ЭПИДЕМИОЛОГИЯ СИНДРОМА ДИАБЕТИЧЕСКОЙ СТОПЫ И АМПУТАЦИЙ НИЖНИХ КОНЕЧНОСТЕЙ В РОССИЙСКОЙ ФЕДЕРАЦИИ ПО ДАННЫМ ФЕДЕРАЛЬНОГО РЕГИСТРА БОЛЬНЫХ САХАРНЫМ ДИАБЕТОМ (2013–2016 ГГ.)

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ОБОСНОВАНИЕ. Изучение эпидемиологических характеристик синдрома диабетической стопы (СДС) представляет особую актуальность в связи с высоким риском ампутаций нижних конечностей у больных сахарным диабетом (СД).

ЦЕЛЬ. Оценить эпидемиологические характеристики развития СДС и ампутаций нижних конечностей у взрослых пациентов с СД 1 и 2 типа (СД1 и СД2) в РФ за период 2013–2016 гг.

МЕТОДЫ. Объектом исследования является база данных Федерального регистра СД – 81 региона РФ, включенных в систему онлайн-регистра. Оценивались показатели на 10 тыс. взрослых пациентов с СД (>18 лет).

РЕЗУЛЬТАТЫ. В 2016 г. распространенность СДС в РФ составила: СД1 – 4,7%, СД2 – 1,9%, с выраженными межрегиональными различиями – 0,15–19,9%, 0,07–10,3% соответственно. Распространенность СДС в РФ в динамике 2013→2016 гг. имеет тенденцию к снижению: СД1 – 506,3→473,6; СД2 – 214,60→194,8/10 тыс. взрослых. Динамика новых случаев СДС/год стабильна при СД1 – 20,8→20,4, отмечается рост при СД2 – 13,2→14,2. Средний возраст развития СДС увеличился на 2 года при обоих типах СД. Средняя длительность СД до манифестации СДС увеличилась: при СД1 – 15,4→19,0 лет, СД2 – 7,4→10,1 года. Соотношение различных форм СДС при СД1: нейропатическая с трофической язвой – 41,6%, нейропатическая (стопа Шарко) – 17,9%, нейроишемическая – 28,3%, ишемическая – 12,2%; СД2: 41,6%, 7,4%, 32,4%, 18,5% соответственно. Количество новых случаев ампутаций/год в динамике: СД1 – 10,5→12,4, СД2 – 9,6→10,9, с выраженной межрегиональной вариабельностью 0,13–2,9% при СД1, 0,04–6,0% при СД2. Средняя длительность СД до ампутации увеличилась: СД1 – 18,4→21,3 года, СД2 – 9,1→9,9 года. Средний возраст развития ампутаций: СД1 – 51,7 года, СД2 – 66,2 года. Отмечается уменьшение доли высоких ампутаций: СД1 – 43,6→37,0%, СД2 – 52,2→45,5% за счет перераспределения в пользу ампутаций в пределах одного пальца стопы: при СД1 – 4,0→10,0%, при СД2 – 2,8→ 9,1%.

ЗАКЛЮЧЕНИЕ. Динамика частоты новых случаев СДС у взрослых пациентов в РФ стабильна при СД1, при СД2 имеет тенденцию к повышению. Выраженные межрегиональные различия в частоте СДС и ампутаций между регионами могут быть обусловлены различиями в качестве оказания специализированной помощи, отсутствием или нехваткой кабинетов диабетической стопы, лечением пациентов с СДС в условиях общей хирургической практики в ряде регионов, что признано менее эффективной стратегией. Отмечается отчетливая положительная динамика уменьшения доли высоких ампутаций, развития СДС в более старшем возрасте и при большей длительности СД, что отражает повышение эффективности мер профилактики поражения нижних конечностей при СД.

КЛЮЧЕВЫЕ СЛОВА: сахарный диабет; Федеральный регистр сахарного диабета; синдром диабетической стопы; ампутации

TRENDS IN THE EPIDEMIOLOGY OF DIABETIC FOOT AND LOWER LIMB AMPUTATIONS IN RUSSIAN FEDERATION ACCORDING TO THE FEDERAL DIABETES REGISTER (2013–2016)

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BACKGROUND: The epidemiological study of diabetic foot (DF) is very important because of high risk lower limbs amputations in patients with diabetes mellitus (DM).

AIMS: The aim of the study was to evaluate the DF prevalence in adult patients with type 1 (T1) and 2 (T2) diabetes in Russian Federation for period 2013–16years.

METHODS: We have used the database of the Russian Federal Diabetes register, 81st regions included in the online register. Indicators were estimated per 10,000 adult DM patients (>18years).

RESULTS: In 2016, the prevalence of DF in RF was T1 4,7%, T2 1,9%, with marked interregional differences: 0,15–19,9%, 0,07–10,3%, respectively. The DF prevalence in RF decreased: T1 506,3→473,6, T2 214,60→194,8. The incidence of new DF

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cases/per year was stable in adults with T1: 20,8→20,4/; increased in T2 13.2→14.2. The mean age of DF diagnosis increased by 2years for both DM types. The average DM duration of DF determine increased T1 15.4→19.0years, T2 7.4→10.1years. Proportion of DF forms: neuropathic with trophic ulcer 41.6%, neuropathic form (Charcot's foot) 17.9%, the neuroischemic 28.3%, ischemic 12.2%, in T2: 41.6%, 7,4%, 32,4%, 18,5%, respectively. The amount of new cases of amputations/per year in dynamics: T1 10,5→12,4, T2 9,6→10,9, with marked interregional differences 0.13–2.9% in T1, 0.04-6.0% in T2. The mean DM duration before amputation increased in T1 18.4→21.3years, in T2 9.1→9.9. The average amputation age: T1 51.7years, T2 66.2years. There was marked decrease in proportion of major amputations: T1 43,6→37,0%, T2 52.2→45.5 by redistribution in one toe amputations T14,0→10.0%, in T22,8→ 9.1%.

CONCLUSIONS: The dynamic of new DF cases in adult patients in Russian Federation is stable at T1, in T2 tends to increase. The interregional differences in frequency of DF and amputations may be due to differences in the quality of specialized care, the lack or shortage of diabetic foot cabinets, treatment of patients with DF in general surgical practice in a number of regions, which is recognized as a less effective strategy. A positive fact that proportion of high amputations declines, DF develops in later age and longer diabetes duration, that may reflect the increasing effectiveness of preventive lower limbs in diabetes.

KEYWORDS: diabetes mellitus; the register of diabetes mellitus; diabetic foot; amputations

BACKGROUND

Monitoring the incidence of chronic complications of diabetes mellitus (DM) is one of the opportunities to evaluate the quality and dynamics of an organisation providing medical care for patients with DM. In 1989, the St. Vincent Declaration was adopted and supported by the European state governments [1]. This declaration defined primary directions to guide an organisation for caring patients with DM as well as responsibilities to aid the reduction of vascular complication incidences of DM by 50%, particularly lower limb amputations. However, till date, limited data are available on this subject.

Most studies related to the course of diabetic foot are devoted to the prevention of lower limb amputation, usually without an analysis of long-term results as well as the survival of patients with DM and diabetic foot. However, few studies analysing this indicatordemonstrate a poorer survival prognosis of patients with diabetic foot, especially those who underwent lower limb amputation, than that of patients with cancer [2]. Notably, life expectancy depends on the level of amputations; thus, the average survival term in the group of patients with DM undergoing minor amputations was 51 months, which was significantly higher than that in the group of patients with major amputations (40 months) ($p = 0.016$) [3]. Additionally, diabetic foot represents one of the most costly pathologies in terms of treatment cost. According to the International Diabetes Federation, treating patients with diabetic foot increases treatment cost by five times [4].

Hence, the study of the epidemiological characteristics of diabetic foot is of particular relevance, since its development poses an immediate threat of lower limb amputations in patients with DM, leading to loss of labour capacity, reduced quality and expectancy of life and increased public expenses on treatment. This study, to the best of our knowledge, is the first to present the frequency of diabetic foot development and lower limb amputation according to the level and form of lesion based on the analysis conducted by the Federal Registry of DM Patients (FRDM) of the Russian Federation.

AIM

This study aimed to assess the epidemiological characteristics of diabetic foot development and lower limb amputation in adult patients with type 1 and 2 DM over time during 2013–2016.

METHODS

This study targets the FRDM database of 81 regions of the Russian Federation, included in online registry system. The prevalence and incidence rates (new cases/year) of 10,000 adult patients with DM (> 18 years) in 2013–2016 were assessed.

The registration of the incidence of diabetic foot in the FRDM database was performed in accordance with the following modern classification of DM based on the 'Algorithms of specialized medical care' [5]:

- Neuropathic form of the diabetic foot
  - Trophic foot ulcer
  - Diabetic neuro-osteoarthropathy (Charcot foot)
- Ischaemic form of the diabetic foot
- Neuro-ischaemic form of diabetic foot

This classification was included in the FRDM database in 2015 after transition to the online format. In the former FRDM database, diabetic foot were classified according to the outdated classification into three forms: neuropathic with expression, neuro-ischaemic without expression and mixed. Furthermore, there were no technical possibilities for the cancellation of this diagnosis; thus, the diagnosis of diabetic foot, made using this format, was established for the life term.

Diagnosis of diabetic foot of any form implies the presence of ulcers on the lower extremities that must be treated by therapeutic or surgical methods (after amputation). The only chronic form of diabetic foot is diabetic neuro-osteoarthropathy (Charcot foot).

In 2015, the FRDM database was reconfigured to include the possibility of cancellation of diagnosis.

ETHICAL CONSIDERATIONS

The study protocol No. 20 of 14 December 2016 was approved by the Ethical Committee of Endrocrinology Research Centre.

RESULTS

In 2016, the frequency of registration of diabetic foot (all stages) in the Russian Federation was 4.7% for type 1

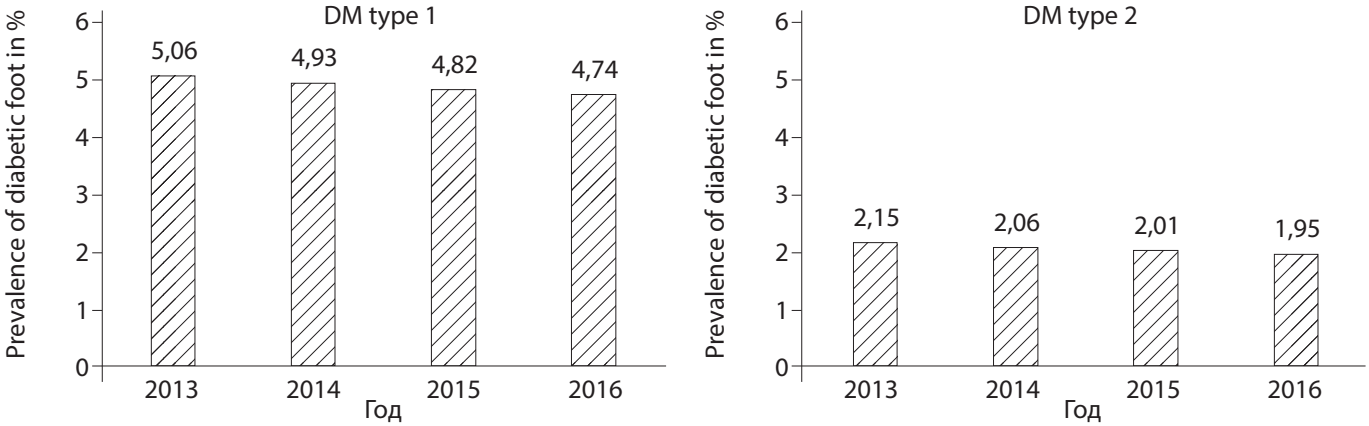

Fig. 1. Prevalence of diabetic foot (% of patients) in adult patients with DM1 and DM2 in 2013–2016 according to the FRDM database (81 regions of the Russian Federation)

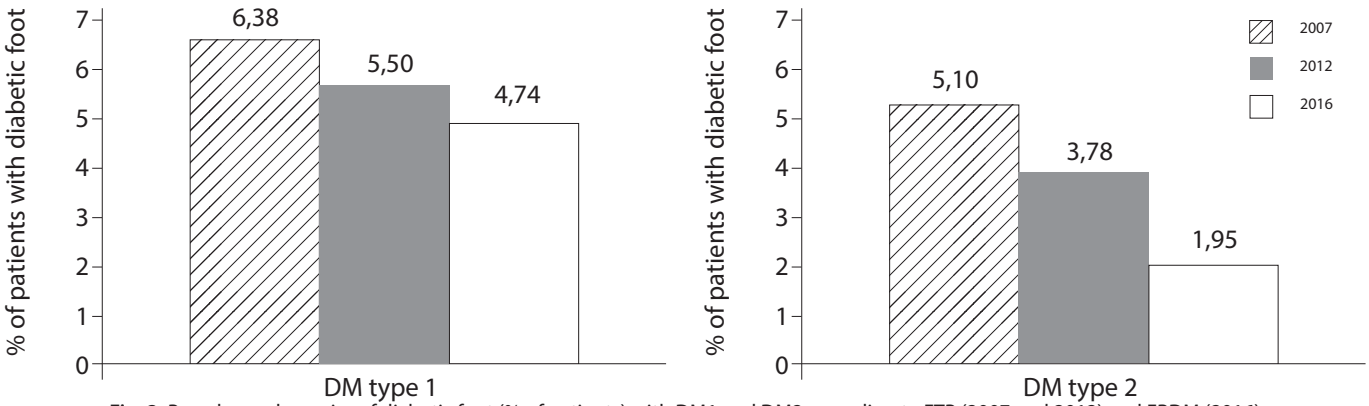

Fig. 2. Prevalence dynamics of diabetic foot (% of patients) with DM1 and DM2 according to FTP (2007 and 2012) and FRDM (2016)

DM (473.6 per 10,000 adult patients) and 1.9% for type 2 DM (194.8 per 10,000 adult patients). According to the Russian Federation, there was a slight decrease in the prevalence of diabetic foot in 2013–2016 (from 506.3 to 473.6 per 10,000 adult patients) with DM1 and from 214.60 to 194.8 per 10,000 adult patients with DM2 (Figure 1).

Additionally, a decrease in the prevalence of diabetic foot was noted in adult patients with DM1 and DM2 in the data from FRDM database compared with that from the Federal Target Program (FTP) 'Prevention and control of socially significant diseases 2007–2012' [6] (Figure 2).

According to the 2016 FRDM data, a significant interregional difference was observed in the frequency of registration of diabetic foot in adult patients with both DM1 and DM2: from 15/10,000 to 1987/10,000 adult patients with DM1 (Fig. 3) and from 7/10,000 to 1032/10,000 adult patients with DM2 (Fig. 4).

According to doctors, especially nonspecialists, diabetic foot has not been accurately defined. Usually, the diabetic foot is diagnosed by any changes in the foot of adult patients with DM, including the damage to the joints of the feet and lower leg, neuropathy without ulcers and without Charcot foot and a history of amputation surgery. Therefore, according to the FRDM database and screening data, the prevalence of diabetic foot can significantly vary [7]. Moreover, according to the survey specified in the mobile diagnostic module 'Diabetes Center', where all patients were examined by a specialist in the field of diabetic foot, the frequency of diabetic foot development was almost two times lower for both types of DM (5.8% vs 10.5% in DM1 and 3.97% vs 5.26% in DM2) [8].

Data on the frequency dynamics of new cases of diabetic foot per year, the mean development age and duration of DM before diagnosis of diabetic foot in adults are shown in Table 1. The incidence of new cases of diabetic foot in adult patients with DM1 was consistent (from 20.8 per 10,000 in 2013 to 20.4 per 10,000 adult patients in 2016), whereas an insignificant growth rate was observed in cases of patients with DM2 (from 13.2 to 14.2 per 10,000 adult patients).

The mean development age of diabetic foot (see Table 1) increased by 2 years for both adult patients with DM1 and those with DM2 (from 44.9 to 46.8 years in adult patients with DM1 and from 64.4 to 66.2 years in those DM2). Additionally, the average DM duration at which diabetic foot developed increased by 3.6 years from 15.4 to 19.0 years in adult patients DM1 and by 2.7 years from 7.4 to 10.1 years in those with DM2 (see Table 1).

In 2015, data on forms of diabetic foot was included in the FRDM database together with the modern classification of complications, with four forms of diabetic foot being excluded [5]. In 2016, the major form of diabetic foot was identified as neuropathic with a trophic ulcer (41.6% of cases of adult patients with DM1 and those with DM2), neuropathic (Charcot foot; 17.9% in adult patients with DM1 and 7.4% in those with DM2), neuro-ischaemic (28.3% in adult patients with DM1 and 32.4% in those with DM2) and ischaemic (12.2% in adult patients with DM1 and 18.5% in those with DM2) (Figure 5).

The prevalence dynamics of amputations indicated a slight increase in new cases of amputations per year in the analysed period (from 10.5 to 12.4 per 10,000 adult patients with DM1 and from 9.6 to 10.9 per 10,000 adult

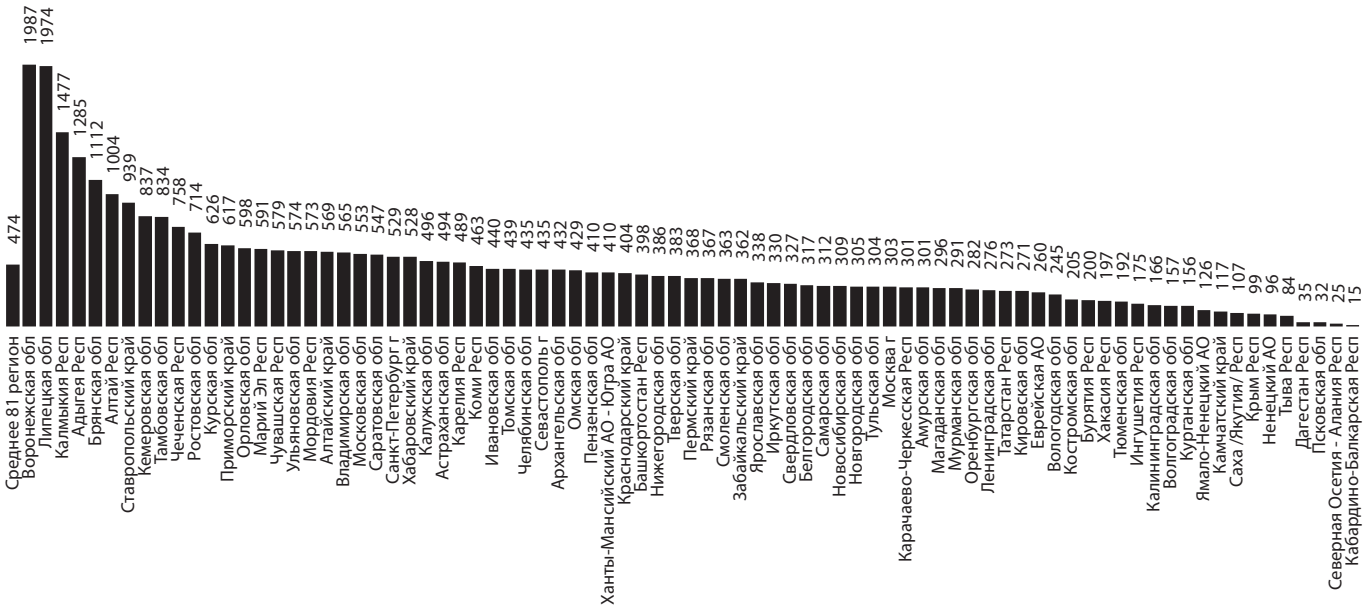

Fig. 3. Prevalence of diabetic foot in Russian regions (per 10,000 adult patients with DM1), as obtained from the FRDM database of 81 regions of the Russian Federation, 2016

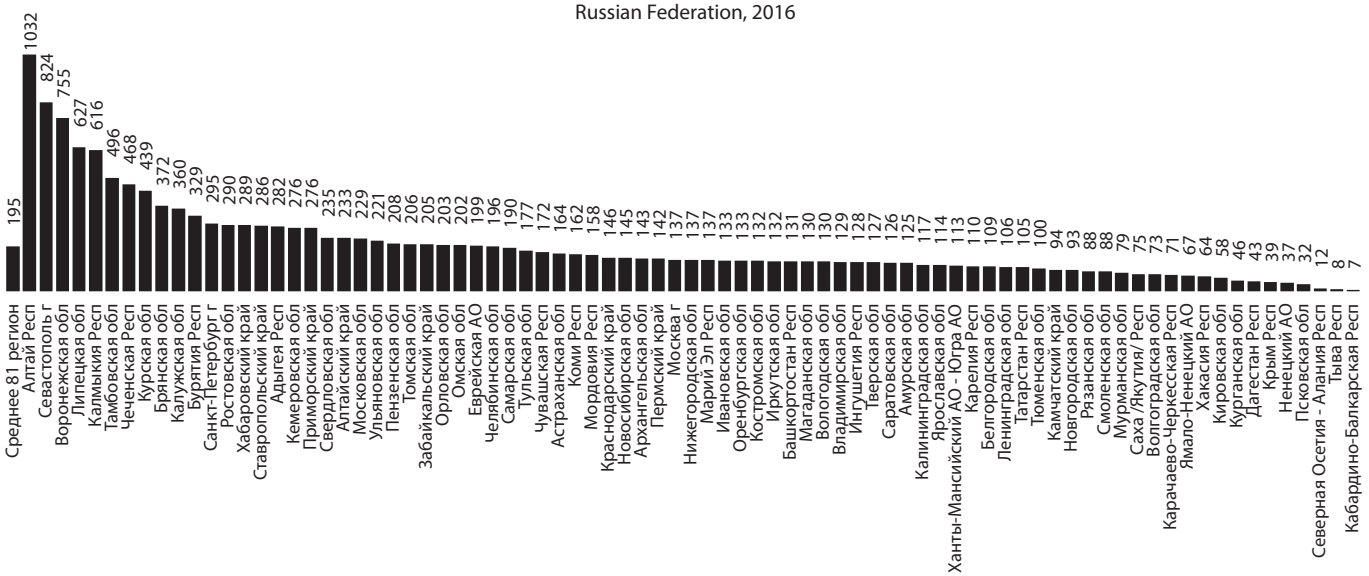

Fig. 4. Prevalence of diabetic foot in the regions of the Russian Federation (per 10,000 adult patients with DM2), as obtained from the FRDM database of 81 regions of the Russian Federation, 2016

Table 1. Data on the frequency dynamics of diabetic foot (new cases per year), average DM duration before the development of diabetic foot and amputations, average development age of diabetic foot and amputations in adult patients with DM1 and DM2 in 2013–2016, according to the FRDM database

Index	DM1				DM2			
	2013	2014	2015	2016	2013	2014	2015	2016
New cases of diabetic foot per 10,000 adult patients (n)	20.8	20.0	18.9	20.4	13.2	13.5	14.3	14.2
Average development age of diabetic foot, years	44.9	44.1	45.9	46.8	64.4	64.5	65.0	66.2
Average DM duration at which diabetic foot develops, years	15.4	15.2	17.5	19.0	7.4	7.8	8.5	10.1
Average DM duration before amputation, years	18.4	20.5	21.9	21.3	9.1	9.5	9.9	9.9
Average development age of amputations, years	51.4	52.3	51.5	51.7	65.9	66.4	66.0	66.2

patients with DM2) (Fig. 6). Additionally, a significant interregional variability was observed in the frequency of amputations: from 2.9 to 0.13% for adult patients with DM1 (in four regions, no amputations were recorded) and from 6.0% to 0.04% for those with DM2 (Fig. 7, 8).

The average duration of DM before amputation increased in adult patients with DM1 from 18.4 to 21.3 years, whereas it increased in adult patients with DM2 from 9.1 to 9.9 years (see Table 1). The average development age of amputations was consistent in adult patients with DM1 and in those with DM2 with 51.7 years in 2016 (51.4 in 2013) and 66.2 years in 2016 (65.9 in 2013), respectively (see Table 1).

Figure 9 presents data on frequency dynamics of amputations in adult patients with DM1 and those with

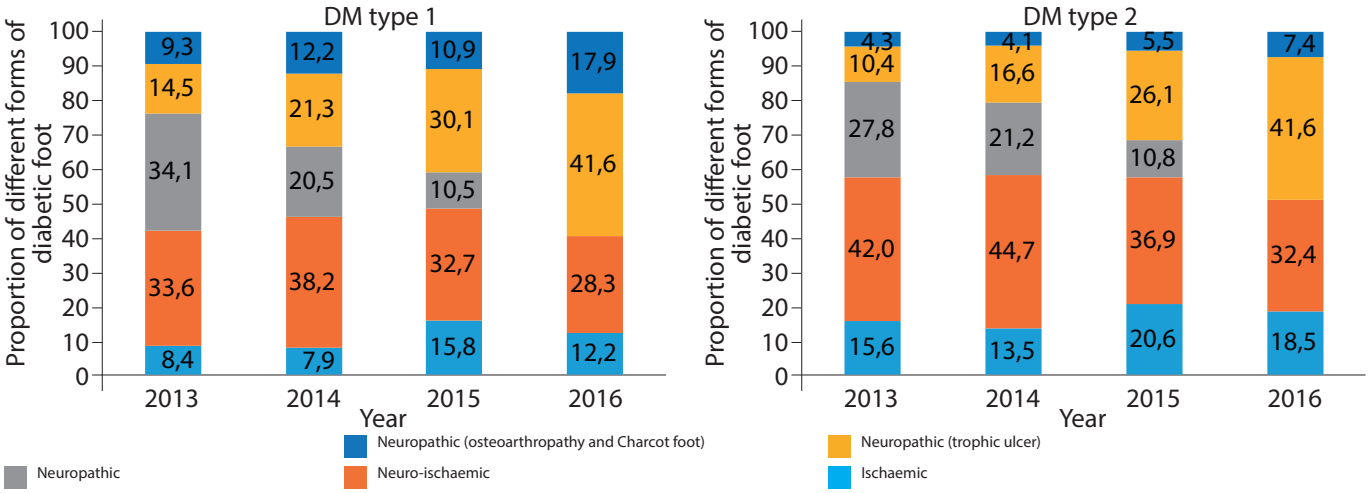

Fig. 5. Ratio of different forms of diabetic foot in adult patients with DM1 and those with DM2 in the dynamics of 2013–2016 obtained from the FRDM database of 81 regions of the Russian Federation

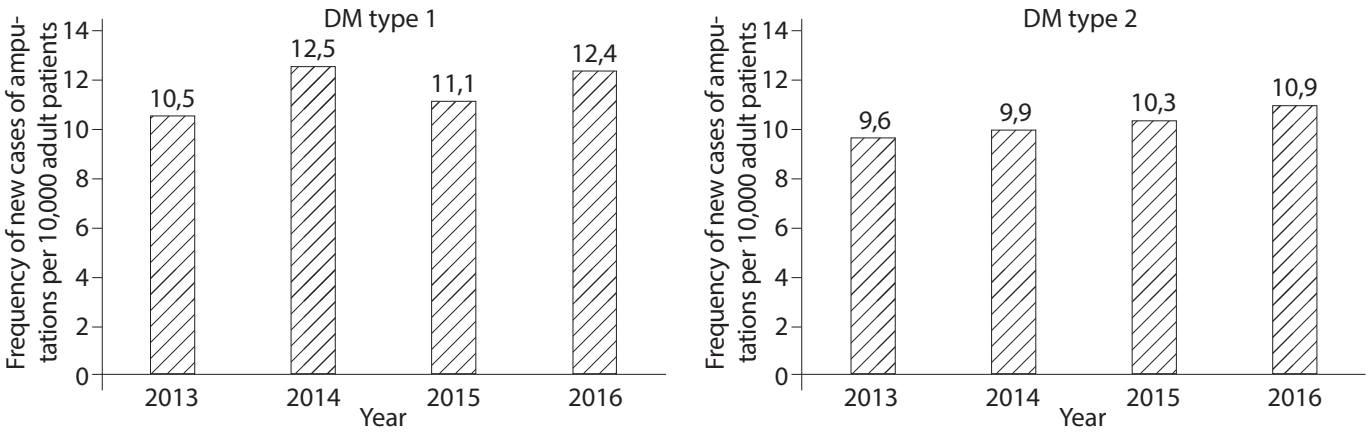

Fig. 6. Data on frequency dynamics of new cases of amputations per year per 10,000 adult patients with DM1 and those with DM2 in 2013–2016 obtained from the FRDM database of 81 regions of the Russian Federation

DM2 in 2013–2016. There was a positive dynamics with a decreased incidence of amputations for both types of DM, from 43.6% in 2013 to 37.0% in 2016 in adult patients with DM1 and from 52.2% in 2013 to 45.5 % in 2016 in those with DM2, due to the redistribution of the ratio in favour of small surgical interventions. The incidence of minimum amputations within one finger increased from 4.0% in 2013 to 10.0% in 2016 in adult patients with DM1 and from 2.8% to 9.1% in adult patients with DM2, respectively. In this case, the ratio of amputations within the foot and at the level of the tibia remained constant. These data demonstrate an improvement in the quality of care for patients with diabetic foot with improved performance of organ-preserving surgeries in the early stages of development of lower extremity lesions.

DISCUSSION

For optimising the FRDM framework, unified requirements were adopted to determine chronic complications of DM [9]. This enabled the acquisition of more reliable information and, in combination with the improvement of the completion quality of documentation related to the FRDM database, minimisation of subjective factors affecting the variability of data for individual regions.

In 2016, data on incidence dynamics of lower limb amputations in patients with DM in 26 countries of the European Organisation for Economic Co-operation and Development from 2000 to 2011 were first published. According to these data, the number of amputations decreased from 13.2 (average, 5.1–28.1) in 2000 to 7.8 (average, 1.0–18.4) per 100,000 patients in 2011. In 2011, 216 amputations per day, or one amputation every 7 min, were performed, which was 40% lower than those in 2000. Simultaneously, a significant variability in data for the European Union (EU) countries was also observed, with the highest rates in Germany (18.4 per 100,000 patients) compared with those in Hungary (1.1 per 100,000 patients) [10]. This variability was due to the following reasons: various ways of coding medical services, significant differences in the prevalence of DM, different levels of specialised medical care and the quality of information collection. A significant limitation of the data presented includes the estimated figure per 100,000 of the population as a whole, without the exception of traumatic amputations and a special focus on the population of patients with DM. Reportedly, the probability of amputation in patients with DM is significantly higher than in the population as a whole. Nevertheless, this work illustrates the need to improve methods of collecting objective information and its importance in improving the quality of organisations providing diabetes care in general and, particularly, the EU countries.

As previously reported in the literature, data on the

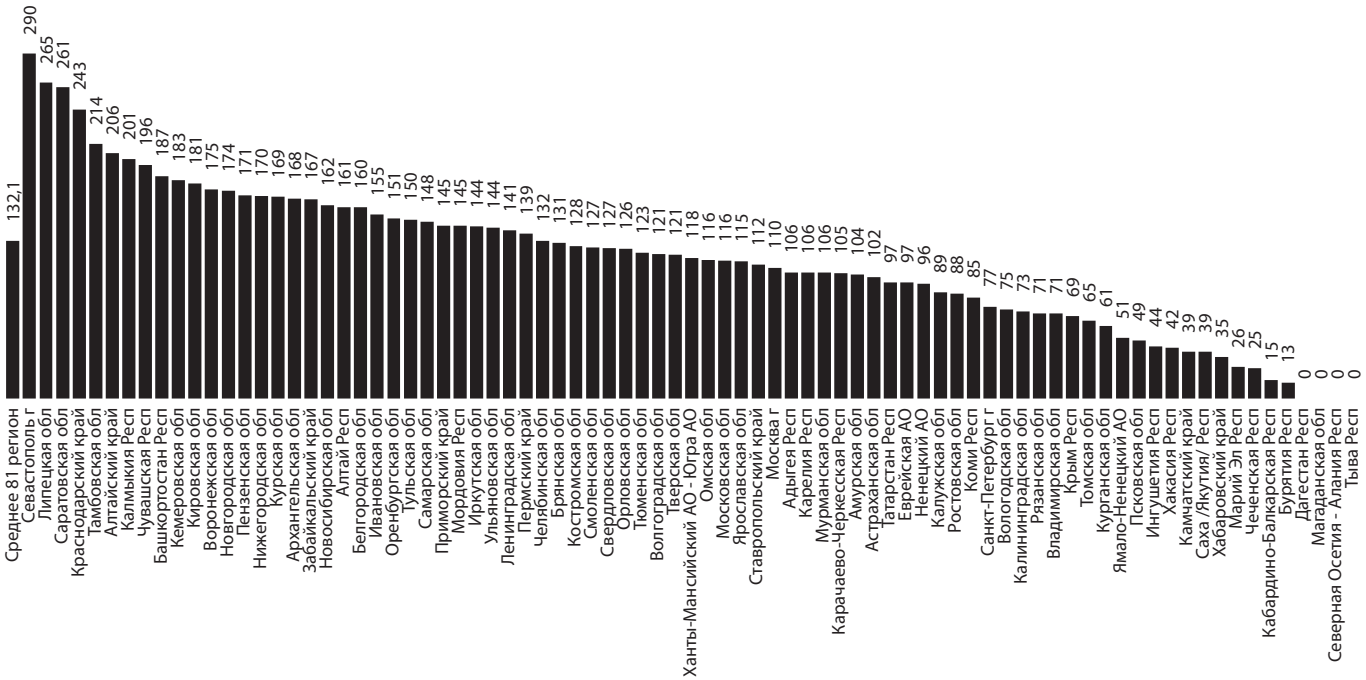

Fig. 7. Prevalence of lower limb amputations in the regions of the Russian Federation (per 10,000 adult patients with DM1) obtained from the FRDM database of 81 regions of the Russian Federation, 2016

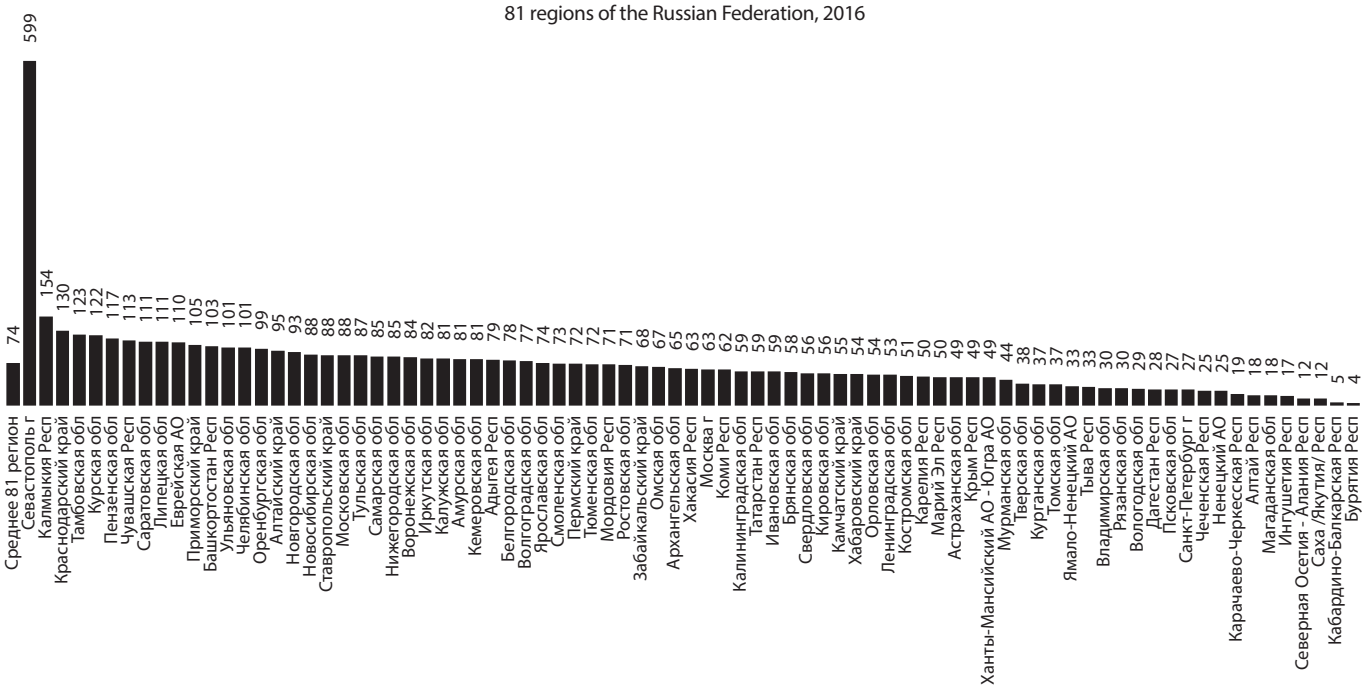

Fig. 8. Prevalence of lower limb amputations in the regions of the Russian Federation (per 10,000 adult patients with DM2) obtained from the FRDM database of 81 regions of the Russian Federation, 2016

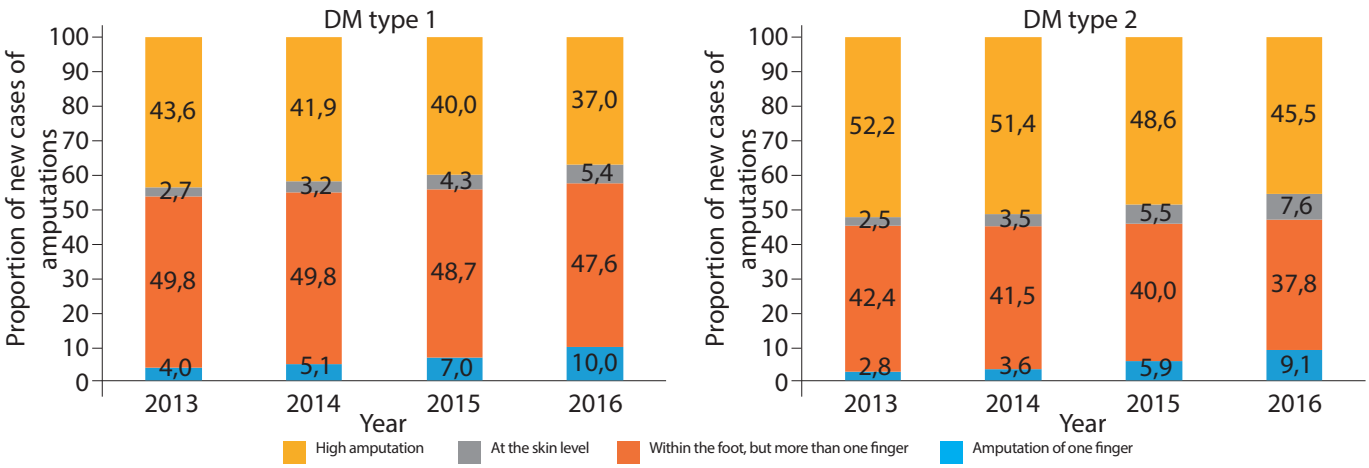

Fig. 9. Amputation distribution (% of patients) in adult patients with DM1 and in those with DM2 in 2013–2016 according to the FRDM database obtained from 81 regions of the Russian Federation

frequency of new cases of amputation in patients with DM also showed high variability (from 46.1 to 9600 per 100,000 patients with DM) compared with data that of new cases of amputation in the general population (3.6–31 per 10,000 people) [11].

In some EU countries, the frequency of amputations in patients with DM was assessed at the national level. These data serve as outcome indicators for the development of diabetic foot and, accordingly, evaluate the quality of the organisations providing specialised care for patients with DM and with this type of complication. Thus, data on the dynamics of the Finnish national registry, which includes 396,317 patients with DM, enabled the monitoring of the service state during 1997–2007. Additionally, frequency data of minor and major amputations as well as a 2-year survival period after minor amputations with a preserved limb were used as indicators of regional differences in the quality of care. A total of 13,469 lower limb amputations in patients with DM were recorded during the study period. The frequency of the first high amputation corrected for the population decreased over the analysed period from 10.0 [95% confidence interval (CI), 9.6–10.5] to 7.3 (95% CI, 6.9–7.6) ($p < 0.001$), and the ratio of low to high amputations increased from 0.86 (0.8–0.92) to 1.35 (1.26–1.46) ($p < 0.001$) [12]. The major finding of this study was the considerable variability in the data, depending on the coverage area of the specialised service, particularly, the positive dynamics in the regions that were the responsibility of university clinics.

Thus, despite the considerable variability in data, the first attempt to analyse FRDM data as well as international data identified a reduction of high amputations for patients with DM1 as well as those with DM2, which indicates an improvement in the quality of care for patients with diabetic foot in the Russian Federation. The pronounced interregional differences in the frequency of registration of diabetic foot and amputations may reflect differences in the quality of both registry management and specialised care within regions, which include managing patients with diabetic foot in general surgical practice without the involvement of endocrinologists and the absence or lack of rooms and departments of diabetic foot. With the improvement in the quality of the FRDM database filling and the information received, constant monitoring of regional databases is warranted. Effective, standardised methods of data collection could contribute to the procurement of more reliable information and the deduction of timely conclusions regarding the necessary efforts to create or change a specialised service for assisting patients with DM with high risk of amputations. Therefore, attention should be paid to the data on increased incidence of new cases of amputations for both DM types on an average in the Russian Federation, which requires further analysis of the probable causes and the development of targeted actions to improve the situation.

CONCLUSION

Frequency dynamics of new cases of diabetic foot in adult patients with DM was found to be consistent in those with DM1 but increased in those with DM2, based on the FRDM data of the Russian Federation in 2013–2016. One of the advantages is the development of diabetic foot at a later age and a longer duration of DM, which reflects an improvement in the quality of patient management by endocrinologists and an increase in the efficiency of prevention of lower limb injuries.

The disadvantages include increased incidence of the frequency of amputations in both types of DM on an average in the Russian Federation. An analysis of the possible causes requires additional research. Nevertheless, the marked interregional differences in the frequency of registration of diabetic foot and amputations may reflect differences in both the registry maintenance and specialised care provision in regions; this includes managing patients with diabetic foot under conditions of general surgical practice in a number of regions, which is considered a less effective strategy, and the absence or lack of rooms and departments of diabetic foot. A distinct positive dynamics was observed regarding a decrease in the proportion of high amputations for patients with DM1 and those with DM2 due to the redistribution of the ratio in favour of minor surgical interventions, which shows an improvement in the quality of care for patients with diabetic foot in the Russian Federation in the recent years. Improving the quality of database filling and constant monitoring of regional databases enables improvement in the quality of the information received.

ADDITIONAL INFORMATION

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