РАСПРОСТРАНЕННОСТЬ САХАРНОГО ДИАБЕТА У ВЗРОСЛОГО НАСЕЛЕНИЯ НОВОСИБИРСКА

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ЦЕЛЬ. Оценить распространенность сахарного диабета 2 типа (СД2) в разных возрастных группах взрослого населения Новосибирска по данным эпидемиологических исследований 2003–2005 и 2013–2016 гг.

МЕТОДЫ. В период 2003–2005 гг. проведено одномоментное обследование репрезентативной популяционной выборки мужчин и женщин 45–69 лет – жителей двух административных районов г. Новосибирска в рамках международного проекта HAPIEE.

В 2013–2016 гг. проводилось популяционное обследование случайной репрезентативной выборки населения 25–44 лет обоего пола – жителей одного из районов Новосибирска.

Для постановки диагноза СД2 использованы критерии АДА (2003, 2013 гг.): уровень глюкозы плазмы натощак ≥7,0 ммоль/л однократно, после 8-часового голодания. Также в группу с СД2 вошли лица с уровнем глюкозы натощак <7,0 ммоль/л, но указавшие, что имеют СД2 и получают соответствующее лечение. Для выявления нарушенной гликемии натощак (НГН) использованы рекомендации ВОЗ, 1999 г., согласно которым НГН определяется при уровне гликемии натощак от 6,1 до 6,9 ммоль/л. Нормогликемия оценивалась как показатель глюкозы плазмы менее 6,1 ммоль/л.

РЕЗУЛЬТАТЫ. Среди жителей 45–69 лет, по данным популяционного скрининга 2003–2005 гг., распространенность СД2 составила 11,3%. Распространенность СД2 по результатам скрининга 2013–2016 гг. среди жителей 25–44 лет – 2,2%, выше у мужчин (3,5%), чем у женщин (1,1%), p≤0,05. Распространенность НГН была высока как в возрасте 45–69 лет – у 18,2% (2003–2005 гг.), так и в молодой возрастной группе 25–44 лет – 21,6% (2013–2016 гг.), что особенно вызывает тревогу.

Менее половины (4,7 из 11,3%) обследованных в возрасте 45–69 лет и только 1 человек в возрасте 25–44 лет знали, что у них есть СД2, что свидетельствует о недостаточном уровне знаний сибиряков о проблеме СД2.

ЗАКЛЮЧЕНИЕ. Среди взрослого населения 45–69 лет в 2003–2005 гг. у 18,2% наблюдалась НГН, у 11,3% – СД2. У лиц 25–44 лет в 2013–2016 гг. выявлена НГН у 21,6%, СД2 – у 2,2%.

КЛЮЧЕВЫЕ СЛОВА: сахарный диабет 2 типа; эпидемиологическое исследование; недиагностированный сахарный диабет; распространенность; Новосибирск

PREVALENCE OF DIABETES IN THE ADULT POPULATION OF NOVOSIBIRSK

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AIMS. To estimate the prevalence of type 2 diabetes mellitus (T2DM) in different age groups of the adult population of Novosibirsk, according to epidemiological studies in 2003–2005 and 2013–2016.

METHODS. We examined a representative population sample (assessed in 2003–2005) of men and women aged 45–69 years in two administrative districts of Novosibirsk, as a part of the international HAPIEE project. According to the tables of random numbers, representative samples of men and women aged 45–69 years were formed, to which letters were sent, inviting them to pass for examination. During 2013–2016, a second population survey was conducted on a random representative sample of a population of 25–44-year-olds of both sexes. Participants were residents of one of the districts of Novosibirsk. T2DM and impaired fasting glucose (IFG) were diagnosed using fasting plasma glucose (FPG) levels (diabetes: FPG ≥7.0 mmol/l; IFG: FPG 6.1–6.9 mmol/l).

RESULTS. The prevalence of T2DM among residents aged 45–69 years was 11.3%, and overall, no significant difference in prevalence was found between females and males (11.3% vs. 11.0%).

However, the overall prevalence of T2DM among residents aged 25–44 years was 2.2%, and prevalence was higher in men (3.5%) than in women (1.1%), p ≤ 0.05.

High prevalence of IFG was found in the 45–69 age group (18.2%, in 2003–2005), and in the younger age group of 25–44 years (21.6%, in 2013–2016). The high rate among young individuals is particularly alarming.

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Less than one half (4.8 out of 11.3%) of participants aged 45–69 tested positive for T2DM, and only one in the age group 25–44 years knew he/she had diabetes. This indicates a lack of knowledge among Siberians about their problem with diabetes.

CONCLUSION. Approximately one in five adults had IFG. Among the adult population aged 45–69 (in 2003–2005), 18.2% had IFG and 11.3% had T2DM. In individuals aged 25–44 years in 2013–2016, IFG was observed in 21.6%, and 2.2% had T2DM ($p \leq 0.05$).

KEYWORDS: diabetes mellitus; epidemiological study; undiagnosed diabetes mellitus; prevalence; Novosibirsk

The prevalence of type 2 diabetes mellitus (DM2) in Siberian Federal District (SFD) has not been adequately studied. SFD is a highly developed industrial and cultural district with a strong scientific potential. The region produces more than 20% of the country's industrial output. SFD includes following 12 constituent entities of the Russian Federation: the Republic of Altai, the Republic of Buryatia, the Republic of Tuva, the Republic of Khakassia, the Altai Territory, the Krasnoyarsk Territory, the Trans-Baikal Territory, Irkutsk, Kemerovo, Novosibirsk, Omsk and Tomsk regions. SFD covers an of 51450000 km2 (29% of the territory of Russia). The population of SFD in 2016 was 19,324,031, with 70.7% is urban population and 29.3% is rural population. The largest cities of the SFD include Novosibirsk, Omsk, Krasnoyarsk, Irkutsk, Barnaul, Novokuznetsk, Kemerovo, Tomsk, Ulan-Ude and Chita. There are 132 cities in the district territory. SFD has the population density of only 3.8 people per km2 and holds the penultimate place among the federal districts. However, the population of SFD is unevenly distributed over its territory. In the Kemerovo region, the population density is 31.6 people per km2, whereas in the north of the Krasnoyarsk Territory, it is 0.3–0.5 people per km2. Novosibirsk is the administrative centre of the district, which had a population of 1,584,138 in 2016 [1].

Since its beginning, the Institute of Therapy has been studying diabetes mellitus (DM) and other non-communicable diseases in different regions of Siberia by employing various methods [2, 3, 4]. Initially, official statistical analysis is performed according to patients' appealability. Since 1985, the Scientific Research Institute of Therapy has established a DM register for each of the Novosibirsk's administrative districts. The method of developing registers enables a fuller accounting of the number of DM patients through the analysis of some additional parameters. In the late 1990s, academician Dedov I.I., the main endocrinologist, along with a team of employees of the Ministry of Health and Social Development of Russia successfully implemented a nationwide state system of the registry of DM (Government decree of 07.10.96 No. 1171 on the federal target program Diabetes mellitus), which undoubtedly was a great achievement. The Novosibirsk city register of DM was enforced in 1999 and since 2002, has been a part of the State Register of DM [5]. To adequately evaluate actual DM frequency (prevalence) in the population, epidemiological research methods are used, particularly including screenings of representative population cohorts.

Comprehensive research on DM prevalence in Novosibirsk population was performed in 2003–2005. This research was included in part in the large international HAPIEE project (Determinants of Cardiovascular Diseases in Eastern Europe: a multicentre cohort study) [4]. The cohort included in this research continues to be monitored to date. Additionally, since 2013, the random representative sampling of the population of a typical Novosibirsk district (aged 25–44 years and including both sexes) is being conducted.

AIM

The study aimed to estimate DM2 prevalence in different age groups of the adult population of Novosibirsk according to results of epidemiological studies conducted in 2003–2005 and 2013–2016.

METHODS

STUDY DESIGN, CONDITIONS AND DURATION AND ACCEPTANCE CRITERIA

The city of Novosibirsk is a large and typical Siberian industrial centre. The overall population of 2 districts is 346000, with 96000 people aged 45–69 years. In 2003–2005, a representative population sample of men and women aged 45–69 years, who were residents of two typical administrative districts of Novosibirsk, was examined according to the framework of HAPIEE (the Principal Investigators were Professor Malutina S.K., MD and Nikitin Yu.P., Academician of RAS). These representative samples were selected according to tables of random numbers on the basis of a list of candidates to whom invitation letters were sent to undergo the examination. With a response (percentage of those who came for the examination) rate of 70%, 9360 people were examined [4].

During 2013–2016, 1331 participants, aged 25–44 years and including both sexes, were examined through the random representative population sampling of one of the typical districts of Novosibirsk.

DESCRIPTION OF MEDICAL INTERVENTION

The research protocols included interviews; assessment of social, demographic, and anthropometric data; and determination of biochemical indicators.

For the determination of glucose levels, blood was sampled from the ulnar vein using the EDTA tube, with participant in a sitting position, on an empty stomach after 10-h fasting. After centrifugation, the serum was stored in a low-temperature chamber (–70°C). Glycaemia levels were determined by enzymatic methods using standard BIOKON reagents using the biochemical analyser FP-901 LabSystem. Blood serum glucose was converted to plasma glucose using the following formula: plasma glucose (mmol/l) = –0.137 + 1.047 × serum glucose (mmol/l) (EASD, 2005). For DM2 diagnosis, the American Diabetes Association (ADA, 2003, 2013) criteria were used: fasting

blood glucose ≥ 7.0 mmol/l once after 8-h fasting [7]. Additionally, the DM2 group included patients with fasting blood glucose ⊠ 7.0 mmol/l at the time of the study, but who, according to medical histories, reported a diagnosis of DM2 with treatment. According to the World Health Organization (WHO) criteria adopted in 1999, impaired fasting glycaemia (IFG) is determined at a fasting glycaemia level of 6.1– 6.9 mmol/l, whereas according to the ADA criteria adopted in 2003 and 2013, IFG is determined at a fasting glycaemia level of 5.6–6.9 mmol/l; these criteria were used to determine IFG. [7, 8, 9] Normoglycaemia was assessed as a blood plasma glucose index of < 6.1 mmol/l [7].

ETHICAL EXPERTISE

This study protocol complies with the GCP standards and is approved by the local ethics committee of the Research Institute of Therapy and Preventive Medicine (Minutes No. 1 of 14.03.2002). All participants of the study signed the informed consent.

STATISTICAL ANALYSIS

All statistical analyses as well as databasing and automated quality control of information preparation were performed in SPSS V-13 package, The statistical significance of differences between the two groups was assessed using the Student's test (t) and that of differences among more than two groups was assessed using single-factor analysis of variance. The Pearson method ($\chi 2$) was used to compare qualitative characteristics. The obtained data in tables and in the text are presented as absolute (n) and relative values (%). Differences were considered as statistically significant at $p < 0.05$, very significant at $p \leq 0.01$ and highly significant at $p \leq 0.001$.

RESULTS

STUDY OBJECTS (PARTICIPANTS)

Among 9360 participants aged 45–69 years examined at the screening stage, no plasma glucose results were not available for 205 participants; thus, these participants were not included in the analysis. DM2 prevalence was examined in a representative sample of 9155 participants from Novosibirsk, including 4169 (45.5%) men and 4986 (54.5%) women.

PRIMARY RESULTS OF THE STUDY

According to the population screening data of 2003–2005, DM2 prevalence among the residents of Novosibirsk (1036 participants aged 45–69 years) was 11.3% as per to the above criteria (see Materials and Methods); prevalence among men was 11.0% (459 participants), whereas that among women was 11.6% (577 participants) ($p > 0.05$). Table 1 shows DM2 prevalence among the subgroups studied. DM2 Prevalence significantly increased with age (Table 1).

In 10.0% (911) of the participants, increased blood glucose levels of >7.0 mmol/l were detected, whereas in 1.3% (125) of the participants had previously been diagnosed with DM2 and had fasting glucose levels <7.0 mmol/l. In total, 3.4% (313) participants of the 10.0% (911) participants with increased blood glucose levels of >7.0 mmol/l were aware that they had DM2. Thus, overall 4.7% of the 11.3% participants with DM2 were aware of their disease. In the entire sample examined, the glucose levels above ≥ 11.1 mmol/l were determined in 2.4% (220) of the participants.

Therapy analysis was conducted with 315 participants, e who reported to be receiving antidiabetic drugs. In total, 82.9% (261) participants received oral antidiabetic drugs and observed dietary recommendations; the average blood glucose level in this group was 10.5 ± 3.7 mmol/l; 14.3% (45) participants received insulin therapy and observed dietary recommendations; the average blood glucose level in this group was 11.1 ± 1.7 mmol/l; 2.8% (9) participants received oral antidiabetic drugs and insulin therapy as well as observed dietary recommendations; the average blood glucose level in this group was 8.4 ± 2.6 mmol/l.

Among participants in the 45–69 year group with previously undiagnosed DM2, the mean fasting plasma glucose level was 8.8 ± 2.8 mmol/l, which was significantly lower than that in patients with previously diagnosed DM2 who received treatment (10.5 ± 3.9 mmol/l, $p = 0.015$).

Among the participants aged 45–69 years, IFG according to the 1999 WHO criteria (6.1–6.9 mmol/l) was detected in 18.2% (1667) participants and IFG according to the 2003 and 2013 ADA criterion (5.6–6.9 mmol/l) was detected in 44.2% (4051) participants.

During the screening, the participants were asked: 'Were you informed that you have diabetes mellitus?' Acceptable responses included (1) yes, I was informed or

Table 1. Prevalence of diabetes mellitus in men and women aged 45–69 years depending on the age of participants

Age, years	Men, %	Women, %	Both genders, %	P m/w
45-49	7.4	5.2	6.2	0.24
50-54	10.0	8.3	9.1	0.08
55-59	11.3**	11.5***	11.4***	0.85
60-64	11.7**	15.0***	13.5***	0.07
65-69	13.4***	16.4***	15.0***	0.13
45-69	11.0	11.6	11.3	0.35

Notes: *p < 0.05, ***p < 0.001; the statistical significance of differences in age ranges in comparison with the age range of 45–49 years; p m/w is the significance of differences between sexes.

Table 2. Awareness of DM2 depending on the age participants

Age, years	Men, %	Women, %	Both genders, %
45-49	18.4	45.6	31.6
50-54	31.3	43.8	37.4
55-59	26.5	49.6	39.2
60-64	38.7*	49.6*	45.3*
65-69	41.2**	54.7**	49.1**
45-69	33.3	50.2	42.7

Notes: *p < 0.05, ***p < 0.001; the statistical significance of differences in age ranges compared with the age of 45–49 years.

Table 3. Age characteristics of DM2 prevalence in men and women aged 25–44 years

Age, years	Men, %	Women, %	Both genders, %	P m/w
25-29	-	-	-	
30-34	2.4	0.7	1.6	0.208
35-39	2.1	1.8	2.0	0.853
40-44	7.7*	1.6	4.5*	0.006
25-44	3.5	1.1	2.2	0.006

Notes: *p = 0.03; the statistical significance of differences in age ranges compared with the age range of 30–34 years.

(2) no, I was not informed. The survey revealed that 43.0% of the respondents with DM2 were aware of the presence of diabetes mellitus. Women in the study reported being better informed regarding their disease than men (Table 2). With increased age, the awareness of the presence of DM2 increased in both men and women.

During an examination for the data validation of the age group of 25–44 years, no plasma glucose results were available for 125 of the 1331 participants examined at the screening stage; thus, they were not included in the analysis. Blood plasma glucose levels were determined in 1206 participants, including 579 (48%) men, and 627 (52%) women. DM2 prevalence according to the population screening data of 2013–2015 among participants aged 25–44 years was 2.2% (27 participants), which was higher among men [3.5% (20 participants)] than among women [1.1% (7 participants)] ($p \leq 0.05$). Table 2 shows DM2 prevalence in the subgroups studied. Of the 27 participants, 1 participant whose fasting plasma glucose level was ≥7 mmol/l was aware of the presence of DM2.

In the young age group (25–44 years), high IFG incidence was observed in 21.6% (261) participants according to the 1991 WHO criterion (6.1–6.9 mmol/l) and in 56.7% (684) participants according to the 2003 and 2013 ADA criterion (5.6–6.9 mmol/l) (Table 3).

SUMMARY AND DISCUSSION OF THE PRIMARY RESULTS

High DM2 prevalence (11.3%, without significant gender differences) was observed in Novosibirsk residents aged 45–69 years in 2003–2005.Our data are comparable with the data of the first national epidemiological cross-sectional study conducted in the Russian Federation (NATION) in 2013–2015 despite the use of different criteria for DM2 diagnosis (Figure 1) [10]. In a study in Novosibirsk region, the fasting plasma glucose index was used, whereas in the NATION study, glycosylated haemoglobin (HbA1c) was used. The use of the HbA1c criterion for DM diagnosis provides lower DM prevalence indices than the use of fasting plasma glucose or a 2-h oral glucose tolerance test [9]. Comparing DM2 prevalence among Novosibirsk residents aged 45–69 years in 2003–2005 with that reported in earlier population studies in Russia is not possible because age subgroups were not separately studied in these reports [11, 19].

With an increase in age, Novosibirsk residents experienced a significant increase in DM2 prevalence, which is 6.2% at the age of 45–49 years, with a maximum of 15.0% at the age of 65–69 years. Moreover, according to the NATION study, the highest DM2 prevalence of 13.6% was observed in participants aged 65–69 years. As the authors of the NATION study aptly noted, these findings are significant because this age group experiences a high prevalence of cardiovascular diseases, for which therapy becomes more complicated in the presence of concomitant DM [13-16].

In the age group of 45–54 years, DM2 is detected more frequently in men than in women; however, after 60 years of age, DM2 is detected more frequently in women than in men although the difference did not reach statistical significance. In the NATION study also, the age-adjusted DM2 prevalence showed no statistically significant difference. Additionally, the authors of the NATION study noted that when considering the individual age groups, a higher DM2 prevalence in women than in men was statistically significant only in individuals who were ≥60 years of age. This finding may be due to a systematic error associated with the survival rate of the age groups being analysed; the risk of death from cardiovascular disease is higher in men than in women [16-20].

Notably, among patients aged 45–69 years with previously undiagnosed DM2 and in those who had blood glucose levels of >7.0 mol/l during screening, the mean fasting plasma glucose level was 8.8 ± 2.8 mmol/l, which was significantly lower (10.5 ± 3.9 mmol/l, $p = 0.015$) than that in patients with previously diagnosed DM2 and who received treatment. The lower glucose levels in patients with previously undiagnosed DM2 are explained by a recent increase in glycaemia levels and inadequate antidiabetic therapy in those who received antidiabetic drugs [21].

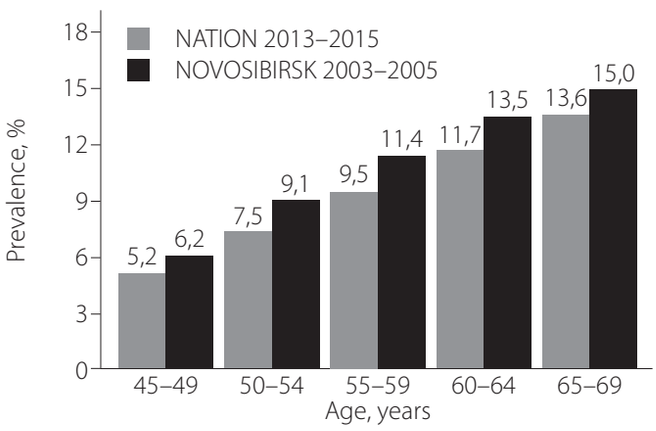

Fig. 1. Prevalence of type 2 diabetes mellitus in participants aged 45–69 years.

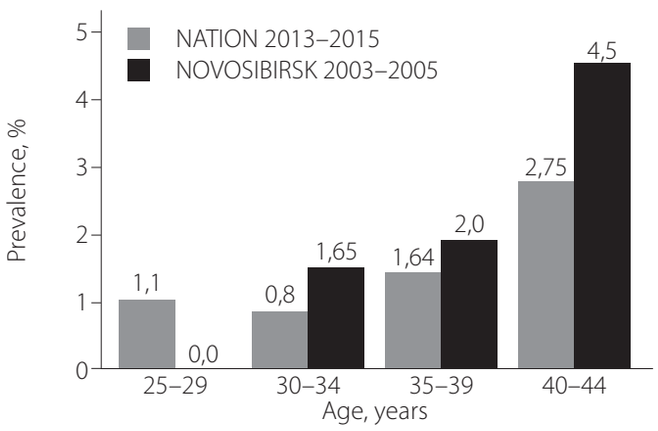

Fig. 2. Prevalence of type 2 diabetes mellitus in participants aged 25–44.

Among participants who were aware of DM2 presence, 18.8% (78) had blood glucose levels of <6.1 mmol/l, whereas 30% (124) had blood glucose levels of <7.0 mmol/l upon examination. Glucose levels of ≥11.1 mmol/l were determined in 13.4% (139) participants. Similar data have been reported in the NATION study, in which among participants with DM2, 19.3% participants had HbA1c levels of >9%.

Compared with the NATION study, a higher DM2 prevalence was noted in the 40–44years age group (Figure 2), which may be explained by the difference in DM2 diagnostic approaches. In contrast to the age group of <45 years, the age group of 25–44 years showed higher DM prevalence in men than in women(due to the subgroup of 40-44 years where it was 7.7 versus 1.6%). The resulting gender differences in DM2 prevalence should be confirmed through further analysis.

The average population value of fasting glucose levels in the whole sample for both sexes was 6.0 mmol/l. Despite the single determination of blood glucose, the generally accepted epidemiological criteria support the Novosibirsk population as a high-risk population for the development of DM

First, in 6.6% of the population aged 45–69 years, diabetes was detected at the first screening, which reflects the frequency of previously undiagnosed DM2.

Secondly, among the study participants, a high IFG prevalence was observed according to the 1999 WHO criteria (6.1–6.9 mmol/l) for the age group of 45–69 years (18.2%) and particularly alarming for the young age group of 25–44 years (21.6%). In the NATION study, prediabetes was revealed in 19.3% of the participants aged 20–79 years (HbA1c levels of 5.7%–6.5% with previously undiagnosed DM2).

Less than half (4.7% out of 11.3%) of the examined participants in the age group of 45–69 years and only 1 person in the age group of 25–44 year were aware of DM2 presence, indicating a lack of knowledge among Siberians regarding DM and its problem. Such low awareness regarding DM2 presence indicates a lack of alertness and a dominance of opinion among young patients that DM2 is a problem among elderly and senile patients. Similar data were also obtained in the Russian NATION study, in which the percentage of participants aged 20–79 years with previously undiagnosed DM2 was 54%.

According to the population screening in 2003–2005, among Novosibirsk residents aged 45–69 years, DM2 prevalence was 11.3%. DM2 prevalence was higher in older age groups, with a maximum frequency of 15% in the age group of 65–69 years. A comparison with DM2 prevalence reported in the NATION study enables the evaluation of the data obtained in the present Novosibirsk-based study as a representative for Russia.

CONCLUSION

According to the population screening data of 2013–2015, DM2 prevalence among the Novosibirsk residents aged 25–44 years was 2.2%, with higher prevalence in men (3.5%) than in women (1.1%) ($p \leq 0.05$). In the young age group, DM2 prevalence increases with age in men, reaching a maximum of 7.7% in the age group of 40–44 years. Compared with the data of the NATION study, a higher DM2 prevalence in the young age groups was noted, which may be explained by the difference DM2 diagnostic approaches.

DM2 prevalence in men and women aged 45–69 years did not reveal a statistically significant difference. In contrast to the participants examined at the age of 45 years in the age group of 25–44 years, DM prevalence was higher in men than in women (due to the subgroup of 40–44 years where it was 7.7 versus 1.6%). The resulting gender differences in DM2 prevalence need to be confirmed through further analysis.

Epidemiological screening enables researchers to reveal both registered cases and undiagnosed cases of DM, often 2 to 3 times greater. It is necessary to introduce a simpler and inexpensive variant of episodic screening examinations resulting in representative sampling useful for monitoring the epidemiological situation of the actual DM prevalence and its risk factors and for predicting and evaluating therapeutic and preventive measures.

The work toward population awareness and screening examinations should be introduced within younger groups of the population (i.e. before the age 40 years) with the intention of the early correction of carbohydrate disorders and primary prevention of DM and its complications.

ADDITIONAL INFORMATION

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Conflict of interest. The authors declare no obvious and potential conflicts of interest related to the publication of this article.

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Participation of authors. Mustafina S.V.: processing of statistical data, writing of Materials and methods and Results sections for the age group of 45–69 years, and data discussions. Rymar O.D.: writing the Introduction, Materials and methods, Results, and Discussion sections for the age group of 45–69 years. Malyutina S.K.: managing the screening of men and women aged 45–69 years in Novosibirsk and editing the text. Denisova D.V.: managing the screening of men and women aged 25–44 years in Novosibirsk and editing the text. Shcherbakova L.V.: databasing, statistical analysis, writing of the Materials and methods section, and design of the tables. Voevoda M.I.: data analysis, participation in writing of all sections.

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