

Assessment of cardiovascular complication risk using the Score2-Diabetes scale in patients with type 2 diabetes mellitus in comorbidity with other somatic diseases

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Aim—to assess the 10-year risk of cardiovascular complications using the Score2-Diabetes scale in patients with type 2 diabetes mellitus (T2DM) in comorbidity with other somatic diseases.

Materials and methods. This crosssectional (clinical) study included 224 patients aged 40–65 years with T2DM according to WHO criteria (1999–2013). Inclusion criteria: presence of risk factors for chronic noncommunicable diseases and somatic diseases. Exclusion criteria: cardiovascular diseases, pulmonary, renal or hepatic insufficiency, and oncological diseases. Patients underwent medical examination, questionnaire survey, instrumental and biochemical tests. Cardiovascular risk was assessed using the SCORE2-Diabetes scale based on the following parameters: age, sex, smoking, systolic blood pressure (SBP), total cholesterol, highdensity lipoprotein cholesterol, age at T2DM diagnosis, glycated haemoglobin level, and glomerular filtration rate. Patients were divided into two groups: the first group included individuals with 1–2 additional somatic diseases, and the second group included those with three or more somatic diseases.

Results. The mean cardiovascular risk (CVR) according to the SCORE2-Diabetes scale in the first group was $23.16 \pm 8.62\%$, and in the second group— $29.94 \pm 13.31\%$ ($p < 0.001$). Gender analysis of CVR showed that in the first group, CVR was comparable between men and women ($23.1 \pm 9.29\%$ and $23.44 \pm 8.14\%$, respectively). In the second group, CVR among women was $31.43 \pm 12.52\%$, among men— $27.72 \pm 14.28\%$. Analysis of CVR categories showed that in the first group, about 60% of patients had very high CVR. High CVR was found in every third patient in this group. In the second group, $\frac{3}{4}$ of patients had very high CVR, and every fifth patient had high CVR. Moderate CVR was observed in up to 4% of cases in both groups; low risk was not detected. Correlation analysis revealed a sig-

nificant positive association between the triglycerideglucose (TyG) index and CVR ($Sp=0.21$, $p=0.023$ for the first group and $Sp=0.2541772$, $p=0.007$ for the second group). A similar positive correlation was found for highsensitivity C-reactive protein (hsCRP) levels ($Sp=0.50$, $p<0.001$ for the first group and $Sp=0.43$, $p<0.001$ for the second group).

Conclusion. Comorbidity of T2DM with a larger number of somatic diseases is associated with more pronounced glycaemic impairment, lipid metabolism disorders, and higher blood pressure levels, which is reflected in the overall risk of cardiovascular complications. High CVR correlates with the TyG index. Thus, the Score2-Diabetes scale can be recommended for clinical practice when developing personalized prevention programmes for cardiovascular events, taking into account the presence of additional somatic diseases.

Keywords: type 2 diabetes mellitus, cardiovascular complication risk, SCORE2-Diabetes scale, risk factors.

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Introduction

Cardiovascular diseases (CVD) hold a leading position in the development of complications and mortality in the EuroAsian region. Type 2 diabetes mellitus (T2DM), given the increasing prevalence and younger age at onset, contributes significantly to the structure of cardiovascular morbidity. In highincome countries, patients with T2DM have on average a twofold higher risk of cardiovascular events (CVE) compared with individuals without diabetes of the same age and sex [1].

At the end of the 20th century, the prevailing view was that T2DM is a CVD equivalent; consequently, patients with diabetes were managed using secondary

prevention strategies. However, this approach has been challenged because not all patients with T2DM have the same CVD risk. Therefore, other potentially important factors, such as disease duration, presence of albuminuria, and comorbidities, should be considered. In recent years, the use of available noninvasive methods, including cardiovascular risk (CVR) assessment scales, has been recommended for developing primary prevention strategies [2].

Previous attempts have been made to create CVR scales for patients with T2DM [3]. The available diabetes-specific models have several limitations, particularly due to population differences and characteristics. These scales are typically based on a small

set of observational and prospective studies and have not undergone systematic statistical adaptation that accounts for variations in CVD incidence across different populations and countries [4, 5]. For example, the PRECISED system was developed using seven variables associated with an increased risk of coronary heart disease (total score from 0 to 9). This scale has been shown to predict not only the presence of coronary heart disease but also the risk of major adverse cardiovascular events in asymptomatic patients with T2DM [6]. However, this scale was based on data from a limited number of patients ($n = 933$).

The capabilities of the European SCORE2 scale, adapted for T2DM, are actively discussed in the literature. It is known that SCORE2 allows the prediction of fatal and nonfatal cardiovascular events (myocardial infarction, stroke) over 10 years and is calculated based on CVD risk factors: age, smoking status, systolic blood pressure (SBP), and nonhigh-density lipoprotein cholesterol [total cholesterol minus HDL cholesterol] [7].

European experts, by extending the recalibrated European 10-year risk models SCORE2 [8], developed an adapted scale for individuals with T2DM. The study included 229,460 patients with T2DM without prior CVD, of whom 43,706 CVD events were recorded during follow-up. The analysis took into account common risk factors, including age, smoking, blood pressure (BP), total cholesterol (TC), HDL cholesterol, and diabetes-related factors (disease duration, glycated haemoglobin level, and glomerular filtration rate [GFR]). The performance of Score2-Diabetes was validated using four cohorts from different European regions (low, moderate, high, and very high CVD risk) [9,12].

It is well known that in real-world clinical practice, patients with T2DM at the time of diagnosis often have a number of additional somatic diseases that may have a pathogenetic or causal relationship. Comorbidity of somatic diseases can worsen the course of the underlying disease and also affect the quality and duration of life in patients with T2DM [8, 13].

Aim—to assess the risk of cardiovascular complications (CVC) using the SCORE2-Diabetes scale in patients with T2DM comorbid with other somatic diseases over the next 10 years.

Material and methods

A cross-sectional clinical study included 224 patients aged 40–65 years with T2DM (WHO criteria,

1999/2013). Inclusion criteria: T2DM with risk factors for chronic noncommunicable diseases and additional somatic diseases. Exclusion criteria: age under 40 or over 65 years, decompensated T2DM, type 1 diabetes, verified atherosclerotic CVD, congenital and acquired heart defects, active infectious disease, pulmonary, renal and hepatic failure with impaired renal function at estimated GFR (eGFR) $<25 \text{ mL/min/1.73 m}^2$ and severe hepatic insufficiency (Child-Pugh class C), oncological diseases, pregnancy, mental disorders, and antidepressant use.

All patients underwent a standard medical examination and questionnaire survey, including information on sociodemographic indicators, behavioral risk factors, past illnesses, presence of chronic diseases, and family history. When collecting this information, data from medical records (discharge summaries and results of clinical, instrumental, and laboratory examinations) were taken into account.

Instrumental examinations included measurement and calculation of anthropometric parameters, BP measurement, heart rate, and resting electrocardiography (ECG).

BP was measured using the standard auscultatory method. The examination was performed with a noninvasive sphygmomanometer on the right arm in a sitting position after 5 minutes of rest in a calm environment. BP readings were recorded twice with a 23 minute interval, and the mean value was calculated from the two measurements. Heart rate was counted over one minute.

Hypertension was diagnosed according to the criteria of the Russian Society of Cardiology (2024).

Standard resting 12-lead ECG was recorded using a Schiller AT10 plus electrocardiograph. Rhythm and conduction disturbances, ectopic activity, and left ventricular hypertrophy according to Sokolow-Lyon criteria were assessed.

Echocardiography was performed via the transthoracic approach in M and B-modes. The following parameters were assessed: left atrial size, interventricular septum and left ventricular posterior wall thickness in diastole, end-diastolic dimension, end-systolic dimension, and left ventricular end-diastolic and end-systolic volumes, ejection fraction, and left ventricular myocardial mass were calculated.

Laboratory tests. Blood sampling from the cubital vein was performed on admission and in the morning on an empty stomach after a 12-hour fast. The follow-

ing biochemical parameters were analyzed: fasting glucose, glycated haemoglobin (HbA1c), lipid profile parameters including total cholesterol (TC), low-density lipoprotein cholesterol (LDLC), triglycerides (TG), HDLC, and creatinine.

The triglycerideglucose (TyG) index was calculated using the formula: $\ln [TG \text{ (mg/dL)} \times \text{fasting glucose (mg/dL)} / 2]$. Conversion: $TG \text{ in mmol/L} \times 88.5 = \text{mg/dL}$; $\text{venous plasma glucose in mmol/L} \times 18 = \text{mg/dL}$.

eGFR (ml/min/1.73 m^2) was calculated using the CKDEPI formula, and creatinine clearance (ml/min) was calculated using the CockcroftGault formula.

CVD risk was assessed using the European SCORE2-Diabetes scale based on the following parameters: age, sex, smoking, SBP, total cholesterol, HDLC, age at T2DM diagnosis, HbA1c, and eGFR. Risk was determined considering geographic regions with low, moderate, high, and very high risk. Russia, like most former USSR countries, belongs to the very highrisk region. The risk of cardiovascular complications was categorized into four grades: $<2\%$ —low risk, $2\text{--}<10\%$ —moderate risk, $10\text{--}<20\%$ —high risk, and $\geq 20\%$ —very high risk.

Ethical approval. The study protocol, medical documentation forms, and patient informed consent were approved by the independent ethics committee.

Statistical analysis

Statistical analysis was performed using the open-source R 4.2.3 environment. Qualitative variables were described as absolute frequencies and percentages; quantitative variables as mean and standard deviation ($M \pm SD$). When comparing two independent groups, Fisher's exact test was used for discrete variables and Welch's ttest for continuous variables. Correlations were calculated using Spearman's rank correlation coefficient. Differences were considered statistically significant at $p < 0.05$.

Results

According to the study protocol, patients with T2DM were divided into two groups depending on the number of additional somatic diseases. The first group included 114 patients with T2DM combined with 12 somatic diseases, while the second group comprised 110 patients with T2DM and three or more somatic diseases.

Table 1 presents demographic indicators, behavioral and biological risk factors, glycaemic status, and renal filtration parameters used to calculate CVR.

The groups were comparable in terms of age and sex distribution.

Table 1. Parameters for calculating the risk of cardiovascular complications using the SCORE2-Diabetes scale

Parameter	(Group 1) T2DM with 12 somatic diseases	(Group 2) T2DM with 3 or more somatic diseases
Age, years	53.02 ± 6.54	54.91 ± 9.17
Sex: male/female	53/61	44/66
Current smoker	20 (17.5%)	24 (22.4%)
SBP, mm Hg	135.4 ± 11.34	139.41 ± 12.68
Total cholesterol, mmol/L	5.19 ± 1.13	5.45 ± 0.89
HDLC, mmol/L	1.06 ± 0.15	1.03 ± 0.1
Age at T2DM diagnosis, years	47.58 ± 6.25	48.08 ± 8.18
HbA1c, %	8.22 ± 1.22	8.61 ± 1.59
eGFR, ml/min/1.73 m^2	81.89 ± 17.67	78.35 ± 16.69

One in five patients, predominantly men, were current smokers, with no difference in smoking frequency between groups. A significant difference was noted in mean age at T2DM diagnosis ($p < 0.005$). HbA1c levels in the second group were significantly higher than in the first ($p < 0.037$). Several risk factors also differed between groups, including SBP ($p < 0.01$) and total cholesterol ($p < 0.05$). For HDLC and eGFR, differences did not reach statistical significance.

The assessment of CVC risk using the European Score2-Diabetes scale showed that the mean risk value in the group with T2DM and 12 somatic diseases was $23.16 \pm 8.62\%$, while in the group with T2DM and three or more somatic diseases the risk was 1.3 times higher at $29.94 \pm 13.31\%$ ($p < 0.001$). Gender analysis of CVR showed that in the first group, CVR was comparable between men and women (23.1 ± 9.29 and $23.44 \pm 8.14\%$, respectively). In the second group, CVR among women was $31.43 \pm 12.52\%$, and among men— $27.72 \pm 14.28\%$.

Analysis of CVR categories shows that in the first group about 60% of patients have very high CVR. In this group, high CVR was found in onethird of patients (Table 2). In the second group, threequarters of patients had very high CVR, and one in five had high CVR. The frequency of very high CVR in the second group was significantly higher than in the first ($p = 0.015$). The opposite pattern was observed for high CVR—it was significantly more frequent in the first

Table 2. CVR categories in two groups of patients with T2DM combined with other somatic diseases

Indicator	Group 1	Group 2	Significance, p
Moderate risk			
Total in group	4 [3.5 %]	4 [3.6 %]	1.000
Men	1 [1.9 %]	1 [2.3 %]	1.000
Women	3 [4.9 %]	3 [4.5 %]	1.000
High risk			
Total in group	42 [36.8 %]	23 [20.9 %]	0.012
Men	22 [41.5 %]	14 [31.8 %]	0.400
Women	20 [32.8 %]	9 [13.6 %]	0.012
Very high risk			
Total in group	68 [59.6 %]	83 [75.5 %]	0.015
Men	30 [56.6 %]	29 [65.9 %]	0.407
Woman	38 [62.3 %]	54 [81.8 %]	0.017

group compared to the second ($p = 0.012$). Moderate risk was found in up to 4% of cases in both groups, while low risk was absent.

Gender analysis of the frequency of different risk grades in the first group showed no significant differences between men and women. In the second group, the frequency of high CVR among men was twice as high as among women: 31.8% and 13.6%, respectively. The frequency of very high CVR among women was 25% higher than among men: 81.8% and 65.9%, respectively.

We also analyzed gender differences in the frequency of different CVR grades between groups. In the first group, high CVR among women was 2.5 times higher than among women in the second group ($p < 0.012$), while the proportion of women with very high CVR in the second group was 1.3 times higher than in the first ($p < 0.017$).

We analyzed the severity of parameters used to calculate CVC risk using the Score2-Diabetes scale in groups of T2DM patients combined with somatic diseases who had high and very high CVR.

At the same CVR grade, namely high CVR in the first group, the age of patients in the first group was higher than in the second group (Table 3). In the second group, the number of smokers was greater than in the first. A similar trend was observed for SBP and HDLC levels. Meanwhile, HbA1c, total cholesterol, and eGFR were comparable in both groups. The mean CVR value in the groups was comparable.

In the very high CVR category, the mean age and diabetes duration were significantly higher in the second group compared to the first (Table 4). In both groups, one in four patients with very high CVR was a smoker. In the group with T2DM and three or more

Table 3. Comparative characteristics of parameters in individuals with high cardiovascular risk

Parameter	T2DM with 12 somatic diseases, n = 42	T2DM with 3 or more somatic diseases, n = 23	Significance, p
Sex: m/f	22/20 [52.4 %/47.6 %]	14/9 [60.9%/39.1%]	0.606
Age	49.5 ± 5.01	45.09 ± 5.17	0.002
Age at T2DM diagnosis	45.21 ± 5.23	40.04 ± 5.41	0.001
Diabetes duration	4.45 ± 2.96	5.13 ± 2.93	0.377
Smoking	4 [9.5 %]	4 [17.4%]	0.439
SBP, mm Hg	132.83 ± 10	140.22 ± 14.77	0.039
TC	4.85 ± 1.19	5.13 ± 0.48	0.186
HDLC	1.16 ± 0.14	1.02 ± 0.11	<0.001
HbA1c, %	7.86 ± 1	7.9 ± 1	0.878
eGFR	87.29 ± 17.65	93.91 ± 12.84	0.088
CVR	15.66 ± 2.68	14.86 ± 3.14	0.308

Table 4. Comparative characteristics of parameters in individuals with very high cardiovascular risk

Parameter	T2DM with 12 somatic diseases, n = 68	T2DM with 3 or more somatic diseases, n = 83	Significance, p
Sex m/f	30/38 [44.1 %/55.9 %]	29/54 [35 %/65 %]	0.315
Age	55.88 ± 5.68	58.59 ± 6.64	0.008
Age at T2DM diagnosis	49.56 ± 6.07	51.18 ± 6.07	0.105
Diabetes duration	6.09 ± 3.80	7.29 ± 3.80	0.056
Smoking	16 [23.5 %]	20 [24.09 %]	1.000
SBP, mm Hg	137.43 ± 11.93	139.7 ± 12.22	0.252
TC	5.40 ± 1.8	5.56 ± 0.97	0.512
HDLC	1.05 ± 0.16	1.03 ± 0.10	0.372
HbA1c, %	8.48 ± 1.28	8.79 ± 1.72	0.207
eGFR	77.68 ± 16.56	73.49 ± 14.53	0.105
CVR	28.71 ± 6.33	35.17 ± 10.89	<0.001

somatic diseases, SBP, total cholesterol, HDLC, HbA1c, and eGFR were comparable to the group with T2DM and 12 somatic diseases. Although both groups were in the very high CVR category, the mean CVR value in the group with T2DM and three or more somatic diseases was significantly higher than in the group with T2DM and 12 somatic diseases ($p < 0.001$).

According to Table 5, in both analysed groups, the mean TyG index was high (≥ 4.5), but in the group with T2DM and three or more somatic diseases it was significantly higher than in patients with T2DM and 12 somatic diseases ($p < 0.001$).

In the subgroups with high and very high CVR, the TyG index in the second group was significantly higher than in the first group.

Table 5. TyG index in groups of patients with T2DM combined with other somatic diseases

Indicator	T2DM with 12 somatic diseases	T2DM with 3 or more somatic diseases	Significance, p
Mean TyG index	5 ± 0.35	5.14 ± 0.15	p<0.001
Subgroup with high CVR, TyG index	4.91 ± 0.51	5.09 ± 0.13	0.035
Subgroup with very high CVR, TyG index	5.06 ± 0.20	5.15 ± 0.16	0.003

Discussion

This cohort study was crosssectional in nature, and its main objective was to assess the 10-year risk of fatal and nonfatal cardiovascular complications in patients with T2DM without established CVD using the European SCORE2-Diabetes scale.

The interaction between T2DM and atherosclerotic CVD has been extensively studied. Carbohydrate metabolism disorders, through direct (insulin resistance and protein glycation) and indirect (endothelial dysfunction, chronic inflammation, and oxidative stress) mechanisms, accelerate atherosclerosis and lead to adverse cardiovascular events [14].

According to the Russian PROGNOSIS IHD registry, which included 504 patients with confirmed coronary heart disease, during 7.3 years of followup, the relative risk of the primary endpoint (allcause death, fatal and nonfatal cardiovascular events) increased 1.7fold in the presence of diabetes, and 2.4fold when diabetes was combined with hypertension [15].

Overall, clinical complications of atherosclerosis contribute to increased morbidity and mortality in patients with diabetes.

Obviously, early identification of individuals with high CVR without manifest atherosclerotic CVD is important for patients with T2DM to prevent various cardiovascular events such as MI, stroke, and death. The development of the European Score2-Diabetes scale expands the possibilities for assessing CVC risk in patients with T2DM without CVD in primary care, which in turn is a significant step towards personalization of primary CVD prevention [16].

There are few studies in the literature assessing CVR in T2DM patients using the European Score2-Diabetes scale. The Score2-Diabetes scale shares some general principles with the Score2 scale developed for the general population, particularly the classification of countries into four CVR groups [17].

The new approach takes into account risk levels not only based on individual indicators but also on the re-

gion where the patient lives. For example, at the same level of risk factor severity, a patient from a lowrisk region will have a lower overall CVC risk compared with a patient from a high or veryhighrisk region [18].

According to this classification, in our cohort of T2DM patients, only 3.3% had moderate risk, and low CVR was absent altogether. This is because Russia belongs to the highCVR countries. High CVR was found in one in four patients, and the majority had very high CVR. However, this only partially explains the causes of very high CVR in the analyzed T2DM group.

The duration of diabetes, degree of glycaemic compensation, and severity of major risk factors are important in shaping CVR [19]. In our cohort, the majority of patients at the time of examination had hypertension (71.6%), hypercholesterolaemia (76.9%), low HDLC (62.5%), and high HbA1c values (only 15% of patients achieved target haemoglobin levels). Only one in five patients smoked, while mean eGFR values corresponded to mildly reduced renal function. Gender differences in the frequency of CVR grades also play a role. Among women with T2DM included in this study, high CVR was found in 23.2%, while among men it was 36.6%. Very high CVR was verified in 72% of women and 61.2% of men.

The aim of this work was to assess the risk of CVC in T2DM patients depending on the number of additional somatic diseases. The presence of additional somatic diseases, with the exception of hypertension and chronic kidney disease with excretory dysfunction, is not taken into account in CVR calculation. However, the presence of somatic diseases pathogenetically linked to diabetes may influence the cardiometabolic profile and CVR.

In the present study, in the group with three or more somatic diseases, every second patient had nonalcoholic fatty liver disease, and up to onethird had other somatic diseases (chronic cholecystitis, chronic pancreatitis, nodular goitre, urolithiasis, and chronic obstructive pulmonary disease). Most patients in the first group had two additional somatic diseases, while in the second group, one in four patients had three or four additional somatic diseases.

In the first group, the frequency of high CVR was significantly higher than in the second group, whereas the opposite trend was observed for very high CVR. With comparable severity of 5 out of 9 parameters at T2DM diagnosis, the mean age, SBP, total

cholesterol, and HbA1c in the second group were significantly higher than in the first. This is reflected in the frequency of very high CVR.

The study also assessed the relationship between the TyG index and CVR level. The TyG index is considered a surrogate marker of insulin resistance and, according to prospective studies, has prognostic significance in the development of CVD [2022].

In our study, the mean TyG index in both groups was above normal, but the combination of T2DM with a greater number of somatic diseases was associated with higher values. This pattern was observed in the subgroups with high and very high CVR. Correlation analysis revealed a significant positive relationship between the TyG index and CVR (Spearman's $\rho = 0.21$, $p = 0.023$ for the first group and $\rho = 0.254$, $p = 0.007$ for the second group). A similar positive correlation was found for high-sensitivity C-reactive protein ($\rho = 0.50$, $p < 0.001$ for the first group and $\rho = 0.43$, $p < 0.001$ for the second group).

Conclusion

The results of the study showed that in patients with T2DM with a mean disease duration of 57 years, about

70% have very high CVR according to the European SCORE2-Diabetes scale, because Russia, like other former USSR countries, belongs to the very high-risk region. In real-world clinical practice, T2DM is often combined with two or more additional somatic diseases, among which hypertension and nonalcoholic fatty liver disease predominate, both having a pathogenetic link with the underlying disease. The combination of T2DM with a greater number of somatic diseases is associated with more pronounced disturbances in glycaemic status, lipid metabolism, and higher SBP values, which is reflected in the overall CVD risk. Furthermore, high CVR showed a correlation with the TyG index.

Thus, the SCORE2-Diabetes scale can be used in clinical practice to develop a personalized cardiovascular prevention programme for patients with T2DM, taking into account the presence of additional somatic diseases.

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