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RISK ASSESSMENT OF CARDIOVASCULAR MORTALITY IN MACEDONIAN TYPE 2 DIABETES PATIENTS BASED ON DECODE MODEL

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Abstract

Aim: To estimate the absolute risk (%) of 5- and 10-years cardiovascular mortality in Macedonian type 2 diabetes patients based on DECODE model, and the gender difference of the estimated risk.

Methods and materials: Observational, cross-sectional study including a cohort of 1,404 type 2 diabetes patients; inclusion criteria: aged 25 to 65 years, absence of confirmed arterial disease, history of ischaemic heart disease, cerebrovascular disease or peripheral arterial disease; and absence of life-threatening conditions, such as cancer; at the time of risk assessment. Absolute risk was assessed based on the following risk factors: gender, age, known diabetes, smoking status, systolic blood pressure and total cholesterol.

Results: From the study cohort, 884 were identified as eligible for analysis, 503 (56.9%) of these were women. The estimated absolute risk (%) of 5- and 10-year cardiovascular mortality, based on DECODE model, was 1.1 ± 1.3% and 5.5 ± 6.1%, respectively; significantly higher absolute risk was estimated in men (1.7 ± 1.6 vs 0.6 ± 0.8, $p < 0.001$ and 8.9 ± 7.6 vs 2.9 ± 2.5, $p < 0.001$, for 5- and 10-years absolute risk, respectively).

Discussion and conclusion: This study is a first assessment of cardiovascular mortality in the Macedonian type 2 diabetic population based on DECODE model. It would be of both clinical and scientific interest to assess the risk prediction accuracy of the model, and to compare it with other diabetes-specific and diabetes non-specific models.

Key words: DECODE, absolute risk, cardiovascular mortality, type 2 diabetes.

Introduction

The number of people with type 2 diabetes is increasing worldwide, and the total number is expected to rise to 552 million in 2030 [1]. The increased prevalence of type 2 diabetes is mainly due to longer life expectancy and the steep rise in obesity prevalence caused by a sedentary lifestyle. Based on the International Diabetes Federation (IDF) estimates, there were 136,700 people with diabetes mellitus in the Republic of Macedonia in 2012, and this number is projected to increase to 166,000 by 2030 [1].

Cardiovascular disease (CVD) is the main cause of mortality in people with type 2 diabetes: it is estimated that 75–80% of people with diabetes die of cardiovascular events, and the risk of coronary artery disease in this population is two to four times higher compared to the non-diabetic population [2, 3].

Absolute risk assessment of CVD based on several risk factors is necessary, such as: 1) CVD is of multifactorial origin; 2) risk factors occur concomitantly; 3) concomitant risk factors exhibit multiplicative effect on the CVD risk [4]. Hence, for the certain level of a single risk factor, absolute CVD risk can vary considerably depending on the level of other risk factors.

There are several risk assessment models based on the general population data, or diabetes non-specific models, such as the Framingham model, [4, 5–11] and risk assessment models specific for the diabetic population, the most widely used being the United Kingdom Prospective Diabetes Study (UKPDS) model [12–16].

Diabetes Epidemiology: Collaborative Analysis of Diagnostic Criteria in Europe (DECODE). The Study Group developed a model for risk assessment of fatal CVD incorporating glucose tolerance status and fasting plasma glucose [10]. The DECODE model was developed based on a large European DECODE cohort assessing cardiovas-

cular mortality over 5-year and 10-year follow-up periods. In addition to the classical cardiovascular risk factors, the DECODE model is unique as it includes, besides known diabetic status, glucose concentrations within the pre-diabetes range, such as Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) [10].

The DECODE cohort included 16,506 men and 8,907 women from 14 European studies. The DECODE risk assessment model was developed based on a major epidemiological DECODE study including the following risk factors: age, fasting and 2h glucose (including cases of known diabetes), fasting glucose alone (including cases of known diabetes), cholesterol, smoking status and systolic blood pressure [10]. Despite the magnitude of the diabetes problem, threatening to become the largest pandemic mankind has ever faced, and its close relation to cardiovascular morbidity and mortality, no study has so far been reported on the risk assessment of cardiovascular mortality in the Macedonian type 2 diabetes population using the DECODE model.

The aim of this study is to estimate the absolute risk (%) of 5- and 10-year cardiovascular mortality in Macedonian type 2 diabetes patients based on the DECODE model, and the gender difference of the estimated risk. Additionally, this study evaluates the cardiovascular risk factors and estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model across glycated haemoglobin (HbA1c) quartiles; and the cardiovascular risk factors across the quartiles of estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on DECODE model.

Materials and methods

This is an observational, cross-sectional study including a cohort of 1,404 type 2 diabetes patients from the Republic of Macedonia, who were prescribed insulin treatment and whose parameters were recorded at the time of insulin treatment prescription, in the period from September 2002 till January 2004.

All diagnostic and therapeutic procedures in the study patients were within the scope of routine clinical practice, hence the study is non-interventional (observational). Patients were prescribed insulin treatment due to inadequate glycaemic control after previous adjustments of their diet, physical activity and/or administered oral anti-diabetic treatment.

Criteria for inclusion of type 2 diabetes patients from the study cohort in the analysis include: age of 25 to 65 years, absence of confirmed arterial disease, history of ischaemic heart disease, cerebrovascular disease or peripheral arterial disease, and absence of life-threatening conditions, such as cancer, at the time of risk assessment. The above inclusion criteria were selected in this study to obtain results with the DECODE model, that will be comparable with the results of other risk assessment models, such as UKPDS, reported to demonstrate the most precise cardiovascular risk assessment within the above-mentioned criteria [12].

The risk score for cardiovascular mortality, over 5 and 10 years of follow-up, were calculated based on the risk score coefficients for gender, age range, known diabetes, smoking status, systolic blood pressure range and total cholesterol range, as described in the DECODE model [10].

The DECODE model for cardiovascular risk assessment includes glucose concentrations within pre-diabetes range, such as Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) [10], however such an extended glucose concentration range was of no significance for this study, as all patients of the study cohort had already been diagnosed with type 2 diabetes.

Absolute risk of cardiovascular mortality for an individual was calculated from the risk score, using the equation:

$$M \times [1 - S^{\exp(\text{risk score}/10)}],$$

where parameter M stands for Multiplying factors and S for Survival factors [10].

Multiplying factors were used as for an Eastern European country in the DECODE model (Men 2.87, Women 2.61), and Survival factors were used as for 5-year and 10-year follow-ups, namely 0.998873 and 0.997508, respectively [10].

Risk assessment of 5-year and 10-year cardiovascular mortality with the DECODE model was performed with the parameters valid at the time when patients were prescribed insulin treatment.

In order to investigate the effect of the level of glycaemic control, as reflected by the HbA1c value, cardiovascular risk factors and estimated absolute risk of 5- and 10-year cardiovascular mortality based on the DECODE model were presented across HbA1c quartiles. Additionally, cardiovascular risk factors were presented across quartiles of estimated absolute risk of 5- and 10-year cardiovascular mortality based on the DECODE model.

The Statistical Package for Social Sciences (SPSS) was used for statistical analysis, including descriptive statistics, Student t-test and Chi-square test. A p value of less than 0.05 was considered statistically significant.

Results

From the study cohort of 1,404 type 2 diabetes patients, 884 were identified as eligible for the analysis by fulfilling the inclusion criteria.

Cardiovascular risk factors and estimated absolute risk (%) of 5- and 10-year cardiovascular mortality in men and women based on the DECODE model are presented in Table 1.

Table 1

Cardiovascular risk factors and estimated absolute risk (%) of 5- and 10-years cardiovascular mortality in men and women based on DECODE model

	Total	Men	Women	*p*-value
Number (%)	884 (100)	381 (43.1)	503 (56.9)	
Age (years) *	48.6 ± 7.2	47.9 ± 7.4	49.2 ± 7.0	< 0.01
HbA1c (%) *	9.5 ± 2.1	9.4 ± 2.0	9.6 ± 2.1	NS
Systolic Blood Pressure (mmHg) *	143.7 ± 20.7	138.6 ± 18.6	147.6 ± 21.4	< 0.001
Total Cholesterol (mmol/l) *	6.1 ± 1.3	6.0 ± 1.3	6.1 ± 1.3	NS
Smokers (%)	323 (36.5)	206 (54.1)	117 (23.3)	< 0.001
DECODE 5-years risk (%) *	1.1 ± 1.3	1.7 ± 1.6	0.6 ± 0.8	< 0.001
DECODE 10-years risk (%) *	5.5 ± 6.1	8.9 ± 7.6	2.9 ± 2.5	< 0.001

* Mean ± standard deviation; NS = non-significant

Out of 884 study patients, 503 (56.9%) were women. The estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model was 1.1 ± 1.3% and 5.5 ± 6.1%, respectively. Age and systolic blood pressure were significantly higher in women (49.2 ± 7.0 vs 47.9 ± 7.4, $p < 0.01$, and 147.6 ± 21.4 vs 138.6 ± 18.6, $p < 0.001$, respectively), the number of smokers was significantly higher in men (206 (54.1%) vs 117 (23.3%), $p < 0.001$), while there was no difference in total cholesterol (6.0 ± 1.3 vs 6.1 ± 1.3, p = NS) and HbA1c value (9.4 ± 2.0 vs 9.6 ± 2.1, p = NS). There was a statistically significant difference in the estimated absolute risk (%) of both 5- and 10-year cardiovascular mortality based on the DECODE model between the genders; in both follow-up periods, a higher absolute risk was estimated in men (1.7 ± 1.6 vs 0.6 ± 0.8, $p < 0.001$ and 8.9 ± 7.6 vs 2.9 ± 2.5, $p < 0.001$, for 5- and 10-year absolute risk, respectively).

Cardiovascular risk factors and estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model across HbA1c quartiles are presented in Table 2.

Table 2

Cardiovascular risk factors and estimated absolute risk (%) of 5- and 10-years cardiovascular mortality based on DECODE model across HbA1c quartiles

	HbA1c			
	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile
Number (Men/Women) (% of total)	223 (97/126) (25.2)	210 (102/108) (23.8)	233 (103/130) (26.4)	218 (79/139) (24.6)
Age (years) *	49.4 ± 6.9	48.5 ± 6.9	48.6 ± 7.1	47.9 ± 7.9
HbA1c (%) *	7.1 ± 0.9	8.7 ± 0.4	9.9 ± 0.4	12.2 ± 1.4
Systolic Blood Pressure (mmHg) *	146.4 ± 20.9	143.4 ± 18.5	143.5 ± 19.6	141.4 ± 23.3
Total Cholesterol (mmol/l) *	6.0 ± 1.4	6.2 ± 1.3	6.1 ± 1.3	5.9 ± 1.1
Smokers (% of total)	84 (26.0)	89 (27.6)	84 (26.0)	66 (20.4)
DECODE 5-years risk (%) *	1.2 ± 1.3	1.3 ± 1.6	1.1 ± 1.3	0.9 ± 1.1
DECODE 10-years risk (%) *	6.0 ± 6.2	6.4 ± 7.5	5.4 ± 5.7	4.3 ± 4.7

* Mean ± standard deviation

The highest (4th) quartile of HbA1c (12.2 ± 1.4%) was associated with the lowest age (47.9 ± 7.9 years), lowest systolic blood pressure (141.4 ± 23.3 mmHg), lowest value of total cholesterol (5.9 ± 1.1 mmol/l), and lowest number of smokers (n = 66, 20.4% of total number of smokers). The estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model was lowest in the 4th quartile of HbA1c (0.9 ± 1.1 and 4.3 ± 4.7, for 5- and 10-year absolute risk, respectively).

Cardiovascular risk factors across quartiles of estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model are presented in Table 3.

Table 3

Cardiovascular risk factors across quartiles of estimated absolute risk (%) of 5- and 10-years cardiovascular mortality based on DECODE model

	DECODE 5-years cardiovascular mortality				DECODE 10-years cardiovascular mortality			
	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile	1st Quartile	2nd Quartile	3rd Quartile	4th Quartile
Number (Men/Women) (% of total)	222 (0/222) (25.1)	207 (99/108) (23.4)	232 (125/107) (26.2)	223 (157/66) (25.2)	223 (0/223) (25.2)	234 (78/156) (26.5)	200 (123/77) (22.6)	227 (180/47) (25.7)
Age (years) *	43.3 ± 4.6	47.4 ± 6.9	49.1 ± 6.8	54.4 ± 5.5	44.3 ± 5.5	48.3 ± 6.7	48.1 ± 7.8	53.6 ± 5.6
HbA1c (%) *	9.8 ± 2.1	9.6 ± 2.0	9.4 ± 2.2	9.2 ± 1.8	9.8 ± 2.1	9.5 ± 2.0	9.4 ± 2.2	9.2 ± 1.8
Systolic Blood Pressure (mmHg) *	141.6 ± 19.6	135.5 ± 19.3	146.7 ± 20.9	150.3 ± 20.1	139.5 ± 20.8	143.6 ± 19.8	141.2 ± 21.1	150.1 ± 19.7
Total Cholesterol (mmol/l) *	6.1 ± 1.3	5.8 ± 1.2	6.0 ± 1.1	6.3 ± 1.5	5.9 ± 1.0	6.0 ± 1.3	6.2 ± 1.4	6.2 ± 1.4
Smokers (% of total)	32 (9.9)	38 (11.8)	110 (34.1)	143 (44.3)	16 (5.0)	39 (12.1)	116 (35.9)	152 (47.1)
DECODE 5-years risk (%) *	0.1 ± 0.04	0.5 ± 0.1	1.0 ± 0.2	2.8 ± 1.6	0.1 ± 0.08	0.5 ± 0.2	1.0 ± 0.3	2.8 ± 1.6
DECODE 10-years risk (%) *	1.2 ± 0.5	2.5 ± 0.8	4.7 ± 1.2	13.3 ± 7.6	1.2 ± 0.4	2.6 ± 0.6	4.8 ± 0.8	13.4 ± 7.5

* Mean ± standard deviation

The highest (4th) quartiles of both DECODE 5- and 10-year cardiovascular mortality risk estimation were associated with the highest age (54.4 ± 5.5 and 53.6 ± 5.6 years, respectively), highest systolic blood pressure (150.3 ± 20.1 and 150.1 ± 19.7 mmHg, respectively), highest total cholesterol (6.3 ± 1.5 and 6.2 ± 1.4 mmol/l, respectively), highest number of smokers (n = 143, 44.3% of total, and n = 152, 47.1% of total, respectively) and lowest HbA1c value (9.2 ± 1.8 and 9.2 ± 1.8%, respectively). The estimated absolute risk of 5-year cardiovascular mortality was highest in the 4th quartile of DECODE 10-years cardiovascular mortality risk estimation (2.8 ± 1.6%), and estimated absolute risk of 10-year cardiovascular mortality was highest in the 4th quartile of the DECODE 5-year cardiovascular mortality risk estimation (13.3 ± 7.6%). There were no men (n = 0) in the first quartiles of both DECODE 5- and 10-year cardiovascular mortality risk estimation.

Discussion and conclusion

One of the key points of the most recent Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) on the management of hyperglycaemia in type 2 diabetes, was that comprehensive cardiovascular risk reduction must be a major focus of therapy [17]. In addition, the joint European Society of Cardiology (ESC) Guidelines strongly recommend the use of risk assessment models confirming the advantages of their use, such as: intuitiveness, models taking into account the multifactorial nature of cardiovascular disease, allowing flexibility in management – if an ideal risk factor level cannot be achieved then the total risk can still be reduced by reducing other risk factors, a more objective assessment of the risk over time, and a common language of risk for clinicians [18].

The EASD recommends using Framingham and DECODE as the preferred prediction models for calculating CVD risk in type 2 diabetes patients [10, 19, 20]. This study is a first assessment of cardiovascular mortality in the type 2 diabetic population in Macedonia based on the DECODE model, and is a first step towards external validation of the DECODE model, taking into consideration that the original DECODE study did not include any Macedonian population. Studies of cardiovascular risk assessment in the type 2 diabetes Macedonian population with other diabetes-specific and diabetes non-specific models have already been reported [21, 22].

The estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model was 1.1 ± 1.3% and 5.5 ± 6.1%, respectively, in both follow-up periods being significantly higher in men than in women (5-years: 1.7 ± 1.6% vs 0.6 ± 0.8%, $p < 0.001$; 10-years: 8.9 ± 7.6% vs 2.9 ± 2.5%, $p < 0.001$), despite significantly higher age and systolic blood pressure in women, and no difference in HbA1c value and total cholesterol. The number of smokers was significantly higher in men than in women, and jointly with gender, appears as the strongest predictor of the cardiovascular mortality in our study. Correlation of male gender with cardiovascular mortality was additionally confirmed by the absence of men (n = 0) in the lowest (1st) quartiles of

both DECODE 5- and 10-year cardiovascular mortality risk estimation, and the fact that 5-year and 10-year cardiovascular mortality risk calculated with the DECODE model were 2.8 times and 3.1 times, respectively, higher in men than in women. However, while women appear to be at lower CVD risk than men, this could be misleading as the risk is only deferred for a certain time period rather than avoided [18].

In comparison, the 5-year CVD mortality of the total DECODE study population was 1.8% in male and 0.6% in female patients; and 10-year CVD mortality was 3.8% and 1.8% in male and female patients, respectively [10]. The lower CVD mortality rate after 10 years follow-up in the DECODE study population compared to the fatal CVD absolute risk assessment in our study could be attributed to the fact that the DECODE population consisted of not only diabetic but also pre-diabetic population where the CVD risk is lower compared to the diabetic population, whereas in our study all patients analysed were diagnosed with type 2 diabetes.

A limitation of the DECODE equation is that it incorporates diabetes, IFG and IGT, based on fasting plasma glucose and/or 2-hour postprandial glycaemia in a categorical fashion, and thus does not adequately consider the effect of different levels of glycaemia [23]. Such a finding has also been confirmed in our study: the estimated absolute risk (%) of 5- and 10-year cardiovascular mortality based on the DECODE model was lowest in the highest (4^{th}) quartile of HbA1c (0.9 ± 1.1% and 4.3 ± 4.7%, respectively for 5- and 10-year absolute risk) (Table 2), and inversely, the highest (4^{th}) quartiles of both DECODE 5- and 10-year cardiovascular mortality risk estimation were associated with the lowest HbA1c value (9.2 ± 1.8% and 9.2 ± 1.8%, respectively) (Table 3). This is in contrast with the risk assessment of diabetes-specific models, e.g. UKPDS, that incorporate glycaemic control as a continuous variable (HbA1c value), and other diabetes-specific parameters such as age at diagnosis of diabetes and duration of diabetes, where the predicted risk is closely related to the HbA1c level [12].

It should be noted that although EASD refers to the DECODE prediction model, it has been validated only once, with moderate performance; and no Macedonian population was included in the validation [23]. Since this study provides information on the cardiovascular risk assessment with the DECODE model in the Macedonian diabetic population, it would be of both clinical and scientific interest to assess its prediction accuracy, or prognostic value, and to compare it with other diabetes-specific and diabetes non-specific models.

The clinical benefit of the cardiovascular risk assessment models is achieved through their ability to inform on the potential for risk reduction, and to convey the expected benefit of treatment to patients. In this context, models such as DECODE can be used as preventive and motivating tools for behavioural changes, especially in patients with type 2 diabetes.

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Резиме

ПРОЦЕНА НА РИЗИК ЗА КАРДИОВАСКУЛАРЕН МОРТАЛИТЕТ КАЈ МАКЕДОНСКИ ПАЦИЕНТИ СО ДИЈАБЕТЕС ТИП 2 ВРЗ ОСНОВА НА МОДЕЛОТ DECODE

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Цел: Да се процени апсолутниот ризик (%) за 5 и 10-годишниот кардиоваскуларен морталитет кај македонски пациенти со дијабетес тип 2 врз основа на DECODE моделот, како и да се одреди разликата во проценетиот ризик помеѓу половите.

Методи и материјали: Опсервациска, кроссекциска студија на кохорта од 1.404 пациенти со дијабетес тип 2; инклузиони критериуми: возраст од 25 до 65 години, отсуство на потврдено артериско заболување, историја на исхемично срцево заболување, цереброваскуларно заболување или периферно артериско заболување; како и отсуство на животно-загрозувачката состојба, како канцер; во моментот на процена на ризикот. Апсолутниот ризик беше проценет врз основа на следниве ризик фактори: пол, возраст, познат дијабетес, пушење, систолен крвен притисок и вкупен холестерол.

Резултати: Од студиската кохорта, 884 беа идентификувани за анализа, 503 (56,9%) од нив беа жени. Проценетиот апсолутен ризик (%) за 5 и 10-годишниот кардиоваскуларен морталитет базиран на DECODE моделот беше 1,1 ± 1,3% и 5,5 ± 6,1%, соодветно; сигнификантно повисок апсолутен ризик беше проценет кај мажите (1,7 ± 1,6 vs 0,6 ± 0,8, $p <$ 0,001 и 8,9 ± 7,6 vs 2,9 ± 2,5, $p <$ 0,001, за 5 и 10-годишниот апсолутен ризик, соодветно).

Дискусија и заклучок: Оваа студија е прва процена на кардиоваскуларниот морталитет кај македонска тип 2 дијабетична популација врз основа на DECODE моделот. И од клинички и од научен интерес е важно да се процени прецизноста на моделот во проценувањето на ризикот и да се спореди со другите дијабетес-специфични и дијабетес-неспецифични модели.

Клучни зборови: DECODE, апсолутен ризик, кардиоваскуларен морталитет, дијабетес тип 2.