

Экономические затраты на сахарный диабет 2 типа и его основные сердечно-сосудистые осложнения в Российской Федерации

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Обоснование. Сахарный диабет 2 типа (СД2) представляет собой комплексную медико-социальную проблему во всем мире, в т.ч. и в Российской Федерации, в связи с распространенностью и вероятностью сердечно-сосудистых осложнений (ССО).

Цель. Определение экономического ущерба от СД2 и ССО.

Материалы и методы. Комплексный анализ затрат (прямых и косвенных) с учетом результатов эпидемиологических, фармакоэкономических и клинических исследований, данных популяционной и медицинской статистики.

Результаты. Расчетные затраты на СД2 составили около 569 млрд руб. в год, что соответствует 1% всего внутреннего валового продукта (ВВП) Российской Федерации, при этом 34,7% от этой суммы приходится на основные ССО – ИБС, инфаркт миокарда, инсульт. Большая часть расходов – немедицинские затраты (потери ВВП) из-за временной нетрудоспособности, инвалидизации, преждевременной смертности – 426,7 млрд рублей в год. Исходя из расчетного числа больных с недиагностированным СД2, но уже имеющим ССО, было установлено, что затраты в этой группе пациентов составляют не менее 107 млрд руб./год (18,8% от всех расходов).

Определена степень связи между расходами при СД2 и степенью контроля заболевания в российских условиях. Расчетные затраты при компенсации СД2 ($HbA_{1c} < 6,5\%$) составили 88 982 руб./пациент/год, в то время как при ее отсутствии ($HbA_{1c} > 9,5\%$) – в 2,8 раза выше, что связано с большим числом ССО при плохом гликемическом контроле.

Заключение. Улучшение диагностики СД2, а также эффективное лечение заболевания на ранних этапах развития может снизить вероятность ССО и существенно уменьшить общественные экономические затраты.

Ключевые слова: сахарный диабет 2 типа; экономика здравоохранения; стоимость болезни

Economic evaluation of type 2 diabetes mellitus burden and its main cardiovascular complications in the Russian Federation

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Background. Diabetes Mellitus Type 2 (DMT2) is a complex medical and social problem in the world and in the Russian Federation also due to prevalence and probability of cardio-vascular complications (CVC).

Aim. Economic burden evaluation of DMT2 in the Russian Federation.

Methods. Complex analysis of expenditures (direct and non-direct costs) based on epidemiological, pharmacoeconomics and clinical investigations, population and medical statistics data.

Results. Calculated expenditures for DMT2 are 569 bln RUR per year, that is correspond to 1% of the Russian GDP, and 34,7% of that are expenditures for main CVC (ischemic heart disease, cardiac infarction, stroke). Main part of expenses are non-medical (losses GDP) due to temporary and permanent disability, untimely mortality – 426,7 bln RUR per year. Expen-

ditures in estimated group of patients with non-diagnosed DMT2 but with already having CVC were at least 107 bln per year (18,8% from total cost). Relationship between cost of DMT2 and degree of it's control was found in the Russian conditions. Estimated cost for compensated patient ($HbA_{1c} < 6,5\%$) per year was 88 982 RUR, in the same time cost of non-control patient ($HbA_{1c} > 9,5\%$) was in 2,8 times higher due to more often main CVC in this group.

Conclusion. DMT2 diagnosis improvement as well as effective treatment of early stages of illness can decrease probability of CVC and social economic expenditures.

Keywords: diabetes mellitus type 2; health care system economics; cost of illness

Background

In recent decades, a global registry of type 2 diabetes mellitus (T2DM) prevalence has been maintained. According to the International Diabetes Federation (IDF), in 2015, there were more than 415 million patients, yet only half knew about their disease status [1]. In Russia, according to the State Register of diabetes mellitus patients, at the beginning of 2015, more than 4 million patients were registered, with 3.7 million of them with T2DM [2]. However, in-depth epidemiological studies in our country suggest that T2DM prevalence is greater than official statistics due to undiagnosed persons [3]. The risk of T2DM is well known and is determined primarily by micro- and macrovascular complications (e.g. ischaemic heart disease, heart attack, stroke, nephropathy and vascular sclerosis of the lower extremities) that lead to temporary or permanent disability, poor quality of life and/or premature death [4]. Myocardial infarction, cerebrovascular diseases and heart failure are among the primary causes of premature death in more than half of T2DM cases (50.7%) [2]. Thus, treatment costs for T2DM patients and economic losses are not only determined by the cost of treatment of the disease itself but also, in many respects, by the costs due to associated cardiovascular complications (CVCs), wherein the incidence is higher in patients with uncompensated disease [5].

Economic analysis, including direct medical costs (costs for outpatient and inpatient care, rehabilitation, ambulance and emergency care) as well as direct (disability payments) and indirect non-medical (loss of gross domestic product (GDP) as a result of disability) costs, is an important means to assess health care resource efficiency for this disease [6]. It should be noted that costs for CVCs may constitute a significant portion of expenses of public health care [7]. Hospitalisation of T2DM patients is resource-intensive, and more than one-third of expenses are incurred upon treating such patients in the wards/intensive care units [8, 9]. In-patient hospital-substituting therapies purposed to efficiently control T2DM, which are often associated with additional investments in drug treatments and rehabilitating patients under outpatient conditions, may reduce financial burden on the medical care system [10].

With known limitations of studies investigating actual practise of indications associated with both the features of the health care system and with different approaches to the practise of managing patients as per various specialists, such data are an important supplement to official statistics

and enable focus on outstanding medical care problems [11, 12]. Data analysis of medical practise in our country revealed high costs regarding T2DM [13]. The average annual costs in 2014 per T2DM patient amounted to 70.8 thousand rubles; however, treatment costs increased several times in patients with uncompensated T2DM and CVCs. However, detailed elaboration of costs regarding CVCs remains unclear due to insufficient data. Nevertheless, it has been suggested that additional costs aimed to achieve target levels of glycated haemoglobin (HbA_{1c}) may be compensated by further reduction of costs for treatment of severe CVCs [13].

Pharmacoepidemiological DM studies conducted in several countries have informed decisions regarding the investing practices in preventive, diagnostic and therapeutic measures. For example, a London School of Economics study revealed that only direct costs of health care systems of five European countries for DM exceeded 90 billion euros/year, which is comparable to the entire annual revenue budget of some countries, such as Poland [14].

Thus, there is suggested evidence that costs associated with T2DM may be very significant, particularly due to CVCs. In our country, economic analysis of T2DM has been conducted, but it did not provide detailed elaboration of costs (direct and indirect). In addition, in view of recently published large-scale epidemiological studies in Russia [15], reassessment of expenses seems appropriate. Identifying viable options to reduce the economic burden of T2DM and associated CVCs in our country is critical for the implementation and determination of public health care system and social insurance expenses as well as economic losses incurred due to aforementioned problems.

Aim

Our aims were: to determine national health care system costs and economic losses associated with T2DM and its CVCs, to justify the possible investments in early diagnostic T2DM programs and to reduce the number of CVCs upon adequate control of disease.

Materials and methods

The following materials and methods were used:

1. Results of the Russian epidemiological study NATION regarding prevalence of the attributive population risk of CVCs [16];

2. The Russian results of the IDMPS (International Diabetes Management Practices Study) [13] regarding patient distribution into groups according to HbA1c indices;
3. Age and gender structure of the population, age-specific mortality by ICD codes and economic parameters (i.e. the value of GDP, average salary and some other indices [17]);
4. Reporting statistical data from forms F. 14, 'Information on the activities of the in-patient facility' (hospitalisation and emergency calls (Emergency Health Services, EHS) based on ICD-10), and F. 12, 'Information on the number of diseases registered in patients residing in the hospital service area' for 2014 [17];
5. Calculations of the average cost of pharmacotherapy for T2DM outpatient treatment, coronary heart disease, rehabilitation after acute myocardial infarction and stroke and 'primary health care standards' according to the relevant disease [18-20];
6. Determination of the cost of outpatient and inpatient medical care, the indices of the program of State guarantees of free medical care and the corresponding calculated diagnostic related groups in 2014 were used [5, 21];
7. Data from relevant literature concerning the relative risks (RR) of CVCs in individuals with T2DM compared with those who do not have T2DM [22-24].

The analysis included statistical data on IHD (ICD codes I20-I25), myocardial infarction (ICD codes I21-22), ischaemic stroke (I63) and haemorrhagic stroke (I61, I62), which were considered as macrovascular complications of T2DM. The analysis did not include heart failure and microvascular complications, since they are not encoded, with no available data on them. To take into account the contribution of T2DM in risks of developing the above states, a population attributable risk (PAR) was used, which represents the highly probable and preventable morbidity in the population under the influence of a particular factor [25]. Using this index, the proportion and then the number of patients with T2DM among Russian patients was defined, in which CHD, myocardial infarction and stroke can be regarded as complications of this disease for future economic calculations.

The value of PAR was determined by the following formula [26]:

$$PAR = \frac{p_0 + p_1 \times RR - 1}{p_0 + p_1 \times RR} \times 100\%,$$

Where:

p_1 - the proportion of patients with T2DM in the Russian population [3]);

p_0 - the proportion of patients without T2DM in the Russian population;

RR - relative risk of cardiovascular diseases in patients with T2DM compared with those without diabetes.

The estimated total costs included direct and indirect costs (economic loss) per year. The direct costs were direct medical costs for outpatient and inpatient care and EHS, including the cost of pharmacotherapy. The direct non-medical costs were the costs for payment of disability

allowances. The calculations were based on the number of hospitalisations, emergency calls and outpatient visits for T2DM and CVCs [17], defined on the PAR with the use of monetary parameters [5, 18-21] (Table 1). The amount of payments of disability allowances was calculated based on the number of patients and the size of disability allowance [27-28].

The costs of CVC drug therapy were calculated on the basis of the 'Standards,' [18-20] taking into account the frequency of provision of medications and recommended dosages. At the same time inside the INN, a medication was selected with the highest cost per unit according to the State Register of limit selling prices (if the drug belongs to the List of vital and essential drugs). The cost of a year of treatment was determined, and the costs were summed.

The indirect costs (economic losses) included GDP shortfall due to the loss of earnings due to temporary disability, physical disability of citizens of working age and premature mortality. Losses associated with premature mortality in the working age group included non-produced GDP as a result of lost years of life in the corresponding age group due to death from T2DM and CVCs, taking into account the coefficient of population employment [17]. Losses due to disability were defined as follows. First, the number of disabled T2DM patients with CVCs, with approximation of the Federal State Statistics Service data calculated based on the proportions of working-age persons with persistent disability in each of the disability groups. Then, the estimated number of unemployed disabled persons was multiplied by the GDP per head of population; as a result, the figure of societal indirect costs taking into account disability was obtained. Indirect costs due to temporary disability due to T2DM and CVCs were calculated as payment of salaries for days of disability per the estimated number of patients in this group. To do this, the amount of the average gross salary in the country was multiplied by the estimated number of days of temporary disability due to T2DM and CVCs [29].

The complex economic assessment on the expenses for T2DM and CVCs compared to GDP was made on the basis of all costs of diagnosed T2DM + CVC, taking into account the cost of T2DM itself and calculations of costs for CVCs in the proposed number of patients with undiagnosed T2DM [3]. It was assumed that the risks of CVCs when diagnosed or undiagnosed with T2DM were the same.

Differentiation of costs and their comparisons were made for artificially selected subgroups of patients with T2DM in accordance with HbA1c levels. Distribution into groups was made based on reasonable assumption that the proportions of patients are identical to those obtained in the national epidemiological studies [3, 13]. The costs for each subgroup of patients were defined as the cost per one patient, taking into account the correction factor. The latter, in turn, was calculated as the ratio of costs per one patient with a certain HbA1c level and the weighted-average costs per one T2DM patient in general [5].

Depending on the HbA1c level, the groups with 'low risk of CVCs' (HbA1c < 8%) and 'high risk of CVCs' (HbA1c ≥ 8%) were arbitrarily defined based on CVC incidence (Table 1) [30]. The weighted averages of CHD incidence, myocardial infarction and stroke were calculated for these groups individually by the following formulas:

$$C1 = \frac{\sum_{(<6)+(6-<7)+(7-<8)} OC}{\sum_{N<6+(6-<7)+(7-<8)}} \times 1000,$$

и

$$C2 = \frac{\sum_{(8-<9)+(9-10)+(>10)} OC}{\sum_{N(8-<9)+(9-10)+(>10)}} \times 1000,$$

Where:

C1 - weighted average of the complications in the low risk group;

C2 - the weighted average of complications in the high risk group;

OC - the number of relevant complications;

N - the size of the groups.

The figures denote the groups according to HbA1c levels.

On the basis of indices calculated as delineated via 'low risk' and 'high risk' CVC groups, the parameters of the costs for one patient in each of the groups were determined.

It is important to note that all economic calculations associated only with T2DM (without CVCs) related to diagnosed T2DM, and the costs associated with T2DM + CVCs represented the costs both for diagnosed and undiagnosed T2DM. The number of patients was determined by the latter on the basis of epidemiological data [3].

The main economic parameters used in the analysis are presented in Table 2.

The estimated number of patients with persistent disability (disabled) T2DM + CVCs was defined as follows: the sum of the number of persons with disabilities with primary T2DM diagnosis based on official statistics [12] and the calculated number of persons with disabilities based on the proportion of disability due to CHD, myocardial infarction and stroke in the general morbidity patterns on these nosologies, as approximated by the number of T2DM patients. All statistical and economic calculations were performed in the Microsoft Excel 16.0.7 program.

Results

Major studies and meta-analyses showed that T2DM significantly increases the risk of CVC. A meta-analysis of

Table 1

Complications of T2DM, ranked by the level of glycated haemoglobin [30] *

Complications	HbA1C level					
	<6%	6-<7%	7-<8%	8-<9%	9-<10%	≥10%
All the complications	229/9195	391/11432	369/8464	268/5605	159/2542	88/1334
Mortality	56/10113	101/13 143	116/10 054	84/6595	47/3137	19/1537
Acute myocardial infarction	100/9870	163/12 590	159/9579	101/6331	60/3016	23/1490
Stroke	32/9916	67/12869	59/9822	32/6424	13/3062	9/1509

Note: * the numerator is the number of events (complications) and the denominator is the number of patient-years

Table 2

The main parameters of costs included in the analysis

Parameter	Cost, rubles
Hospitalisation	19 186,00
Emergency medical services (call)	1 507,40
Outpatient visit to an endocrinologist *	1 417,00
Outpatient visit to a cardiologist *	970,11
Outpatient visit to a neurologist *	951,46
CHD drug therapy per year for 1 patient	27 628,20
Drug therapy after myocardial infarction (rehabilitation during one year) for 1 patient	26 832,20
Drug therapy after stroke (rehabilitation during one year, excluding antihypertensive therapy) for 1 patient	17 642,82
Disablement payout (per patient/month)	
Group 1	12 787,40
Group 2	10 379,40
Group 3	8 447,40
GDP per head of population in 2014	488 782,00
Average salary in 2014	32 495,00

Notes: * taking into account the correction factor for the respective medical specialty in the Government benefits scheme [21, 31]

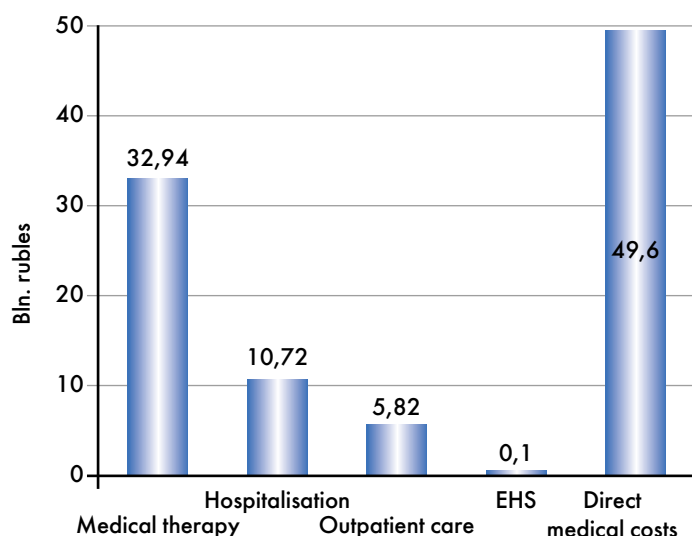


Fig. 1. Structure of the direct medical costs of T2DM and cardiovascular complications in the Russian Federation (per year).

64 cohort studies revealed that the risk of CHD in patients with T2DM was 2.82 (95% CI 2.35-3.38) for women and 2.16 for men (CI 1.82-2.56) [22]. The risk of non-fatal, acute and recurrent myocardial infarction calculated separately from CHD was 1.54 (CI 1.12-2.3) [24]. Mortality from CHD with T2DM is quite high, the risk is 2.31 (CI 2.05-2.60), and it should be noted that with the prevalence of T2DM in the population at 10%, it causes 11.6% of all deaths from cardiovascular diseases [23]. Recalculation for the Russian population, made on the basis of a Russian epidemiological analysis of the prevalence of T2DM [3], indicates that for at least 6.6% of all annual deaths with post-mortem diagnosis of CHD, stroke was associated with T2DM.

The proportion of CVC in patients with T2DM, calculated on the PAR parameter, under the Russian conditions, taking into account the generally accepted

parameters of RR amounted to 7.45% for CHD, including myocardial infarction, separately for acute myocardial infarction, including recurrent, it was 2.83%, for ischaemic stroke it was 3.74%, for haemorrhagic stroke it amounted to 1.49%. Besides, mortality from CHD in T2DM patients is at the level of 6.61%.

The direct medical costs for T2DM amounted more than 30 billion rubles, and the costs for CVC associated with it were 19.2 billion rubles/year, accounting for more than 49.606 billion rubles/year of economic costs in total (Table 2). This amount also includes the costs of medical therapy, including pharmacotherapy of T2DM both with and without CVC (Fig. 1). Notably, almost 22% expenses are associated with inpatient care, while outpatient care is almost 2 times more cost-effective.

The estimated number of patients with disabilities due to T2DM and T2DM + CVC in our country is 774,380 people, with the majority (65%) belonging to the 2nd disability group and 29% belonging to the 1st disability group. Direct non-medical costs (payment of pensions and disability allowances) in patients with T2DM only amount to 68.42 billion rubles/year, and 24.06 billion rubles/year are added taking into account T2DM + CVC, amounting to more than 92.48 billion rubles/year in total (Table 2). Thus, the direct costs, according to our estimates, may be more than 142 billion rubles/year (49.60 billion rubles + 92.48 billion rubles).

The indirect costs for T2DM amounted to 75% of the total costs (Table 3) for T2DM and associated CVCs. The total numbers of premature deaths in the economically active age group from T2DM and associated CVCs amounted to almost 60,000, which, taking into account the analysis of years of survival by gender and age pyramid, corresponds to no less than 300,000 lost years of potential life, which corresponds to the shortfall in the contribution to GDP of 90.25 billion rubles annually. The proportion of losses of GDP due to premature death from T2DM + CVC accounts for 66.6%, which amounts to 26.5% due to only

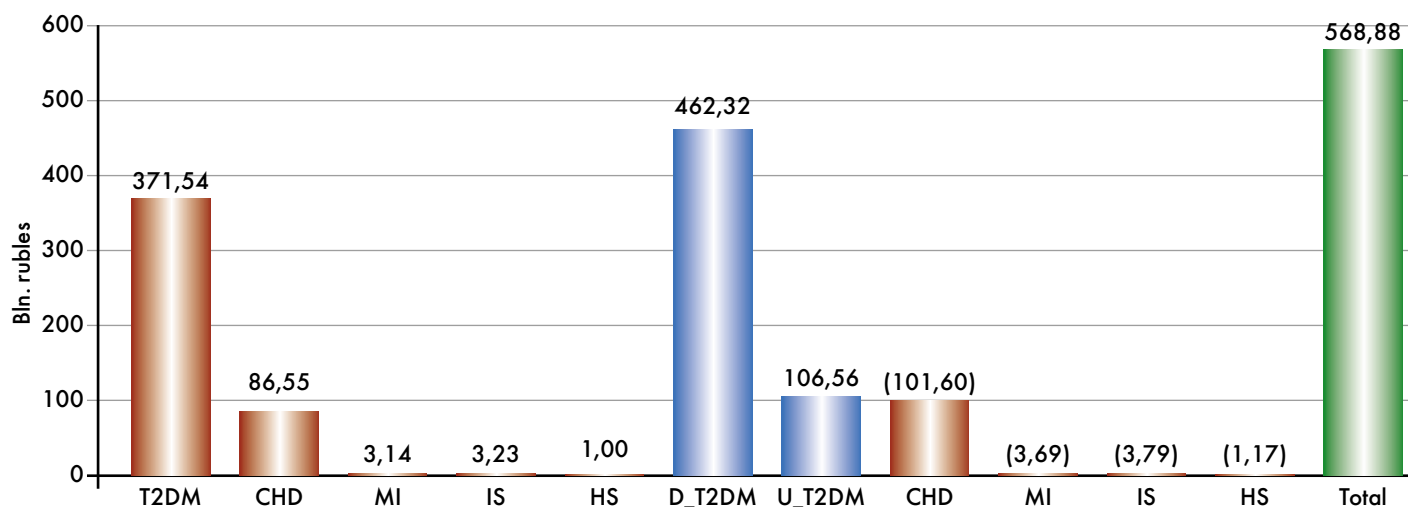


Fig. 2. Estimated distribution of the total costs of T2DM and its cardiovascular complications in the Russian Federation per year.

Notes: T2DM - diabetes mellitus type 2, D_T2DM - diagnosed diabetes mellitus type 2, U_T2DM - undiagnosed diabetes mellitus type 2, CHD - coronary heart disease, MI - myocardial infarction, IS - ischaemic stroke, HS - haemorrhagic stroke.

Table 3

Estimated costs for T2DM and its cardiovascular complications (rubles/year)

Index	T2DM	Cardiovascular complications associated with T2DM					T2DM+CVC in total
		CHD	Myocardial infarction	Ischaemic stroke	Haemorrhagic stroke	All CVCs	
Hospitalisations	7 351 238 577	2 869 335 160	218 703 333	460 619 876	20 562 128	3 350 517 163	10 701 755 740
EHS	67 300 888	68 245 949	6 261 209	13 703 208	579 205	82 528 362	149 829 250
Outpatient care	5 253 301 101	552 741 515	5 004 081	9 971 216	663 830	563 376 561	5 816 677 662
Medical therapy	17 712 981 131	15 031 807 881	142 513 187	181 340 265	12 072 657	15 225 220 803	32 938 201 934
Direct medical costs, total	30 384 821 697	18 522 130 506	372 481 811	665 634 565	33 877 819	19 221 642 890	49 606 464 587
Direct non-medical costs, total	68 420 765 377	23 564 625 929	560 698 658	469 021 031	31 224 891	24 064 871 850	92 485 637 227
Direct costs in total	98 805 587 075	42 086 756 434	933 180 469	1 134 655 596	65 102 710	43 286 514 740	142 092 101 814
GDP losses due to premature death	23 915 794 227	60 076 716 686	3 867 598 218	4 264 632 934	1 998 227 972	66 339 577 593	90 255 371 820
GDP losses due to disability	246 922 931 329	85 042 113 719	2 023 499 087	1 605 852 465	106 908 996	86 754 875 181	333 677 806 510
Loss of earnings (temporary disability)	1 899 160 603	942 433 190	8 532 039	15 794 686	1 051 525	959 279 402	2 858 440 004
Indirect costs, total	272 737 886 159	146 061 263 596	5 899 629 344	5 886 280 086	2 106 188 493	154 053 732 175	426 791 618 334
TOTAL of all costs	371 543 473 233	188 148 020 030	6 832 809 812	7 020 935 682	2 171 291 203	197 340 246 915	568 883 720 148

T2DM. Most GDP losses account for only T2DM (73.8%), GDP losses on this parameter with T2DM + CVC amount to 26.2% (Table 3). In general, the expenses (economic losses) of our state are not less than 333.6 billion rubles/year, which corresponded to 0.47% of GDP for 2014. The loss of income due to temporary incapacity for work is not less than 2.8 billion rubles/year, which further negatively affects the social insurance system providing payments on that expenditure line. If all the costs, both direct and indirect, are summed up, they will amount to at least 1% of GDP. Thus, a well-founded conclusion can be made about the significant economic damage that T2DM causes to the Russian economy, which imparts the relevance for effective control of the disease and prevention of its CVC.

While summarizing the data for all direct and indirect economic expenses, we concluded that the estimated economic damage to our country associated with diagnosed T2DM + CVC is 463.32 billion rubles/year, and with undiagnosed T2DM (costs for CVC), 106.56 billion rubles/year are added, which corresponds to 568.88 billion rubles/year in total (Fig. 2). In the analysis of the total economic damage on individual nosologies, it was revealed that more than half of the costs are associated with T2DM, and among the CCOs associated with T2DM, most expenses are associated with coronary heart disease (188.15 billion rubles/year in total). In case of undiagnosed T2DM, the costs for coronary heart disease are greater than those in case of diagnosed T2DM, which reflects, in our opinion, the effect of treatment of T2DM, preventing both the development and progression of CVCs.

According to epidemiological data, the acceptable values of HbA1c (less than 6.5% to 7.5%) were observed in 47.9% cases, and 52.1% patients had uncompensated T2DM. Further, HbA1c of half of them was above 8.5%, which is very dangerous in terms of the development and

progression of CVCs [5]. The results of calculation of costs confirmed the hypothesis that more funds are spent for uncompensated T2DM patients than for patients with the controlled disease (Fig. 3). The average economic damage per patient with T2DM increases with decompensation of the disease, which is associated with a large number of CVCs and, accordingly, the additional costs for their treatment. The greatest costs are accounted for patients with HbA1c > 9.5%; they exceed those for a patient with satisfactory compensation by 1.81-fold (HbA1c is less than 6.5% to 7.5%).

The weighted average frequencies of CVCs were found to be significantly lower in the group of low risk (Table 4). Thus, the reduction of absolute risk of all CVCs with T2DM with acceptable values of HbA1c was 37.4%, that of myocardial infarction was 22.4% and that of death from CVC was 38.4% compared with that of a group with inadequate control of T2DM. In this regard, it is consistent that in the group where HbA1c is greater than 8.5%, higher expenses are expected (Table 4). The group of T2DM patients with a high risk of CVC under Russian conditions can include 869,565 patients (23.5% patients on [5]) of the total number of diagnosed patients. When approximating the data obtained on the costs for the entire population of T2DM patients to conditionally determined risk groups, it was found that the costs for 1 patient in this group are expected to be more than 210 thousand rubles/year, which is almost 2-fold higher than that in the group with a lower risk of CVC. This relates to both direct and indirect costs.

Discussion

The data obtained on different costs depending on the degree of compensation of T2DM represent a higher incidence of CVC when there is insufficiently poor

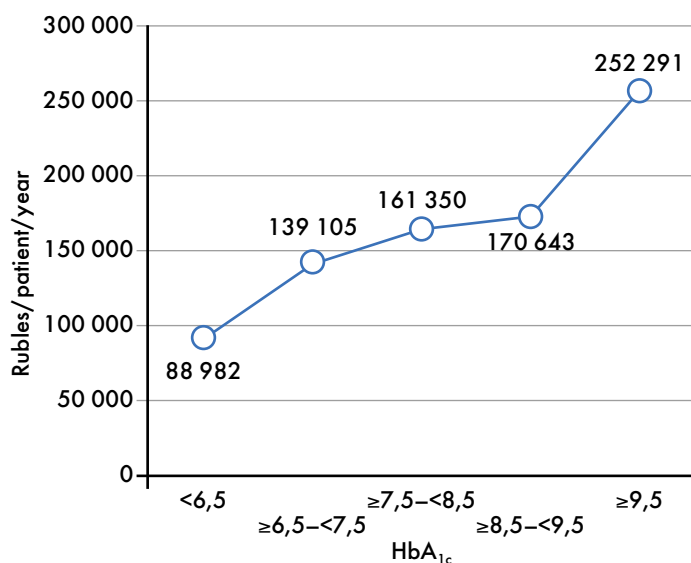


Fig. 3. Expenses in 1 case of T2DM, depending on the extent of the disease compensation.

control of the disease. Therefore, one of the mechanisms of the potential reduction of the economic burden of T2DM is the prevention of its complications, which can be implemented through improving glycaemic control. Pharmacotherapy enables to effectively implement glycaemic control. Different medications for the treatment of T2DM, including insulin, can be used as a tool for 'transfer' from the high risk group to the lower risk group because at high values of HbA_{1c} they are more preferable [4]. The predictable economic effect of pharmacotherapy (including cardiovascular medications) is possible to be evaluated in further analyses by analysing the difference between the additional costs of its implementation and the expected benefit from the reduction of CVCs. In this case, it is necessary to consider that the direct medical costs must be complemented with the costs for potential hypoglycaemic events that may increase the cost depending on the frequency [32]. When improving the parameters of compensation of carbohydrate metabolism, i.e. during 'transfer' of the patient from the high risk group to the

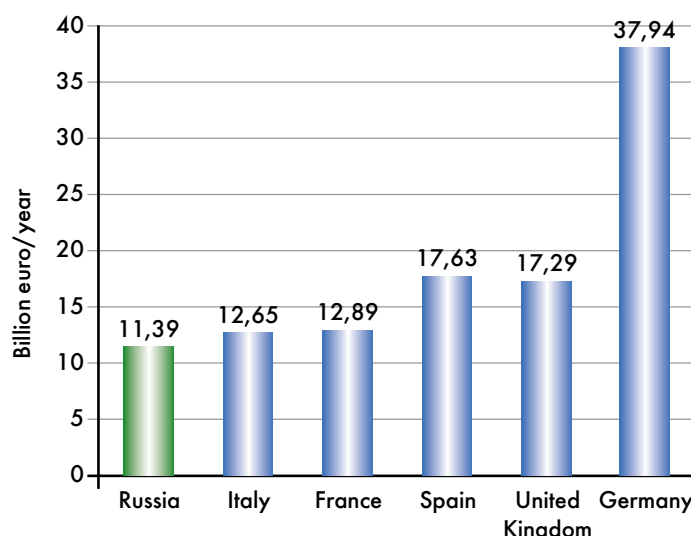


Fig. 4. Comparison of the annual costs for T2DM, including cardiovascular complications, using the data [14] and the results of this analysis.

lower risk group, one can expect a decrease in the number of non-fatal myocardial infarction by 22.4%, that of all cardiovascular events associated with T2DM by 37.4% and that of mortality associated with T2DM by 38.4% [30]. Reduction of the number of these events will have a proportional effect on costs of patients with T2DM.

We can assume that the costs for T2DM and CVC in undiagnosed patients are higher than those determined in the course of this examination as the level of compensation of carbohydrate metabolism in them is much worse, which means that the incidence of CVCs is higher and the survival rate is lower [33-35]. Consequently, the costs for a patient which T2DM diagnosed at an early stage even without associated complications will be lower. In accordance with the recommendations on pharmacotherapy of T2DM [4], it can be effectively treated initially with metformin having a low cost. In case of late diagnosis of T2DM or in case of poor control of the disease, the costs are much higher and the medical prognosis deteriorates, which should also be considered.

Table 4

Estimated costs on groups of risk of cardiovascular complications in patients with type 2 diabetes mellitus

Parameter	Group of 'low risk of complications'	Group of 'high risk of complications'
Morbidity of T2DM *	34.00	54.32
Rate of mortality at T2DM *	8.20	13.31
Incidence of myocardial infarction at T2DM *	13.17	16.98
Incidence of stroke at T2DM *	4.85	4.91
Weighted average costs (rub./patient/year)	136 049	210 579
Of them		
Related to T2DM	88 855	137 532
Direct	22 194	34 352
Indirect	66 661	103 108
Related to CVC	47 194	73 048
Direct	11 788	18 245
Indirect	35 406	54 803

Note: * per 1000 patients

Conclusion

1. The annual economic costs for T2DM and associated CVCs are at least 1% GDP, which indicates a significant socio-economic significance of diabetes in our country. In the overall structure, the health care system costs amount to 8.72% and the direct non-medical costs (social insurance funds) amount to 16.26%. Economic losses amount to 75.02%.
2. In the structure of the health care costs for T2DM and associated CVCs, the costs for hospitalisation and pharmacotherapy prevail compared with those for outpatient care. The in-patient substitutional technologies implemented on the basis of early diagnosis of T2DM and its timely pharmacotherapy aimed at disease control are the prospects for budgetary savings, reducing the risk of CVCs and deterioration of primary disease.
3. The monetary relationship between the degree of compensation of T2DM and the amount of necessary funds for treatment was determined, with insufficient compensation of the disease the costs per patient being 2.8 times higher than with proper control of T2DM. Thus, it is further possible to calculate the economic feasibility of various options. The effect will be determined by the difference in additional investments in the disease control and savings due to the improved course of T2DM and reduction.

Limitations of the study.

- Outpatient visits were modelled on the basis of F.12.

- Emergency calls were accounted only in the cases that resulted in hospitalisation.
- The assumption was made that the CVC risks in cases of diagnosed and undiagnosed T2DM are the same.
- The costs for medical therapy of CVCs were calculated in accordance with the standards of medical care.
- When determining the number of patients with disabilities in each group of CVC, the distribution on disability groups of patients with T2DM on the basis of the register was used.

Additional information

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Conflict of interest

O.I. Karpov is an employee of the stock company 'Sanofi Russia'. The other authors declare no potential conflicts of interest in connexion with this work.

Author contributions

I.I. Dedov, A.V. Kontsevaya - concept, analysis design, calculations; M.V. Shestakova - writing and editing the article; Y.B. Belousov - validation of methods of epidemiological and economic analyses, reviewing; Y.V. Balanova, M.B. Hudyakov - modelling, calculations; O.I. Karpov - analysis concept, writing the article.

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