Scotland (DARTS) database model.
- US Atherosclerosis Risk in Communities (ARIC) model.
- UK Prospective Diabetes Study (UKPDS) risk engine model.

is the most commonly recommended model by professional guidelines including the Canadian Diabetes Association, the Australian National Vascular Disease Prevention Alliance, the National Institute for Health and Clinical Excellence, and the International Diabetes Federation.[13]

Like the tools derived from the general population, most of the diabetes-specific tools were developed based on American and European populations and very few were based on Eastern Asian populations. These tools differ in the study sample sizes, which range from more than 1,000 to more than 35,000 patients. Most were derived using prevalent T2DM cases, and only the UKPDS tool was derived using newly diagnosed diabetic patients. The majority of the models predict five-year risk with an average of eight predictors. The most commonly used predictors in these models are age, sex, diabetes duration, glycated hemoglobin levels, lipid-related entities, microalbuminuria, and smoking. Again, some tools have tried to include non-traditional factors, but the value of adding them is thought to be small.[16,18] The studies also differed in their statistical analysis methods similarly to the tools developed for the general population.

CVD risk assessment in Oman

T2DM and its complications have imposed a considerable burden in Oman. Three consecutive epidemiological surveys have shown a gradual increase in the prevalence of T2DM from 10% to 12.3% over 17 years.[21-24] It is estimated that by 2050 there will be around 350,000 people with T2DM living in Oman.[25] Moreover, a hospital-based study showed that more than half of the Omani patients who presented for coronary artery bypass surgery had diabetes.[26] Additionally, related data showed a high prevalence of CVD traditional risk factors among Omanis.[24,27,28] Therefore, the growing trend of T2DM and CVD risk factors inevitably makes the problem of CVD challenging to the Oman healthcare system.

To date, no risk assessment tool derivative studies have been conducted in any Arab countries, including Oman. Therefore, the use of external risk assessment tools is encouraged in the clinical setting, at least for the time being, for the sake of disease management. The Department of Non-Communicable Disease Control (NCDC) has encouraged the use of the WHO/ISH EMRO-B charts designed for patients in the Eastern Mediterranean region (as Oman is part of this region) and these have been widely distributed in primary care institutions.[29,30] However, the use of these charts in diabetes care is thought to be rare. This lack of use can be explained partially by the lack of knowledge about the importance of such risk assessment tools and their clinical implications.[29]

In the Arab world, no studies were found related to testing the validity of the existing CVD risk tools on diabetic populations apart from one comparison study conducted in Oman. In this study, the FG-CVD risk model was observed to overestimate the CVD risk compared to the WHO/ISH risk charts when applied to a sample of Omani patients with T2DM.[31] For example, the FG-CVD tool identified a higher proportion of patients compared to the WHO/ISH tool at 10-year CVD risk especially in the intermediate risk group of patients. The FG-CVD tool identified almost double the number of men eligible for aspirin treatment at CVD risk thresholds of 10% compared to the WHO/ISH charts (86% vs. 43%, respectively). In women, the proportions were 66% and 45%, respectively. For statins, the figures were 60% and 37% for men and 28% and 36% for women, respectively. This means that if the FG-CVD risk tool were applied in the Oman health setting, the diabetes care costs would sharply increase.

Critical arguments on the application of the existing tools

The tools that were primarily derived from general populations are not specific for T2DM populations, which carry a higher risk. In addition, these tools have not included important risk factors like glycemic control, diabetes duration, and microalbuminuria.[16,32] Moreover, most of the two types of tools have been derived from western populations (European and US populations), and very few have been derived from East Asian populations. Only a few tools were validated externally on diabetic populations and these studies demonstrated poor performance of these tools when applied to diabetic patients.[33–35] Also, the external validation studies were conducted on European, Australian and other populations, which share similar ethnicities and lifestyles with the populations used to develop these tools.

The differences in sociodemographic factors, culture, lifestyle, and the distribution of various CVD risk factors and CVD occurrence in those

populations should be considered in the application of such tools in different populations. Despite the similarities between the populations for which existing models were derived, developing a model specific for each unique population is a common rationale mentioned in the studies that gave rise to the current models. In fact, due to the strong relationship between diabetes and its complications with the patient's geographical location and environmental and lifestyle characteristics, the existing risk models are not always applicable to different populations. Therefore, it is better for each particular population to have its own risk assessment tool.[14,15]

Additionally, the time since some of these tools were derived and the major differences in the clinical practices nowadays leads us to question the validity of applying these risk tools even in populations with similar ethnicities.[15]

The existing tools have not been validated in any Arab population including Omanis. However, as mentioned before, external validations in non-Arab patients with diabetes have shown a poor performance of these tools.[33–35] The single study conducted in Oman, comparing the FG-CVD risk tool to the WHO/ISH charts currently used, has shown significant discrepancies in the risk assessment results between the two tools when applied to a sample of Omani patients with T2DM. Although the study concluded that the FG-CVD tool overestimated the risk and the number of patients eligible for primary prevention of CVD compared to the joint WHO/ISH chart, it is difficult to judge which one is more relevant and closer to the real situation as both tools are not Omani-specific.[31]

Moreover, the WHO/ISH risk charts were not derived from original studies but derived using databases related to the prevalence of the CVD risk factors and CVD event rates for the Eastern Mediterranean region. Although this region includes Arab populations mostly, it also includes a non-Arab population (Iranians). Therefore, these charts are not that specific. Additionally, these charts have not included other important risk factors related to patients with diabetes, like glycosylated hemoglobin and diabetes duration.

Therefore, due to the above limitations, physicians may be faced with uncertainties in the CVD risk estimation using these external tools. This, in turn, may affect the clinical management of diabetic patients and the costs of the diabetes care.

CONCLUSION

The applicability and accuracy of the existing CVD risk tools for local populations is questionable since these tools are not considered the optimal ones to be applied in different populations. It seems that there is a need for a population-specific risk assessment tool for Omani patients with T2DM to monitor their CVD risk and inform future treatment and case management strategies.

Disclosure
The authors declared no conflicts of interest.

REFERENCES

1. Sharma MD, Farmer JA, Garber A. Type 2 diabetes and cardiovascular risk factors. Curr Med Res Opin 2011 Nov;27(S3)(Suppl 3):1-5.
2. van Dieren S, Beulens JW, van der Schouw YT, Grobbee DE, Neal B. The global burden of diabetes and its complications: an emerging pandemic. Eur J Cardiovasc Prev Rehabil 2010 May;17(1)(Suppl 1):S3-S8.
3. Martín-Timón I, Sevillano-Collantes C, Segura-Galindo A, Del Cañizo-Gómez FJ. Type 2 diabetes and cardiovascular disease: Have all risk factors the same strength? World J Diabetes 2014 Aug;5(4):444-470.
4. Smith-Palmer J, Bae JP, Boye KS, Perez-Nieves M, Valentine WJ. PCV30 - Traditional And Non-Traditional Risk Factors For Cardiovascular Disease In Type 2 Diabetes: Systematic Review Of Longitudinal Studies. Value Health 2014 Nov;17(7):A478.
5. McGill HC Jr, McMahan CA, Gidding SS. Preventing heart disease in the 21st century: implications of the Pathobiological Determinants of Atherosclerosis in Youth (PDAY) study. Circulation 2008 Mar;117(9):1216-1227.
6. Greenland P, Knoll MD, Stamler J, Neaton JD, Dyer AR, Garside DB, et al. Major risk factors as antecedents of fatal and nonfatal coronary heart disease events. JAMA 2003 Aug;290(7):891-897.
7. Kengne AP, Patel A, Marre M, Travert F, Lievre M, Zoungas S, et al; ADVANCE Collaborative Group. Contemporary model for cardiovascular risk prediction in people with type 2 diabetes. Eur J Cardiovasc Prev Rehabil 2011 Jun;18(3):393-398.
8. Moons KG, Kengne AP, Woodward M, Royston P, Vergouwe Y, Altman DG, et al. Risk prediction models: I. Development, internal validation, and assessing the incremental value of a new (bio)marker. Heart 2012 May;98(9):683-690.
9. Lloyd-Jones DM. Cardiovascular risk prediction: basic concepts, current status, and future directions. Circulation 2010 Apr;121(15):1768-1777.
10. Rydén L, Standl E, Bartnik M, Van den Berghe G, Betteridge J, de Boer M-J, et al; Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC); European Association for the Study of Diabetes (EASD). Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: executive summary. Eur Heart J 2007 Jan;28(1):88-136.
11. British Cardiac Society; British Hypertension Society; Diabetes UK; HEART UK; Primary Care Cardiovascular Society; Stroke Association. JBS 2: Joint British Societies' guidelines on prevention of cardiovascular disease in clinical practice. Heart 2005 Dec;91(Suppl 5):v1-v52.
12. Chia YC. Review of tools of cardiovascular disease risk stratification: interpretation, customisation and application in clinical practice. Singapore Med J 2011 Feb;52(2):116-123.

13. van Dieren S, Beulens JW, Kengne AP, Peelen LM, Rutten GE, Woodward M, et al. Prediction models for the risk of cardiovascular disease in patients with type 2 diabetes: a systematic review. Heart 2012 Mar;98(5):360-369.
14. Liau SY, Izham MI, Hassali MA, Shafie AA. A literature review of the cardiovascular risk-assessment tools: applicability among Asian population. Heart Asia 2010 Jan;2(1):15-18.
15. Lagani V, Koumakis L, Chiarugi F, Lakasing E, Tsamardinos I. A systematic review of predictive risk models for diabetes complications based on large scale clinical studies. J Diabetes Complications 2013 Jul-Aug;27(4):407-413.
16. Chamnan P, Simmons RK, Sharp SJ, Griffin SJ, Wareham NJ. Cardiovascular risk assessment scores for people with diabetes: a systematic review. Diabetologia 2009 Oct;52(10):2001-2014.
17. Siontis GCM, Tzoulaki I, Siontis KC, Ioannidis JPA. Comparisons of established risk prediction models for cardiovascular disease: systematic review. BMJ. 2012 May 24;344(may24 1):e3318–e3318.
18. Cooney MT, Dudina AL, Graham IM. Value and limitations of existing scores for the assessment of cardiovascular risk: a review for clinicians. J Am Coll Cardiol 2009 Sep;54(14):1209-1227.
19. U.S. Preventive Services Task Force. Using nontraditional risk factors in coronary heart disease risk assessment: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2009 Oct;151(7):474-482.
20. Echouffo-Tcheugui J-B, Kengne AP. Comparative performance of diabetes-specific and general population-based cardiovascular risk assessment models in people with diabetes mellitus. Diabetes Metab 2013 Oct;39(5):389-396.
21. Asfour MG, Lambourne A, Soliman A, Al-Behlani S, Al-Asfoor D, Bold A, et al. High prevalence of diabetes mellitus and impaired glucose tolerance in the Sultanate of Oman: results of the 1991 national survey. Diabet Med 1995 Dec;12(12):1122-1125.
22. Asfour MG, Samantray SK, Dua A, King H. Diabetes mellitus in the sultanate of Oman. Diabet Med 1991 Jan;8(1):76-80.
23. Al-Lawati JA, Al Riyami AM, Mohammed AJ, Jousilahti P. Increasing prevalence of diabetes mellitus in Oman. Diabet Med 2002 Nov;19(11):954-957.
24. Al Riyami A, Elaty MA, Morsi M, Al Kharusi H, Al Shukaily W, Jaju S. Oman world health survey: part 1 - methodology, sociodemographic profile and epidemiology of non-communicable diseases in oman. Oman Med J 2012 Sep;27(5):425-443.
25. Al-Lawati JA, Panduranga P, Al-Shaikh HA, Morsi M, Mohsin N, Khandekar RB, et al. Epidemiology of Diabetes Mellitus in Oman: Results from two decades of research. Sultan Qaboos Univ Med J 2015 May;15(2):e226-e233.
26. Pieris RR, Al-Sabti HA, Al-Abri QS, Rizvi SG. Prevalence Pattern of Risk Factors for Coronary Artery Disease among Patients Presenting for Coronary Artery Bypass Grafting in Oman. Oman Med J 2014 May;29(3):203-207.
27. Mabry RM, Winkler EA, Reeves MM, Eakin EG, Owen N. Correlates of Omani adults' physical inactivity and sitting time. Public Health Nutr 2013 Jan;16(1):65-72.
28. Directorate of Research & Studies, Ministry of Health. World Health Survey, Oman, 2008. [Internet]. Oman: Ministry of Health; 2008. Available from: www.moh.gov.om/ en/reports/WHSSurvey2008(1).pdf
29. Dr Ahmed AL-Busaidi- Director of the Department of Non-Communicable Disease Control-Ministry of Health. Oman. An interview on The Use of Cardiovascular Risk Assessment Tools in Diabetes Clinics in Oman. 2015.
30. Department of Non-communicable Diseases Surveillance and Control. Directorate General of Health Affairs-Ministry of Health. Operational and Management Guidelines for the National Non-Communicable Diseases Program [Internet]. First edition. Sultanate of Oman: Ministry of Health; 2010. Available from: http://www.moh.gov.om/en/reports/Guidelines_Manual_for_the_national_NCD_screening_program.pdf
31. Al-Lawati JA, Barakat MN, Al-Lawati NA, Al-Maskari MY, Elsayed MK, Mikhailidis DP, et al. Cardiovascular risk assessment in diabetes mellitus: comparison of the general Framingham risk profile versus the World Health Organization/International Society of Hypertension risk prediction charts in Arabs–clinical implications. Angiology 2013 Jul;64(5):336-342.
32. Coleman RL, Stevens RJ, Retnakaran R, Holman RR. Framingham, SCORE, and DECODE risk equations do not provide reliable cardiovascular risk estimates in type 2 diabetes. Diabetes Care 2007 May;30(5):1292-1293.
33. Davis WA, Colagiuri S, Davis TM. Comparison of the Framingham and United Kingdom Prospective Diabetes Study cardiovascular risk equations in Australian patients with type 2 diabetes from the Fremantle Diabetes Study. Med J Aust 2009 Feb;190(4):180-184.
34. Kengne AP, Patel A, Colagiuri S, Heller S, Hamet P, Marre M, et al; ADVANCE Collaborative Group. The Framingham and UK Prospective Diabetes Study (UKPDS) risk equations do not reliably estimate the probability of cardiovascular events in a large ethnically diverse sample of patients with diabetes: the Action in Diabetes and Vascular Disease: Preterax and Diamicron-MR Controlled Evaluation (ADVANCE) Study. Diabetologia 2010 May;53(5):821-831.
35. Simmons RK, Coleman RL, Price HC, Holman RR, Khaw K-T, Wareham NJ, et al. Perfor-mance of the UK Prospective Diabetes Study Risk Engine and the Framingham Risk Equations in Estimating Cardiovascular Disease in the EPIC- Norfolk Cohort. Diabetes Care 2009 Apr;32(4):708-713.