ORIGINAL STUDY

Фармакоэпидемиологические аспекты мониторинга здоровья пациентов с сахарным диабетом 2 типа: результаты Российского наблюдательного многоцентрового эпидемиологического исследования ФОРСАЙТ-СД 2

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Обоснование. *На фоне стремительного роста заболеваемости сахарным диабетом 2 типа (СД2) проведение наблюдательных многоцентровых исследований позволяет получать объективную информацию об эпидемиологической ситуации в отношении СД и его осложнений, оценивать эффективность различных схем проводимой терапии и диагностических стратегий, направленных на выявление системных сосудистых осложнений заболевания.*

Цель. *Анализ основных эпидемиологических и социально-демографических показателей, в условиях типичной клинической практики качества гликемического контроля и мониторинга проведения диагностических и лечебно-профилактических мероприятий у больных СД2, проживающих в различных по численности населения городах и населенных пунктах Российской Федерации (РФ).*

Материалы и методы. *ФОРСАЙТ-СД2 – всероссийское многоцентровое наблюдательное эпидемиологическое исследование, в которое было включено 2014 больных из 45 различных городов и населенных пунктов РФ, получавших сахароснижающую терапию, обратившихся за первичной медицинской помощью к врачам-эндокринологам государственных амбулаторно-поликлинических медицинских учреждений РФ с 01.01.2014 г. по 31.12.2014 г. Для проведения сравнительного анализа типичной практики ведения пациентов с СД2, живущих в различных городах в РФ, проводили стратификацию пациентов на группы на основании численности населения.*

Результаты. *В наблюдательном эпидемиологическом исследовании среди обследованных пациентов средний уровень гликированного гемоглобина (HbA_{1c}) составил 7,9±1,9%, у 36% больных HbA_{1c}>8%. Выявлена высокая частота осложнений СД: распространенность ретинопатии – у 63,2% больных, нефропатии – 34,4% (из них 7,8% – стадия хронической болезни почек С3а-С5), периферической полинейропатии – 63,3%, синдрома диабетической стопы – 13,7%, остеоартропатии – 5%. Количество осложнений СД коррелировало с показателем уровня HbA_{1c} и длительностью заболевания, причем одновременное влияние этих факторов приводило к достоверному росту у больного количества хронических осложнений заболевания ($r=0,338$ для длительности СД2 и $r=0,262$ для показателя HbA_{1c}, $p<0,001$). Несмотря на высокую частоту обращений пациентов на консультацию к эндокринологу (83% больных), а также достаточно большой процент госпитализаций в текущем году (46% больных), скрининг хронических осложнений СД2 в 2014 г. проводился в недостаточном объеме.*

Заключение. *Полученные результаты исследования ФОРСАЙТ-СД2 свидетельствуют о сохраняющейся высокой распространенности хронических осложнений заболевания на фоне недостижения целей гликемического контроля и несоответствия частоты проведения диагностических мероприятий существующим стандартам оказания медицинской помощи больным СД2.*

Ключевые слова: *сахарный диабет 2 типа; наблюдательное исследование; распространенность осложнений сахарного диабета; типичная практика ведения*

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Assessing routine healthcare pattern for type 2 diabetes mellitus in Russia: the results of pharmacoepidemiological study (FORSIGHT-DM2)

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Rationale. *The rising incidence of type 2 diabetes mellitus (T2DM) allows researchers to conduct observational multicentre studies and obtain objective information about the epidemiology of diabetes and its complications and evaluate the efficacy of different therapies and diagnostic strategies designed to identify systemic vascular complications.*
Aims. *To analyse epidemiological and socio-demographic parameters, the quality of glycaemic control, diagnostic monitoring and therapeutic measures typical among patients with T2DM living in Russian towns of different populations.*
Materials and methods. *FORSIGHT-DM2 is an all-Russian multicentre observational epidemiological study that involves 2014 patients with T2DM from 45 different towns in the Russian Federation (RF). All patients have had T2DM for at least 1 year. They received glucose-lowering therapy and primary medical care from RF public outpatient health institutions between 01.01.2014 and 31.12.2014. For comparative analysis of the typical treatment for patients with T2DM, we stratified patients into groups based on the number of residents.*
Results. *The data reveal a lack of glycaemic control (average HbA_{1c} 7.9% ± 1.9%), with HbA_{1c} > 8% in 36% of patients. The frequency of T2DM complications was high and the prevalence of retinopathy was 63.2%, nephropathy was 34.4% (7.8% had chronic kidney disease G3a-G5), peripheral polyneuropathy was 63.3%, 'diabetic foot' syndrome was 13.7% and osteoarthropathy was 5%. The number of T2DM-related complications is correlated with the HbA_{1c} level and disease duration. Moreover, simultaneous influence of these factors led to a significant increase in the number of chronic complications associated with T2DM ($r = 0.338$ for T2DM duration, $r = 0.262$ for HbA_{1c}; $p < 0.001$). Despite the high frequency of patient consultations with endocrinologists (83%) and a large percentage of hospitalisations in the current year (46%), the screening of chronic complications of T2DM in 2014 is insufficient.*
Conclusion. *The results indicate insufficient glycaemic control among patients with T2DM and a higher prevalence of chronic complications compared with the national register of diabetic patients.*
Keywords: *type 2 diabetes mellitus; observational study; prevalence of chronic complications of the type 2 DM; typical clinical practice*

As of 01.01.2015, a total of 4.094 million patients with type 2 diabetes mellitus (T2DM) were registered in the State Register of Diabetes Patients (SRDP) in the Russian Federation (RF), which corresponds to 2.8% of the total population of Russia. [1]. However, a recent nation-wide study (NATION) on revealed that the actual prevalence of T2DM may be two times higher than that suggested by the number of cases registered in the SRDP. The study estimated the prevalence of T2DM to be of the order of 5.44%, which corresponds to an estimated case load of more than 6 million in the age-group of 20 to 79 years. The study findings suggest that more than half (54%) of all patients with T2DM may not be aware of the disease, which indicates poor awareness of the disease among the Russian population [2].

Modern strategy for management of T2DM includes lifelong administration of medications and promotion of lifestyle changes including healthy dietary habits, adequate physical activity, self-monitoring of glycaemic control, and regular medical examination for timely detection and treatment of complications and comorbid conditions such as dyslipidemia, arterial hypertension and coronary heart disease [3].

Over the past 20 years of its implementation, the Federal Target Program (FTP) "Diabetes mellitus" (which became a sub-program of the FTP "Prevention and Control of Social Diseases" in 2002) has managed to develop infrastructure and institutionalize a diabetology service in the country. The key elements of this program includes establishment of regional diabetes centers, assistance rooms for patients with "diabetic foot", and specialized ophthalmologic services for diagnosis and treatment of diabetic retinopathy. Moreover, "Schools for diabetic patients" were established, where patients acquire the necessary skills for self-management of their disease [4]. However, despite the obvious progress in this respect, several challenges continue to persistin Russia in relation to diabetes control. These include measures to improve the organization and standardization of diabetology care to the population and continous update of the State Register of DM patients (SRDP), timely provision of life-saving medicines and means necessary for self-monitoring, training of specialists and patient health education .

Disease-specific observational epidemiological studies are often conducted in different countries to assist in

planning and organization of specialized medical care to patients with chronic diseases including T2DM These studies typically generate in-depth information on socio-demographic characteristics of patients, the nature of specialized medical care provided to them, the frequency and prevalence of DM complications and comorbidities, and the efficacy of pharmacotherapy. A special place among modern tools for assessment of relevant data about the social aspects of healthcare delivery is held by pharmacoepidemiological (PE) and clinical and economic studies that provide valuable data reflecting the main aspects of the practice of patient management, both at the federal level and in some regions. For example, these studies help characterize typical stereotypes associated with drug therapy, and suggest ways to optimize it.

The SRDP was established in 2000 and has since been the source of data for clinical and epidemiological monitoring of T2DM in the country. It is used to estimate prevalence and incidence of DM, as well as the prevalence of complications, disablement and mortality of patients, provided with medicines [5]. Since 2008, in various regions of Russia the controlled and epidemiological studies are held, that allow for a more accurate evaluation of the main epidemiological indices such as the prevalence of DM and its complications, as well as to evaluate the typical practice of patient management [6].

Despite the great progress made in the availability and quality of specialized diabetology care, significant government expenses for treatment of patients (70.8 thousand rubles per year per patient in 2014) [7], and the appearance in the arsenal of doctors-endocrinologists of innovative antidiabetic drugs with proven efficacy, in real life a sufficiently large number of patients fail to achieve compensation of carbohydrate metabolism. In a prospective observational study DIA-CONTROL conduceted in 2010-2011, 38% of the T2DM patients examined had poor glycemic control (HbA1c ≥ 8%) [8]. In another prospective observational study A1chieve conducted in 2008-2010, the mean HbA1c level in the study population was 10.0 (± 1.7) % [9]. Moreover, findings of DIA-CONTROL study indicate considerable underreporting of the frequency of complications of T2DM in the SRDP [1].

What are the main causes, and what should be done to change the situation in our country? What are the main therapeutic approaches to management of T2DM in outpatient settings? And how does the real picture compare with the declared national and international standards for treatment of T2DM? All of the above was the background for the All-Russian multicenter research project "Pharmacoepidemiological and clinical and economic aspects of improvement of medical care for patients with type 2 diabetes mellitus in the Russian Federation" (FORSIGHT-DM2).

Aims

To analyze the main epidemiological and socio-demographic parameters, the quality of glycemic control and to assess and compare the utilization of diagnostic, therapeutic and preventive activities by patients with T2DM in Russian towns with different population (size?), in typical clinical practice.

Main research objectives

- study the basic socio-demographic and epidemiological indices of the T2DM patient cohort under study;
- assess the quality of glycemic control, the prevalence of chronic complications of T2DM and comorbidities in patients living in Russian towns with different population size;
- study the scope, timeliness of diagnostic and medical-preventive activities at outpatient settings, and to assess their compliance with current national and international guidelines;
- compare the prevalence of T2DM chronic complications in Russia reported from "DIA-CONTROL" study (2010-2011)with that based on the State Register of diabetes mellitus patients for 2012 and 2014.

Methods

FORSIGHT-DM2 is a multicenter observational epidemiological study (cross-sectional type) conducted to assess glycemic control and the prevalence of complications, to identify the features of pharmacotherapy, the quality of life, patient satisfaction, and medication adherence among T2DM patients. The study design is shown in Figure 1.

The study included patients over 18 years old suffering from T2DM for at least one year, receiving hypoglycemic therapy, who sought medical advice from endocrinologists of state outpatient medical institutions of the Russian Federation (clinics and endocrinological health centers) between 01/01/2014 and 12/31/2014.

The exclusion criteria were: age less than 18 years; type 1 diabetes mellitus; severe somatic, oncological or mental diseases.

A total of included 2014 T2DM patients from 45 different cities and towns (urban settlements) of the Russian Federation, who agreed to take part in the study and signed the patient information sheet.

To conduct the survey of patients, the study group led by Chief endocrinologist of Russia, academician of RAS, Ivan Dedov, designed the "Patient questionnaire FORSIGHT-DM2". The purpose of this questionnaire was to optimize the collection of the most important socio-demographic and clinical characteristics of patients with T2DM, which represented different social and economic strata of the Russian population living in towns with different population (sizes) (Table 1).

Information on each patient was collected by co-investigators from several sources: original medical records, patient interview and questionnaires for the assessment of the outcomes. Demographic, clinical, test results and treatment details were obtained from medical records and information was entered in the CRF. If the patient's original

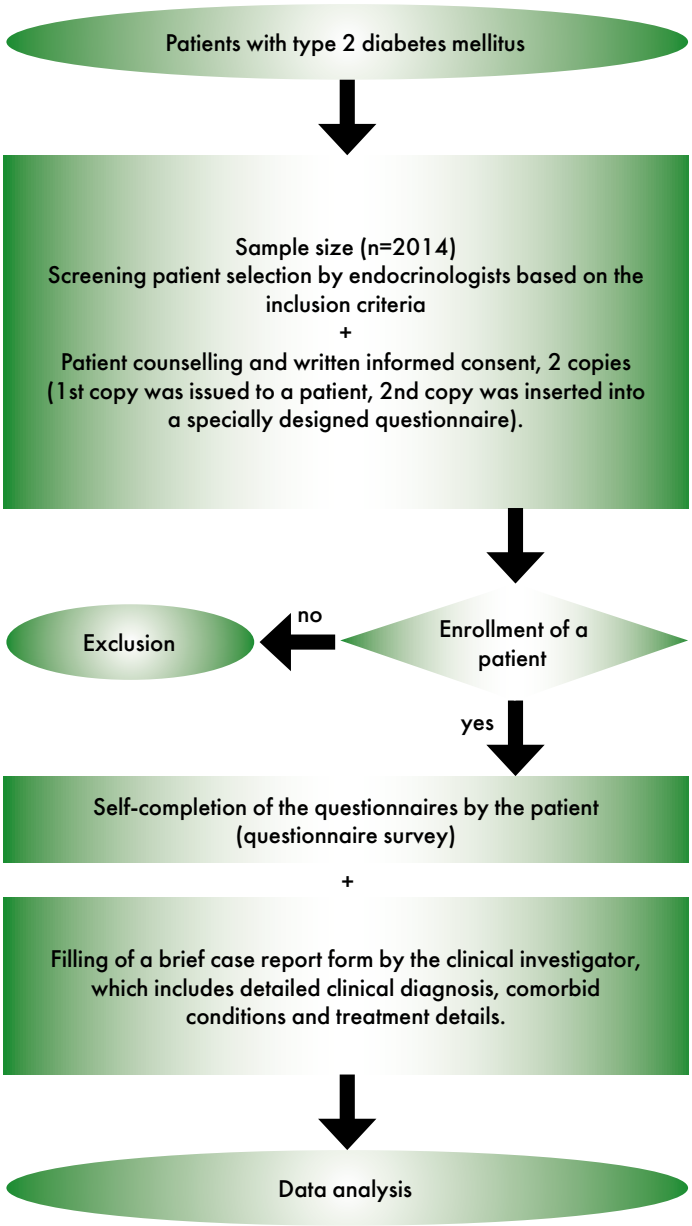

Fig. 1. The study design of FORSIGHT-DM2.

medical records did not contain relevant information pertaining to diabetic complications, the patient underwent outpatient examination by an ophthalmologist to assess the condition of the retina, an attending physician-co-investigator examined the feet to determine sensitivity, and a urine test for the presence of protein was performed.

Comparative analysis of the typical practice of management of T2DM patients who lived in various cities in Russia was performed by stratification of patients into groups based on the population size (Table 2).

The study did not involve any intervention in the treatment strategy. The non-interventional clinical study "Pharmacoepidemiological and clinical and economic aspects of the improvement of the organization of medical care for patients with type 2 diabetes mellitus in the Russian Federation (FORSIGHT-DM2)" was approved by the Interacademic Ethics Committee (abstract of minutes No. 09-12 of 09/21/2012).

Prior to patient enrollment, all patients were individually counseled on the aims and objectives of the project by a doctor. Subsequent to this, patients signed a consent form ("Patient information sheet") in duplicate, one of which was issued to the patient.

Statistical analysis

Minimum sample size was calculated using the formula

$$n \geq \frac{p(1-p)z^2}{e^2} \; / \; (1 + (\frac{z^2 p(1-p)}{e^2 N})) = 384,$$

where n is the sample size; p is the estimated frequency of the studied characteristic in the population (50%); z is value of the normalized deviate determined for the confidence level of 95% (1.96); e is allowable sampling error (5%), and N is the size of the general population (140,000,000).

The socio-demographic characteristics of the patients were analyzed by descriptive statistics using the application program package developed by IBM (USA) - Statistical Package for the Social Ssience18.0 for Windows (IBM SPSS Statistics). Data on normally distributed continuous variables are presented as mean (M) ± standard deviation (SD); non-normally distributed continuous variables are presented as median (Me) and interquartile range [25th and 75th percentile]. Between-group differences with respect to normally distributed quantitative variables were assessed by Student's t-test, while those with respect to non-normally distributed quantitative variables were assessed by Chi-squared (2) test . Multi-group comparisons of quantitative variableswere performed using analysis of variance (ANOVA). Between-group differences associated with a p value < 0.05 were considered statistically significant. Spearman correlation analysis was performed to assess the relationship between two variables.

Results

Analysis of main socio-demographic indices

Of the 2014 patients, 640 (31.8%) were men and 1368 (67.9%) were women (Table 3). Median age of patients was 60 years (range, 54-75). Mean age (±SD) of patients was 59.6 (± 10.05) years.

Most of the respondents were educated up to secondary (46.0%) or higher (30.5%) level. At the time of the study, 41.6% patients were pensioners, 35.9% were employed and 20% were unemployed. Among the employed patients, 29% reported that missed work due to illness; 38% patients had a disability (Group 1: 2.5%; Group 2: 16.5%; Group 3: 19.0%). Median disease duration (number of years elapsed since disease onset at the time of survey) was 7 years (range, 3-12). Forty percent of patients reported disease duration of ≥ 5 years; 23% reported disease duration between 5 and 10 years, while 37% patients had the disease for > 10 years (Table 4).

In the study cohort, 84.6% of patients reported compliance with physician recommendations related to diet and regular physical activity. The study did not include

Table 1

Information collected in the patient questionnaire	
Index set	Main indices
Socio-demographic	Gender, age, weight, height, education, employment, presence of disability, contacts with the health care system.
Health status in the past and present	Duration of disease, diagnoses, hospitalization, surgical history
Dynamic outpatient surveys	Frequency of seeking by the patient of an advice of the endocrinologist, physician, cardiologist; frequency determining the basic biochemical parameters (lipid profile, creatinine, HbA1c, microalbuminuria); frequency of fundoscopy, examination of feet with sensitivity determining.
lifestyle characteristics	Compliance with the recommended proper nutrition and regular physical activity, training in "School for T2DM patients", frequency of self-monitoring of glycemic control and blood pressure
Features of hypoglycemic, lipid-lowering, antihypertensive and antiplatelet therapy*	International nonproprietary name (INN), dosage, frequency, duration of intake of hypoglycemic, antihypertensive, lipid-lowering and antiplatelet drugs
Assessment of quality of life, patient satisfaction and medication adherence	Filling common (generic) questionnaires to assess the quality of life: the European quality of life questionnaire (Euro Quality of Life (EQ-5D), the questionnaire for the assessment of treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire (DTSQs)), the questionnaire for the assessment of the medication adherence.

Note: * - in-depth analysis of the therapy and diagnostic scales will be discussed in the second part of the report on the study.

Table 2

Stratification of patients disaggregated by cities and towns with different population sizes					
Factor	Cities on the population size *(n=2014)				
	Group 1	Group 2	Group 3	Group 4	Group 5
Population size	>5 mln.	> 1 mln.	> 500 thous.	>100 тыс.	<100 тыс.
	> 100 thous.	< 100 thous.	335 (16,6%)	564 (28,8%)	420 (21,5%)
Number of patients (%)	400 (20.5%)	354 (18.1%)	335 (16.6%)	564 (28.8%)	420 (21.5%)
Cities and towns	Moscow, Saint Petersburg	Kazan, Krasnoyarsk, Nizhny Novgorod, Samara, Saratov, Ufa, Chelyabinsk	Barnaul, Krasnodar, Naberezhnye Chelny, Penza, Tyumen, Yaroslavl	Arkhangelsk, Balashikha, Noginsk, Nizhnekamensk, Odintsovo, Yoshkar-Ola, Smolensk, Elista, Zheleznodorozhny, Armavir, Zheleznodorozhny, Rubtsovsk, Podolsk, Dzerzhinsk, Bryansk, Yakutsk, Elektrostal, Novorossiysk, Nalchik, Magnitogorsk, Shchelkovo, Sergiyev Posad, Vladimir, Kirov, Mytishchi	Boksitogorsk, Chekhov, Troitsa, Elektrougli, Vsevolozhsk, and other small towns and urban settlements.

a more detailed assessment examination of the dietary habits and physical activity of patients.

Median body mass index (BMI) in the overall study population was 30.8 kg/m2 (range, 27.6-34.6). Only 10% of the patients had their BMI within the normal range, while 33% patients were overweight; 33%, 14% and 8% patients were obese (1st degree, 2nd degree and 3rd degree obesity, respectively; Fig. 2).

No significant difference with respect to BMI was observed between patients based on the place of residence. in comparison in all cities regardless of the population size the patients predominated, who had overweight and obesity except for doubling the number of patients who suffered from obesity of third degree in small towns and settlements with the population of less than 100 thousand people (Fig. 3).

Quality assessment of glycemic control and the prevalence of chronic complications of T2DM and comorbidities

40.9% of patients received treatment with insulin preparations in combination with different oral antidiabetic drugs (OADs) or in the mode of basal-bolus insulin therapy, 59% received oral antidiabetic drugs (OADs). Mean HbA1c level among patients on insulin therapy and OADs was 8.8% (± 2.0%) and 7.4% (± 1.6%), respectively. A more detailed analysis of the drug therapy will be presented in subsequent publications.

Mean fasting and postprandial blood sugar levels in the entire cohort were 7.7 (± 2.5) mmol/L and 10.8 (± 2.3) mmol/L, respectively. Among patients receiving OAD therapy, mean fasting and postprandial blood glucose levels were 7.05 (± 1.7) mmol/L and 8.5 (± 2.4) mmol/L, respectively (Fig. 4).

Patients on insulin therapy had higher mean fasting and postprandial blood glucose levels of 8.7 (± 3.1) mmol/L, and 14.5 (± 2.9) mmol/L, respectively.

HbA1c levels during the last 6 months were determined in 45% of patients of the cohort under study. The mean HbA1c level was 7.9 (± 1.9) %. Analysis of this marker of

Table 3

Demographic indices of patients enrolled in the study FORSIGHT-DM2

Demographic indices		In all groups		Group 1		Group 2		Group 3		Group 4		Group 5	
		n	%	n	%	n	%	n	%	n	%	n	%
Age*	< 45 years old	132	6.8	46	11.5	34	9.6	4	1.9	33	5.9	15	3.6
	45-49 years old	125	6.4	32	8	23	6.5	13	6	27	4.8	30	7.2
	50-54 years old	257	13.2	47	11.8	48	13.5	26	12	67	11.9	69	16.5
	55-59 years old	380	19.5	49	12.3	82	23.1	39	18.1	113	20.1	97	23.2
	60-64 years old	464	23.8	77	19.3	80	22.5	59	27.3	149	26.5	99	23.7
	> 65 years old	592	30.3	149	37.1	87	24.2	75	34.7	173	30.8	108	25.8
	Average age (SD)	59.61 (10.05)		59.53 (11.57)		57.59 (10.56)		61.39 (8.22)		60.4 (10.26)		59.39 (8.26)	
Sex**	Male	617	31.6	188	47.2	115	32.6	53	24.4	143	25.4	118	28.1
	Female	1333	68.4	210	52.8	238	67.4	164	75.6	419	74.6	302	71.9

Table 4

Distribution of the disease duration, the level of glycated hemoglobin (HbA1c), and the number of identified T2DM complications disaggregated by place of residence of the patients

Indices	Group 1 (n = 400) n (%)	Group 2 (n = 354) n (%)	Group 3 (n = 217) n (%)	Group 4 (n = 564) n (%)	Group 5 (n = 420) n (%)	In all groups (n = 1955) n (%)
Duration of the disease *						
≤ 5 years	152 (38.5)	146 (42.4)	48 (22.4)	284 (51.5)	132 (31.9)	762 (39.7)
> 5 but < 10 yeras	104 (26.3)	80 (23.3)	52 (24.3)	109 (19.8)	99 (23.9)	444 (23.1)
≥ 10 years	139 (35.2)	118 (34.3)	114 (53.3)	158 (28.7)	183 (44.2)	712 (37.1)
Level of HbA1c*						
≤ 7	114 (58.8)	62 (36.3)	22 (21.8)	101 (38.4)	41 (25.9)	340 (38.3)
>7 but ≤ 8	46 (23.7)	52 (30.4)	28 (27.7)	67 (25.5)	35 (22.2)	228 (25.7)
>8	34 (17.5)	57 (33.3)	51 (50.5)	95 (36.1)	82 (51.9)	319 (36.0)
Number of complications *						
No	14 (4.2)	37 (10.9)	5 (2.9)	13 (2.6)	20 (5.4)	89 (5.2)
1	71 (21.5)	70 (20.6)	18 (10.3)	58 (11.5)	35 (9.5)	252 (14.7)
2	45 (13.6)	55 (16.2)	29 (16.6)	105 (20.8)	55 (14.9)	289 (16.8)
3	54 (16.4)	44 (13.0)	33 (18.9)	89 (17.6)	58 (15.8)	278 (16.2)
4	36 (10.9)	46 (13.6)	28 (16.0)	86 (17.0)	52 (14.1)	248 (14.4)
5	33 (10.0)	28 (8.3)	18 (10.3)	52 (10.3)	41 (11.1)	172 (10.0)
>5	77 (23.3)	59 (17.4)	44 (25.1)	102 (20.2)	107 (29.1)	389 (22.7)

Notes: * on chi-square test p <0.001

overall glycemic control revealed that the target value of HbA1c ≤ 7% was observed only in 38.3% of patients, 25.7% and 36% of the patients had HbA1c levels in the range of 7-8% > 8%, respectively(Fig. 5).

On analysis of HbA1c levels disaggregated by place of residence, 17 % of T2DM patients resident in cities with population of > 5 million people i.e., Moscow and St. Petersburg (Group 1) were found to be in a state of glycemic decompensation (HbA1c > 8%), while 23.7% patients had HbA1c levels in the range of 7 - 8% (Table 3, Fig. 5). Similar results were obtained among patients living in cities that had a population > 1 million people (Group 2) and > 500 thousand people (Group 3). A different pattern was observed in cities that had a population of 100 - 500 thousand people (Group 4) and < 100 thousand people (Group 5) in that about half of all patients had decompensated disease; HbA1c levels < 7% was observed in only one out of four patients.

It was in small cities and residential areas that the largest number of late complications of DM (five or more complications) were registered in 35 and 40% of patients, respectively. A comparable figure was observed among residents of the cities of Moscow and St. Petersburg (33%), while the lowest figure in this respect was seen in Group 2 patients.

Among the chronic complications of T2DM, a high prevalence of diabetic retinopathy (63.2%) and peripheral neuropathy (63.3%), diabetic foot syndrome (13.8%), diabetic osteoarthropathy (6.8%) was seen (Table 4). Diabetic nephropathy was registered in 34.4% patients; 7.8% of these patients suffered from chronic renal failure.

In all groups, there was a high incidence of cardiovascular diseases. The most common condition was arterial hypertension (detected in 69.1% patients), followed by heart rhythm disorders (29.4%), angina pectoris (27.3%), chronic heart failure (16.3%), ischemic heart disease (history of myocardial infarction: 10.2%) and acute cerebrovascular accident (ACVA: 7% patients). A high prevalence of non-alcoholic fatty liver disease (18.9%), urolithiasis (13.3%) and gout (5%) was also observed in the

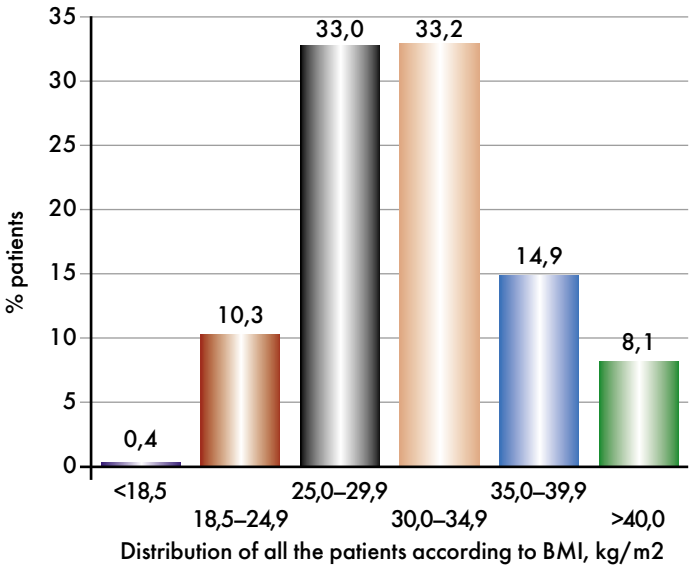

Fig. 2. Distribution of boby mass index in the study population

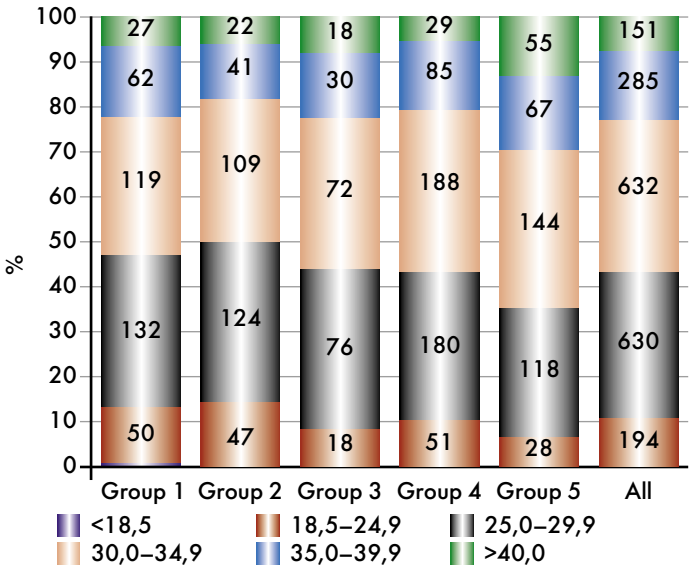

Fig. 3. Distribution of patients with type 2 diabetes mellitus on the BMI index in different groups depending on the place of residence.

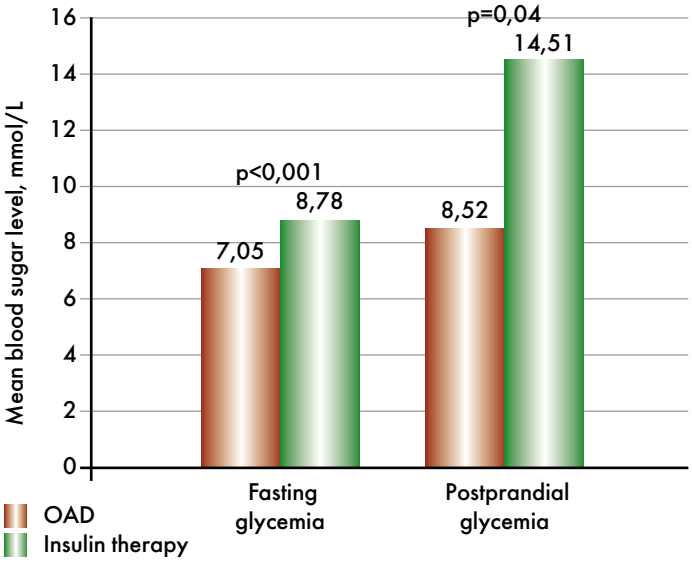

Fig. 4. Mean fasting and postprandial blood sugar levels in patients with type 2 diabetes mellitus on insulin therapy and oral antidiabetic drugs

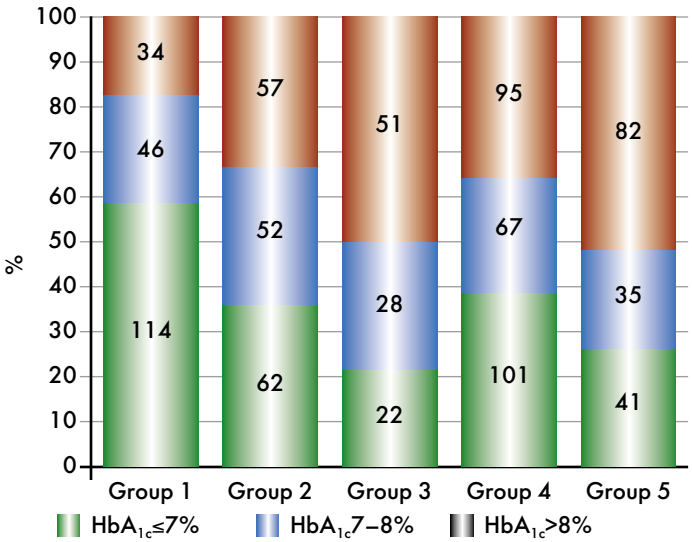

Fig. 5. Levels of glycated hemoglobin (HbA1c) in patients disaggregated by place of residence

study population.

Spearman correlation analysis revealed a statistically significant correlation between duration of T2DM and incidence of T2DM complications($p < 0.001$) such as diabetic retinopathy ($r = 0.131$), nephropathy ($r = 0.240$), diabetic foot syndrome ($r = 0.244$), neuropathy ($r = 0.260$), osteoarthropathy ($r = 0.138$), as well as comorbidities including angina pectoris ($r = 0.206$), arterial hypertension ($r = 0.018$), heart rhythm disorder ($r = 0.168$), chronic heart failure ($r = 0.181$), myocardial infarction ($r = 0.137$), ACVA ($r = 0.088$), chronic renal insufficiency ($r = 0.150$), non-alcoholic fatty liver disease ($r = 0.087$), gout ($r = 0.051$), and urolithiasis ($r = 0.071$).

Correlation between high HbA1c levels and development of T2DM complications such as retinopathy ($r = 0.075$), nephropathy ($r = 0.091$), diabetic foot syndrome ($r = 0.157$), neuropathy ($r = 0.199$), and osteoarthropathy ($r = 0.137$) was also observed. The simultaneous influence of risk factors such as the duration of T2DM and high level of HbA1c was associated with a significant increase in the number of chronic complications of T2DM in a patient ($r = 0.338$ and $r = 0.262$, respectively, $p < 0.001$) (Table 4).

Comparison of T2DM complications among patients living in cities with different population sizes was significantly different (Table 5). Moscow and St. Petersburg showed a significantly higher incidence of obesity, fatty hepatosis, urinary stone disease, gout, as well as old myocardial infarction and ACVA as compared to that in cities with less population (Groups 2-5). At the same time, the frequency of chronic complications of T2DM such as retinopathy, peripheral polyneuropathy and nephropathy was relatively low as compared to that in patients in Groups 3-5.

The highest incidence of cardiovascular complications of T2DM (heart rhythm disorders, heart failure, old

Table 5

Prevalence of complications and comorbid conditions disaggregated by place of residence

Complications and comorbidities	Group 1	Group 2	Group 3	Group 4	Group 5	In all the groups
	(n=383)	(n=347)	(n=204)	(n=532)	(n=385)	(n=1851)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Arterial hypertension *	237 (61.8)	215 (61.9)	164 (80.4)	384 (72.1)	279 (72.5)	1279 (69.1)
Obesity *	201 (52.4)	105 (30.2)	80 (39.1)	275 (51.6)	184 (47.8)	845 (44.2)
Retinopathy *	91 (23.8)	147 (42.4)	107 (52.5)	290 (54.5)	140 (36.4)	775 (41.9)
Neuropathy *	82 (21.4)	128 (36.9)	87 (42.6)	196 (36.8)	141 (36.6)	634 (34.2)
Heart rhythm disorders *	97 (25.4)	90 (25.8)	50 (24.5)	163 (30.6)	145 (37.6)	545 (29.4)
Angina pectoris *	117 (30.5)	60 (17.2)	75 (37.0)	151 (28.4)	103 (26.7)	506 (27.3)
Non-alcoholic fatty liver disease **	94 (24.5)	62 (17.8)	34 (16.8)	89 (16.7)	71 (18.5)	350 (18.9)
Heart failure *	70 (18.4)	38 (10.9)	40 (19.6)	68 (12.8)	86 (22.3)	302 (16.3)
Nephropathy *	51 (13.3)	45 (13.0)	41 (20.1)	66 (12.4)	91 (23.6)	294 (15.9)
Diabetic foot syndrome *	56 (14.6)	47 (13.5)	24 (11.8)	43 (8.1)	85 (22.1)	255 (13.8)
Urinary stone disease *	76 (19.9)	36 (10.3)	19 (9.2)	60 (11.2)	56 (14.5)	247 (13.3)
Myocardial infarction *	51 (13.3)	21 (6.0)	21 (10.3)	40 (7.6)	55 (14.2)	188 (10.2)
Chronic renal insufficiency *	30 (7.8)	19 (5.5)	12 (6.0)	27 (5.1)	56 (14.5)	144 (7.8)
ACVA ***	32 (8.4)	18 (5.2)	12 (6.0)	31 (5.9)	37 (9.6)	130 (7.0)
Osteoarthropathy ****	17 (4.4)	29 (8.4)	17 (8.3)	28 (5.3)	35 (9.1)	126 (6.8)
Gout *****	34 (8.9)	9 (2.6)	8 (3.8)	21 (3.9)	21 (5.4)	93 (5.0)
Other complications/ diseases******	55 (14.4)	45 (13.0)	26 (12.9)	85 (16.1)	99 (25.6)	310 (16.8)

Notes: * on chi-square test p <0.001, ** p = 0.052, *** p = 0.120, **** p = 0.035, ***** p = 0.001, ****** p = 0.006.

myocardial infarction, ACVA) was observed in cities with a population of less than 100 thousand people (Group 5). The highest prevalence of nephropathy and chronic renal failure, diabetic foot and diabetic osteoarthropathy was also observed in Group 5. Diabetic retinopathy was significantly more common among patients in Groups 3 and 4, while peripheral neuropathy was more common in Group 3 and diabetic nephropathy was more common in Groups 3 and 5. The highest prevalence of arterial hypertension was noted in Group 3 (80.4%); this disease was detected less often among the residents of large cities with populations over 1 million people (61.9%), and in Moscow and St. Petersburg (61.8%).

Evaluation of scope and timeliness of diagnostic, therapeutic and preventive interventions for T2DM patients in outpatient settings

Most patients surveyed (88%) noted that they were routinely monitored at a primary care facility; 8.4% were monitored at an endocrinology clinic, while 2.8% are monitored at a private medical center. T2DM patients sought medical care most often from an endocrinologist (83%) or therapist (79%); 40% of respondents were routinely examined by an ophthalmologist, while 31% were routinely examined by an neuropathologist. During the preceding year, 34% of patients had consulted a cardiologist, 14% had consulted a surgeon, 12% had consulted an urologist, while 9% patients had consulted a gastroenterologist.

More than half of the patients claimed to have had attended three or more different specialists; 22% and 23% patients, respectively, attended one or two specialists, while 1.3% did not seek specialized medical care. 45% of patients reported that they visited an endocrinologist every month, 25% patients visited an endocrinologist once every 3 months, 10% patients visited once every 6 months, 12% visited once a year, while 7% of patients did not seek help from an endocrinologist for more than 1 year.

About 50% of patients were monitored at an outpatient setting during the preceding year . At the same time, we identified a considerably high rate of hospital admissions in our study cohort: 38% of them spent 2 to 4 weeks in the hospital in the preceding one year, and 8.3% of the patients were hospitalized for more than a month. Median duration of hospital stay was 10 days (range, 1-20).

Only 55% of patients reported that they had ever received training in a "School for T2DM patients", Of these, 44% were trained more than 3 years ago, 10% were trained 2 years ago, 26% were trained 1 year ago, and 20% were trained within the last one year. Daily monitoring of glycemic level with the use of individual means for self-control such as glucometers was performed by 53.5% of the patients; 29.0% of patients monitored their blood sugar irregularly; 15.7% of patients did not self-monitor their glycemic control because of the lack of glucometer or test strips.

Of note, 72.2% of all patients regularly underwent blood pressure measurement, which corresponded to the average prevalence of hypertension in the study cohort.

Examination of feet by an endocrinologist for assessment of foot sensitivity was performed 1 time per year for 62% of the patients, once in 3 years for 14% of patients; 24% of patients in this study never had their feet examined by an endocrinologist.

Seventy percent of all patients underwent ophthalmoscopic examination with dilated pupils once a year, while 19% patients underwent ophthalmoscopic examination once in 3 years; 11% of patients have never underwent an ophthalmologic examination.

Biochemical analysis of blood was performed 2 times a year for 37% patients, once a year for 42%, and once in 3 years for 7% patients; biochemical analysis was not conducted for 15% patients. Data on total cholesterol levels in the preceding one year was available for 79% of patients (1591 patients). Normal levels of total cholesterol (< 4.5 mmol/L) were observed in 37.2% of patients, while 34.7% of patients had total cholesterol level above the normal limit, and in 28.2% of patients this index was not determined or its results were not known. Sixty percent of patients with proven hypercholesterolemia received regular cholesterol-lowering treatment.

Discussion

To date, in the world there is an accumulated wide experience of control epidemiological studies among T2DM patients. The first works date back to the late 90s of the previous century. In 1998, the first European study on the analysis of the cost of diabetes mellitus in Europe - Cost of Diabetes in Europe (CODE-2) was conducted. In this study direct and indirect costs of treatment of T2DM were calculated on the basis of questionnaire surveys in eight European countries (France, Germany, Belgium, Italy, Netherlands, Spain, Sweden and the UK). The prevalence of chronic complications of T2DM and their impact on the cost of treatment and the patient's quality of life were also estimated [10]. In the CODE-2 study, 69% of patients had HbA1c levels of >7%.

Another large-scale multinational epidemiological study RECAP-DM was conducted across Finland, France, Germany, Norway, Poland, Spain and the UK in 2008. The study assessed the level of glycemic control across Europe and the assessment of impact of intensification of T2DM treatment by addition of sulphonylurea or thiazolidinedione to metformin [11]. Only 26% patients were found to have achieved the target HbA1c levels of less than 6.5%, which was the norm accepted in that period of time for T2DM patients.

Since 2008, three prospective observational studies have been conducted in the Russian regions to analyze the typical practice of T2DM treatment, , to assess glycemic control and the prevalence of T2DM complications: an international study IMPROVE (2008) [12], a multicenter national study A1chieve (2008-2010) [9] and the DIA-CONTROL study (2010-2011) [8]. A characteristic feature of non-interventional observational studies is non-interference in the doctor's treatment decision-making; the primary objective is to collect more information from a sufficiently large population in order to optimize the organization and delivery of diabetology care in real-world setting.

Since 2000, clinical and epidemiological data pertaining to DM in Russia is collected in SRDP [1]. It serves as a source of comprehensive information on epidemiology of diabetes, including prevalence, trends in complications, health status of patients, quality of care, and to predict medical, social and economic aspects of the disease. [2]. However, due to impossibility to perform the systematic monitoring of such important parameters as the quality of data entry in the register and the regularly of the information updating, there are significant deviations between the published generalized statistical indices of SRDP and the results of the control and epidemiological studies on assessment of the actual prevalence of DM complications [1, 4].

To assess the compliance of a typical clinical treatment practice to the recommended standard of specialized medical care to T2DM patients in the Russian Federation, we assessed the the basic interventions for prevention and early diagnosis of chronic complications of the disease. Table 6 compares the actual frequency of preventive measures based on data from the FORSIGHT-DM2 study with the frequency recommended by the working group of experts in the "Algorithms of specialized medical care to patients with DM" edited by I.I.Dedov, M.V.Shestakova, 2015 [13].

Table 6 shows that every second patient did not follow the recommendations for regular monitoring of glycemic level, which was probably not due only to the lack of possibility of independent measurement of blood sugar (only 16% of respondents claimed to have a glucometer and/or test strips) but also to the low motivation or poor awareness of patients about the necessity to comply with this therapeutic strategy. The survey data once agains confirm the importance of the individual or group training for all patients in the "School for T2DM patients" in order to create "the behavior of patients, due to DM" [4]. According to our study, almost half of all DM patients (45%) never had a structured therapeutic training.

On the other hand, the lack of information on the HbA1c level in the last 6 months in 55% of the study population indicates non-compliance with the recommended standards of specialized medical care (recommended frequency: once in 3 months). Despite the relatively low cost of this laboratory test and its important role in monitoring of glycemic control and adequacy of hypoglycemic therapy, the possibility of free evalution of this index in the outpatient clinic, the continued poor compliance needs to be addressed (only 45% of the study population had undergone HbA1c analysis in the preceding 6 months, and according to SRDP in 2014 this figure was available for analysis only in 8% of patients).

At the same time, the majority of patients were regularly examined in an outpatient setting by an endocrinologist (83%) or a physician (79%), and 45% patients sought endocrinological consultation every month!

In the study cohort, a high frequency of scheduled in-patient examination and treatment (46% of patients) is registered, and the average duration of hospitalization was

Table 6

Recommended basic preventive measures for the prevention and early diagnosis of T2DM complications [5] and the actual frequency of their performance in the Russian Federation according to the study FORSIGHT-DM2

Preventive measures	Recommended measures	Actual frequency of performance, %
Regular self-monitoring of glycemia	With OAD and/or agonists of glucagon-like peptide-1 and/or basal insulin – at least 1 time a day + 1 glycemic profile 1 (not less than 4 times a day) once a week	54
Measurement of HbA1c level	Once in 3 months	45
Training in the "School for T2DM patients"	Indicated to all patients with newly diagnosed disease	55
Regular fundal examination with dialted pupils	Once a year	70
Regular examination of feet	During every visit to the doctor, the determination of feet sensitivity - 1 time a year.	62
BP Control	During every visit to the doctor.	
When hypertension - independent measurement 2-3 times a day.	72	
Urine analysis for microalbuminuria	Two times a year	75
Consultation by a cardiologist	Once a year	34
Frequency of biochemical analysis of blood	Once a year in the absence of changes	79

Notes: * - the data are published not for all preventive measures and surveys

20.5 days. Despite the high frequency of hospital treatment in this study population, and a significant duration of hospital stay, only 34% of patients examined by a cardiologist (the minimum recommended frequency of cardiological consultation is once per year); urine test for quantitative assessment of proteinuria was not performed among 25% of patients for the last 3 years (recommended frequency: twice a year); the examination of feet for sensitivity was not performed in 38% of patients (recommended frequency: once a year); fundal examination with pupil dilation was not performed in 30% of patients.

Thus, it can be argued that the scope and frequency of preventive measures for the prevention, early diagnosis and retardation of progression of T2DM complication in 2014 did not correspond to those recommended in the existing national guidelines.

Among patients who performed self-monitoring of glucose levels, the differences were seen depending on the type of hypoglycemic therapy. Patients on oral hypoglycemic therapy showed a significantly lower variability in glycemia levels in comparison of the mean fasting and postprandial glucose levels (7.05 mmol/L fasting and 8.52 mmol/L, respectively) than among patients on insulin therapy (8.78 mmol/L fasting and 14.5 mmol/L, respectively) (Figure 4). It is obvious that the insulin therapy for T2DM was prescribed only in patients with an absolute or relative deficiency of insulin production in patients with long-standing disease and those with chronic complications.

Comparative assessment of HbA1c levels according to SRDP and the FORSIGHT-DM2 study is shown in Fig. 6. According to SRDP in Russia in 2014, 28.5% of T2DM patients had decompensated DM (HbA1c > 8%); however, the figure is based on an estimated 8.4% of the total patients[1]

In the FORSIGHT-DM2 study, data on HbA1c level was available for 45% of the study cohort, of which 38% of patients had compensated disease (HbA1c≤7%) and 26% had a satisfactory glycemic control (HbA1c 7% - 8%). More than 1/3 of patients (35.7%) did not achieve the therapeutic goal of compensation of carbohydrate metabolism (HbA1c> 8%). Mean HbA1c level in the study cohort was 7.9 (± 1.9) %. It should be noted that the mean HbA1c levels did not differ from that reported in the epidemiological study DIA-CONTROL in 2011, in which 36% of the patients had not achieved optimal glycemic control (HbA1c≤8%).

The absence of positive dynamics of the studied index over the past 3 years stands for the revision of existing therapeutic strategies used in typical clinical practice of treatment of T2DM patients in Russia. On the other hand, low availability of measurement of this DM compensation marker for patients is an alarm signal of the need for cost optimization and redistribution of financial resources allocated annually by the government for treatment of T2DM patients. The large amount of expenditure in 2014 for long-term inpatient treatment should be diverted to dynamic preventive measures to prevent the development of the disease complications and to organize training of patients in the"School for T2DM patients".

It is interesting to compare the values of prevalence of chronic complications of T2DM obtained from different sources. The Table 7 summarizes the results of the studies FORSIGHT-DM2 (2014), DIA-CONTROL (2010-2011) [6,8] and SRDP for 2012 [4] and 2014 [1].

In the FORSIGHT-DM2 study, decrease in incidence of autonomic neuropathy from 4.7% (2010-2011) to 1.2% as well as that of diabetic peripheral polyneuropathy from 82.5% (2010-2011) to 63.3% was observed. At the same time, the prevalence of polyneuropathy according to SRDP in 2014 was 3 times lower (19%) than that in the FORSIGHT-DM2 study (63%). This discrepancy may be due to either insufficient diagnostics of peripheral

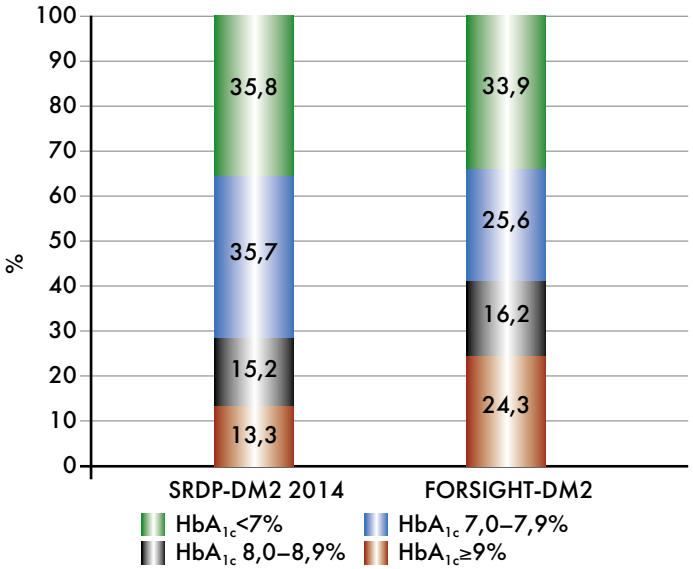

Fig. 6. Comparison of patients distribution by level of HbA1c (%) in the study FORSIGHT-DM2 and according to SRDP-DM2 in 2014.

polyneuropathy (examination of feet with the definition of sensitivity), or errors in information entry in the information database [1].

The prevalence rates of diabetic nephropathy in the study cohort of patients and those calculated on the basis of the data in the available documentation of analysis of urine for the presence of protein also revealed a positive dynamics compared to the results of the screening of 2011 (reduction in the incidence of this complication of T2DM was 6.2%). The prevalence of nephropathy in the study FORSIGHT-DM2 based on microalbuminuria and proteinuria amounted in total to 34.4%; 7.8% of patients with nephropathy had chronic kidney disease (GFR <29 mL/min/1.73 m2); In SRDP, the 2014 figure was understated by 7 times (4.9%). A similar tendency was seen in relation to the other chronic complications of T2DM.

The most common comorbid conditions in this study cohort was obesity (57%), while 33% of patients were over weight (Fig. 2). The incidence of obesity among T2DM patients in the FORSIGHT-DM2 study is consistent with data of SRDP for 2014. Moreover, the study provides additional information such as 33% of patients had 1 degree of obesity, 14.9% had 2 degree and 8% of patients suffered from morbid obesity.

The number of complications of T2DM correlated with HbA1c level and disease duration. The highest incidence of chronic complications of T2DM, i.e., diabetic nephropathy, retinopathy, diabetic foot syndrome and osteoarthropathy, was seen in small towns with population less than 100 thousand people, while in cities with population of over 1 million, (including Moscow and St. Petersburg), the the most prevalent comorbidities were obesity, non-alcoholic fatty liver disease, urinary stone disease, gout, old myocardial infarction and acute cerebrovascular disorder.

Limitations of the study

The present study shares the limitations inherent to all observational non-interventional studies. The study design does not exclude the possibility of systematic errors due to the non-randomized design and the probability of incomplete or inaccurate data. However, the study design enabled collection of a large array of data and provides a better idea about the health of the patients and other variables of interest in real-world clinical settings in Russia.

Conclusion

Health monitoring of patients with T2DM, conducted in 45 cities of the Russian Federation, as part of the multicenter observational epidemiological study FORSIGHT-DM2 in 2014, helpedcharacterize certain clinical and epidemiological features of the disease in Russian cities with varying population size. A number of problems relating to the organization of specialized medical care in typical outpatient settings were identified. More than one-third of patients (36%) have decompensated glycemic control (HbA1c> 8%), and 80% of patients have a high incidence of chronic complications of T2DM; this was especially observed among patients living in Russian towns rather small in population. Delayed diagnosis, lack of awareness and necessary knowledge among patients about their disease (training in a "School for T2DM patients" was attended by 55% of the patients), low frequency of self-monitoring (only 54% performed daily measurement of glycemic level), a discrepancy between the recommended measures aimed at timely detection of complications and the existing standards of specialized medical care in our country indicate a lack of volume and quality of medical care for patients with T2DM.

Significant differences in SRDP data regarding the prevalence of T2DM complications in 2014 with the results of the epidemiological study conducted is an alarm signal which indicates the inadequate reliability of the information on the complications of T2DMin the unified information database, as well as the absence of its regular updates.

According to the World Health Organization, no country in the world has sufficient financial resources to meet fully the growing needs of national health care, and in these conditions, rational management and optimization of scarce budgetary resources is a priority for the organization of diabetology care to the population. It is possible that the introduction of certain amendments in the Order of Ministry of Health of Russia of November 12, 2012 No. 899n "The procedure for provision of medical care to adult population on the profile of "Endocrinology" [14] and provision of its implementation on the entire territory of the Russian Federation" will improve the quality of the provision of specialized care to patients with type 2 diabetes mellitus.

Table 7

The actual (data of the studies DIA-CONTROL and FORSIGHT-DM2) and the recorded (SRDP data) prevalence of chronic complications of T2DM and comorbidities in the Russian Federation, 2010-2104, %

Index	SRDP. 2012. (n=3 453 680)	DIA-CONTROL. 2010-2011 (n=9844)	SRDP. 2014 (n=1 836 958)	FORSIGHT-DM2. 2014 (n=2014)
Autonomic neuropathy	5.72	4.7	-	1.9
Diabetic peripheral polyneuropathy	18.35	82.46	19.0	63.3
Diabetic nephropathy (taking into account the result of urine examination for proteinuria)	12.6	40.62	4.9	34.4
Chronic renal failure				7.8
Diabetic retinopathy	17.51	38.4	15.3	63.2
nonproliferative stage	-	-		54.1
preproliferative stage	-	-		7.9
proliferative stage	-	-		1.1
Diabetic lower limb macroangiopathy	12.56	4.91	8.3	4.5
Diabetic foot syndrome	3.78	4.65	2.4	13.7
amputation (within the foot. but more than one toe)	0.31	0.7	0.6	1.0
amputation (at the level of lower leg and above)	0.36	0.1		0.1
Diabetic osteoarthropathy			-	5.0
Cardiovascular diseases				
Arterial hypertension	46.51	87.18	37.6	69.1
Angina pectoris	14.45	27.6	11.5	27.0
Myocardial infarction	3.84	-	3.7	10.2
Stroke	3.81	-	4.4	7.0
Heart rhythm disorders				29.4
Heart failure				16.3
Other diseases				
Cataract	12.76	-	5.8	14.3
Obesity			57.1	45.7
Non-alcoholic fatty liver disease				18.9
Urinary stone disease				13.3
Gout				5.0
Other diseases				16.8

Примечания: * – данные опубликованы не для всех осложнений СД2 и стадий осложнений

Additional information

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Conflict of interests

The authors declare no explicit and potential conflicts of interests associated with the publication of this article.

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