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Проблемы вакцинации от новой коронавирусной инфекции при ревматических болезнях

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Обоснование. Ограничение распространения новой коронавирусной инфекции среди пациентов с ревматическими заболеваниями является одной из приоритетных задач современной ревматологии. Вакцинация может быть одним из способов решения этой задачи.

Цель исследования — на основании данных, полученных в ходе реальной клинической практики, и материалов, опубликованных в периодической печати, оценить результаты вакцинации пациентов с ревматическими заболеваниями против COVID-19.

Материалы и методы. Проведен анализ 68 статей, представленных в рейтинговых медицинских журналах, и данных Санкт-Петербургского регистра пациентов с ревматическими заболеваниями по состоянию на 01.09.2021 ($n = 16\ 263$) для оценки эффективности и безопасности вакцинации от COVID-19. Сравнены показатели регистра с популяционными данными Минздрава России по заболеваемости и смертности от новой коронавирусной инфекции.

Результаты. Несмотря на наличие у ревматологических пациентов показателей, сопоставимых с популяционными показателями заболеваемости COVID-19 (26,2 и 34,1 % соответственно) и смертности от новой коронавирусной инфекции (3,47 и 2,8 % соответственно), пациенты с ревматическими заболеваниями демонстрируют втрое меньшую частоту вакцинации от COVID-19 (13,2 против 31,8 % в популяции на 01.09.2021). Причем по рекомендации ревматолога пациенты вакцинировались в 8,2 % случаев, а 75,2 % ревматологических пациентов прошли вакцинацию по своей инициативе. Анализ данных 2134 ревматологических пациентов, вакцинированных до 01.09.2021, продемонстрировал снижение заболеваемости новой коронавирусной инфекцией до 0,25 % у вакцинированных больных по сравнению с заболеваемостью невакцинированных пациентов (25,6 %) при отсутствии смертельных исходов среди привитых. Тяжелые нежелательные реакции на прививку среди вакцинированных ревматологических пациентов не зарегистрированы. У 12 % привитых отмечены пирогенные поствакцинальные реакции, артралгии и миалгии, 11 пациентов продемонстрировали затяжную пирогенную реакцию, миалгии, артралгии, повышение креатинфосфокиназы, разрешившиеся в течение 6 мес. Обострения основного ревматического заболевания легкой и средней степеней тяжести после вакцинации отмечены в 12 % случаев, все обострения устранены при помощи стандартной тактики, рекомендованной Ассоциацией ревматологов России.

Вопросы о сроках и необходимости ревакцинации, а также о долгосрочной эффективности и безопасности вакцинации не решены. Определение уровня антител к коронавирусной инфекции может быть использовано в формировании индивидуальных планов вакцинации ревматологических пациентов.

Выводы. Данные регистра показывают эффективность и безопасность вакцинации от COVID-19 ревматологических больных в краткосрочной перспективе, в том числе в отношении обострения ревматического заболевания, и обуславливают необходимость соблюдения мер эпидемиологической безопасности после вакцинации.

Ключевые слова: новая коронавирусная инфекция; COVID-19; вакцинация; ревматические болезни; инфекция; ауто-иммунные болезни.

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Problems associated with new coronavirus infection vaccination in patients with rheumatic diseases

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BACKGROUND: Decreasing new coronavirus infection-associated morbidity and mortality among patients with rheumatic diseases is one of the main goals of current rheumatology. Vaccination may be one of the ways to limit the incidence of new coronavirus infection in patients with rheumatic diseases.

AIM: To evaluate the results of vaccination in the patients with rheumatic diseases against the new coronavirus infection according to the data from real clinical practice and a review of the literature.

MATERIALS AND METHODS: 68 out of 556 literary medical sources and data from the St. Petersburg register of patients with rheumatic diseases as of September 1, 2021 ($n = 16,263$) have been analyzed. The data from the register have been compared with the population data on morbidity and mortality from a new coronavirus infection (data of the Ministry of Health of the Russian Federation).

RESULTS: Despite the matched incidence rates of new coronavirus infection associated mortality and morbidity in rheumatological patients and population (morbidity 26.2 and 34.1% mortality 3.47 and 2.8%, respectively), the patients with rheumatic diseases demonstrate three times lower frequency of vaccination against new coronavirus infection (13.2% of patients versus 31.8% in the population, respectively). Vaccination is prescribed by rheumatologists in 8.2%; 75% of patients are self-vaccinated. Data analysis from 2,134 rheumatological patients vaccinated in 2021 have shown a decrease in the incidence of the new coronavirus infection to 0.25% compared to the incidence of unvaccinated patients (25.6%) in the absence of deaths among the vaccinated. There were no serious adverse reactions to vaccination among the vaccinated rheumatological patients; in 12% of the cases, pyrogenic post-vaccination reactions, arthralgias and myalgias have been noted. A prolonged pyrogenic reaction, myalgia, arthralgia, hypercreatinophosphataemia have been revealed in 11 patients, who recovered within 6 months. Exacerbations of the underlying rheumatic disease after vaccination has been revealed in 12% of the cases, all the exacerbations have been resolved with the use of standard tactics recommended by the Association of Russian Rheumatologists.

The question of the timing and the necessity of revaccination, as well as the long-term efficacy and safety of vaccination, has not yet been resolved. Determining the level of antibodies to coronavirus infection can be a useful option in the formation of an individual vaccination plan for rheumatological patients in the present conditions.

CONCLUSIONS: The register data show the efficacy and safety of vaccination against COVID-19 in rheumatological patients in the short term, including in relation to exacerbation of rheumatic disease, and justify the need to comply with epidemiological safety measures after vaccination.

Keywords: new coronavirus infection; COVID-19; vaccination; rheumatic diseases; infection; autoimmune diseases.

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BACKGROUND

Limiting the spread of a coronavirus disease-2019 (COVID-19), which turned into a pandemic, is a priority of our time, which changed all aspects of people's lives [1, 2]. Despite progress in understanding the pathogenesis of COVID-19 and the application of national and international recommendations for its treatment, which include genetically engineered biological therapies, low levels of mortality and disability among those affected have not yet been achieved. The unprecedented epidemiological measures taken to limit the spread of the virus (including due to non-compliance with anti-epidemic measures by part of the population) cannot be considered fully effective because COVID-19 morbidity continues to have a wave-like pattern. COVID-19 control should mainly focus on increasing the number of persons who are vaccinated and develop herd immunity. The currently organised COVID-19 vaccination, in contrast to the preventive seasonal vaccination of the population, is conducted for the first time for a pandemic viral infection. The above provisions suggest that collecting data on the efficacy and safety of different COVID-19 vaccines is a high priority. The information obtained will help fight the pandemic more effectively, and the experience gained will be useful in future epidemiological situations similar to the present one [3, 4].

While COVID-19 vaccination has a strong evidence base, data on its use in patients with autoimmune rheumatic diseases receiving immunosuppressive therapy are limited. This determines the need for registers to assess the efficacy and safety of COVID-19 vaccination in patients with rheumatic diseases. Studying vaccination in patients with musculoskeletal diseases is important owing to their high prevalence and frequent development of comorbidities.

While international registers showed no tendency for COVID-19 to aggravate the course of patients with rheumatic diseases [5–7], the need for COVID-19 vaccination of such patients in the United States, United Kingdom, European Union and Korea is highly accepted by experts [7–9]. In 2021, the first evidence from real clinical practice on the safety of COVID-19 vaccination of patients with rheumatic diseases appeared [7–10]. However, these vaccines are not used in Russia [7–10]. Thus, the need to investigate the efficacy and safety of vaccination of Russian patients with rheumatic diseases was the prerequisite for this study.

The **aim of the study** was to evaluate the results of vaccinating patients with rheumatic diseases against COVID-19 according to real clinical practice data and review of the literature.

MATERIALS AND METHODS

This paper is presented in two parts:

- *Analysis of COVID-19 vaccination data* according to PubMed, MedLine and eLibrary databases. Search words

and phrases used were as follows: COVID-19, vaccination, coronavirus, rheumatic diseases and autoimmune diseases. Papers written in languages other than Russian or English and materials that did not contain access to the full text and did not correspond to the main aim of the study were excluded from the analysis.

- *Analysis of our data* on the specifics of vaccination against COVID-19 of patients at the Clinical Rheumatology Hospital No. 25, a rheumatology centre in St. Petersburg. Data were collected for the period from March 1 to September 1, 2021.

After receiving patients' informed consent to participate in the study, data on patients with rheumatological conditions were transferred to the St. Petersburg register of patients with rheumatic diseases from the Ariadna Medical Information System of the Clinical Rheumatology Hospital No. 25. All materials included in the register were anonymised and did not allow identification of personal patient data. The register included data on nosological forms of rheumatic diseases and their activity. Data on COVID-19, its duration and outcomes were collected separately. The indications for COVID-19 vaccination of patients, type of the vaccine used, presence and severity of adverse reactions after vaccination, timing of their occurrence and licences were examined. Simultaneously, cases of rheumatic disease exacerbations after vaccination and their peculiarities were registered. Some patients voluntarily filled out additional questionnaires about the social and medical aspects of vaccination and its acceptability. Data on deceased patients were collected from autopsy reports. Statistical data processing was performed using the SPSS Statistics for Windows version 17 (SPSS Inc., Chicago, IL, USA) software package and descriptive statistics methods. Differences were considered significant at $p < 0.05$.

RESULTS

1. Literature analysis

Among the available 556 references, 5 papers were devoted to rheumatic disease vaccination. One of the studies presented the vaccination results of 118 patients with rheumatic diseases, whereas others described data on vaccination and the frequency of exacerbations of rheumatic diseases [7–11]. A total of 488 papers were excluded from the analysis according to the exclusion criteria.

The analysis of medical databases allows to conclude that the incidence of COVID-19 in patients with rheumatic diseases (without distinguishing individual nosological forms) does not differ from the general population [12–15]. Data from seven rheumatology centres in Spain indicate that the odds ratio of COVID-19 in rheumatic diseases is 1.31 [13]. Other registers demonstrate similar data

[12–15]. By contrast, some studies in Italy and the United States have shown that patients with autoimmune diseases (e.g., systemic lupus erythematosus) fall ill more frequently if exposed to an infected patient than their healthy relatives (67% versus 34%) [6, 16]. The question is which of the results that are comparable to Russian data should be investigated. Generally, the number of studies showing no differences in the incidence of COVID-19 with and without rheumatic diseases prevails [1, 2, 5, 6, 12, 14, 15].

Importantly, many studies have shown that the severity of COVID-19 in patients with rheumatic diseases does not differ from that in individuals without such pathologies, as measured in the general population of patients with rheumatological diseases [1, 17–20]. However, patients with certain nosological forms (systemic lupus erythematosus, systemic sclerosis and vasculitis) showed a higher rate of hospitalisations and a more severe course of COVID-19 [1, 17–20]. Patients with drug-induced immunosuppression had a longer period of virus elimination, according to standard polymerase chain reaction, than the general population [12].

The evidence of the lack of difference in the incidence and course of COVID-19 in patients with rheumatological diseases and general population was the first prerequisite that allowed experts from different countries to suggest that patients with rheumatic diseases have no additional risks when vaccinated against COVID-19, whereas the efficacy of COVID-19 vaccination has not yet been well evaluated and should be further studied. The few published papers on the vaccination of patients with rheumatological diseases have emphasised that by the end of 2021, the optimal approaches to vaccine selection remained unknown, the most effective administration regimens were not specified and re-vaccination or booster administration of vaccines to patients with rheumatic diseases was an open question [4, 7–9, 21, 22]. Prior to January 2021, only one study [11] indicated that 118 of 43,000 patients with rheumatic diseases (not specified) included in the register were vaccinated. However, data on the efficacy and safety of vaccination of these patients were not presented, which some authors regarded as an indication of the lack of specific safety signals in that sample [9, 11].

In October 2021, Li et al. presented data from a Hong Kong register that included 5,493 patients with rheumatoid arthritis; of these patients, 653 were vaccinated with BNT162b2:671 (CoronaVac, 4). However, no significant association between rheumatoid arthritis exacerbations and COVID-19 vaccination was found in the Hong Kong register. For BNT162b2 and CoronaVac vaccines, the adjusted incidence ratios were 0.86 (95% confidence interval [CI] 0.73–1.01) and 0.87 (95% CI: 0.74–1.02), respectively. In addition, that paper did not report an association between the frequency of rheumatoid arthritis exacerbations with

COVID-19 vaccination and the antirheumatic treatment received ($p > 0.1$ for all) [10].

Several studies on vaccination of patients with rheumatological disease have analysed RNA-containing peptide and vector vaccines. However, the authors did not specify which vaccine was preferable for patients with rheumatic diseases [8, 9, 11].

The main COVID-19 vaccines currently prescribed are presented in Table 1.

In addition to the choice of vaccine, the effect of antirheumatic therapy on the outcome of vaccination, its efficacy and safety is important. Thus, treatment with synthetic disease-modifying drugs does not significantly affect the vaccination outcome (e.g., treatment with methotrexate can be interrupted for 2 weeks before and after vaccination). Similarly, low doses (<10 mg/day) of glucocorticoids have no significant effect on the antiviral immunity after vaccination, whereas high doses may reduce the immune response to the vaccine. Therefore, a reduction of the prednisolone dose to <10 mg/day is recommended, if the clinical situation allows [1, 5].

According to the decision of the Association of Rheumatologists of Russia, a patient with immunoinflammatory rheumatic diseases who receives anti-inflammatory drugs should follow the recommendations given below:

- Stop taking methotrexate for 2 weeks after each vaccination.
- Skip taking targeted synthetic basal anti-inflammatory drugs (mycophenolate mofetil and cyclophosphamide) for 1 week after each vaccination.
- Skip taking abatacept subcutaneously for 1 week before and 1 week after the first dose of the vaccine; the second dose should be given without changes.
- Skip taking abatacept intravenously for 4 weeks before and 1 week after the first dose of the vaccine; the second dose should be given without changes.
- Start vaccination after 12 weeks (minimum) to 6 months (optimal) from the last rituximab injection and 4 weeks before the upcoming infusion [1].

Genetically engineered biologics (except rituximab) are not known to affect the post-vaccination response if the rules and timing of vaccine and drug administration are followed [1].

The analysis of the literature on vaccination of patients with rheumatological diseases indicates the need to maintain a low activity of immunoinflammatory rheumatic disease with simultaneous activation of both the production of antiviral antibodies and T-cell immunity with excess production of CD8⁺- and CD138⁺-lymphocytes and interferons (primarily interferon-gamma) [29].

However, vaccinating patients with rheumatic diseases is clearly necessary, and the only way to get answers to the questions raised is to analyse data from actual clinical

Table 1. Characteristics of vaccines against COVID-19 [11, 23–28]**Таблица 1.** Характеристика вакцин от новой коронавирусной инфекции [11, 23–28]

Vaccine	Manufacturer	Category	Dosing	Efficacy (95% CI), %	Frequency of anaphylaxis, per 100,000 people	Storage temperature, °C
BNT162b2	Pfizer-bioNtech	mDNA	2 injections 21 days apart	95.0 (90.3–97.6)	1	–70
mRNA 1273	Moderna	mDNA	2 injections 28 days apart	94.1 (89.3–96.8)	0.25	–20
ChAdOx1/ AZD1222	Astra-Zeneca	Vector-based (chimpanzee adenovirus vector)	2 injections 8–12 weeks apart	62.1 (41.0–75.7) for standard dosage/standard dosage 90.0 (67.4–97.0) for low dosage/ standard dosage	–	2–8
Gam-COVID-Vac (Sputnik V)	N.F. Gamaleya Federal Research Centre of Epidemiology and Microbiology	Vector-based (adenoviruses type 26 and type 5)	2 injections 21 days apart	91.6 (85.6–95.2)	–	2–8
Ad.26.COV2.S	Johnson & Johnson	Vector-based (adenovirus vector 26)	1 injection	66.9 (59.0–73.4)	–	2–8
NVX-CoV2373	Novavax	Protein subunit (recombinant SARS-CoV-2 glycoprotein)	2 injections 21 days apart 2 injections 14 days apart	89.3 (75.2–95.4) 60.1 (19.0–80.1) for the South African version	–	2–8
CoronaVac	Sinovac	Inactivated coronavirus	2 injections 14 days apart	50.6	–	2–8

practice. Possibly, the results of these studies will show how effective and safe recent COVID-19 vaccines are and when it is better to vaccinate patients with rheumatic diseases.

2. Analysis of clinical practice data

Morbidity and mortality. From March 1 to September 1, 2021, data from 16,263 patients with rheumatic diseases belonging to class XII of the International Classification of Diseases and Causes of Death, Revision 10 (ICD-10), were included in the register at the Clinical Rheumatology Hospital No. 25. Data were included only for patients who had previously provided voluntary informed consent for data processing. According to the register, 4,268 (26.2%) patients had COVID-19 by September 1, 2021 (Table 2).

When analysing the register data, the distribution of nosological forms of rheumatic diseases in patients with COVID-19 agreed with the relative frequency of individual rheumatic diseases in the population. No increase in COVID-19 cases in individual nosological forms of rheumatic diseases was observed.

Among 4,268 patients with COVID-19, 148 (3.47%) died from COVID-19 and its complications. According to the Russian Ministry of Health, the mortality rate in the general population as of 1 September 2021 was 2.8% ($p \geq 0.05$).

Post-vaccination morbidity and reactions, including rheumatic disease exacerbations. Among 16,263 patients who contacted Clinical Rheumatology Hospital No. 25 and were included in the register, 2,134 (13.2%) were vaccinated during the period from the start of vaccination to 1 September 2021 (Table 3). The vast majority (96%) of patients received the combined Sputnik-V vector vaccine from N.F. Gamaleya Federal Research Centre of Epidemiology and Microbiology; 3% received the CoviVac whole-virion vaccine from M.P. Chumakov Federal Research Center for Immunobiological Drug Research and Development; and 1% received the EpiVacCorona peptide vaccine from the Vector State Research Center of Virology and Biotechnology.

The groups of patients with degenerative diseases, inflammatory arthritis, systemic rheumatic diseases and microcrystalline arthritis were identified from the presented

Table 2. Nosological forms of rheumatic diseases (according to the statistical data form of the Ministry of Health of the Russian Federation No. 12) in the patients who had the new coronavirus infection, according to the register of Clinical Rheumatology Hospital No. 25

Таблица 2. Нозологические формы ревматических заболеваний (согласно статистической форме Минздрава России № 12) у пациентов, переболевших новой коронавирусной инфекцией, по данным регистра Клинической ревматологической больницы № 25

No.	Nosological forms of rheumatic diseases	Number of patients (n)	Percentage of patients (%)
1	Degenerative diseases	1,407	33
2	Rheumatoid arthritis	765	17.9
3	Undifferentiated arthritis	305	7.1
4	Gout	210	4.9
5	Systemic lupus erythematosus	172	4.1
6	Psoriatic arthritis and spondyloarthritis	166	3.9
7	Osteoporosis	161	3.8
8	Inflammatory spondylopathies	142	3.3
9	Other systemic connective tissue lesions	126	3
10	Axial spondylitis	117	2.7
11	Sjögren's syndrome	87	2.1
12	Systemic vasculitis	75	1.7
13	Rheumatic polymyalgia	58	1.3
14	Systemic sclerosis	49	1.1
15	Dermato- and polymyositis	15	0.3
	Others	413	9.7
	Total	4,268	100

Table 3. Nosological forms of rheumatic diseases in vaccinated patients (according to the statistical data form of the Ministry of Health of the Russian Federation No. 12) according to the register of Clinical Rheumatology Hospital No. 25

Таблица 3. Нозологические формы ревматических заболеваний у вакцинированных пациентов (согласно статистической форме Минздрава России № 12), по данным регистра Клинической ревматологической больницы № 25

No.	Nosological forms of rheumatic diseases	Number of patients (n)	Percentage of patients (%)
1	Degenerative diseases	882	41.3
2	Rheumatoid arthritis	290	13.6
3	Osteoporosis	186	8.7
4	Gout	126	5.9
5	Undifferentiated arthritis	153	7.2
6	Psoriatic arthritis and spondyloarthritis	62	2.9
7	Inflammatory spondylopathies	52	2.4
8	Ankylosing spondylitis	48	2.2
9	Other systemic connective tissue lesions	35	1.6
10	Rheumatic polymyalgia	33	1.5
11	Systemic lupus erythematosus	31	1.5
12	Sjögren's syndrome	28	1.3
13	Systemic vasculitis	22	1.0
14	Systemic sclerosis	10	0.5
15	Dermato- and polymyositis	2	0.1
	Others	246	11.5
	Total	2,134	100

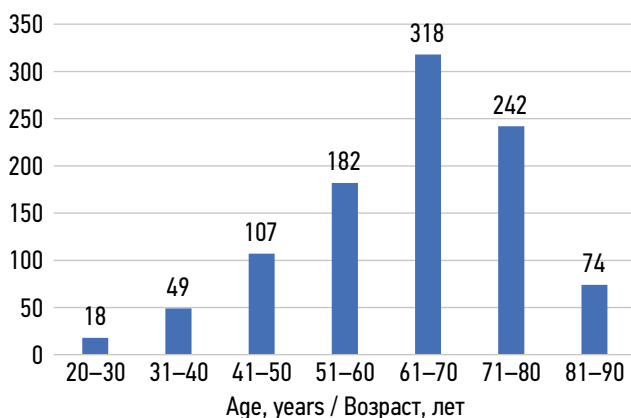


Fig. 1. Distribution of the vaccinated patients with degenerative joint diseases by age

Рис. 1. Распределение вакцинированных пациентов с дегенеративно-дистрофическими заболеваниями позвоночника и суставов по возрасту

sample. Among the vaccinated patients with degenerative diseases of the joints and spine (dorsopathy, osteoarthritis and osteoporosis; $n = 1,068$), patients aged >61 years prevailed (634 [59.4%]) (Fig. 1). The sample included 152 (14%) men and 916 (86%) women. The following vaccination features of patients with degenerative joint diseases were observed: 129 (12%) people were vaccinated after suffering COVID-19 and 22 (2%) people contracted COVID-19 within a month after vaccination, which was regarded as a consequence of non-compliance, with recommendations on using personal protective equipment and limiting contacts until immunity had been developed.

Despite the high incidence (52%) of comorbidities and chronic pain syndrome (82%), patients with degenerative joint diseases ($n = 84$) reported satisfactory acceptability of vaccination during an anonymous survey.

Among 605 vaccinated patients with inflammatory arthritis (rheumatoid arthritis, psoriatic arthritis and spondyloarthritis), 217 (36%) were men and 388 (64%) were

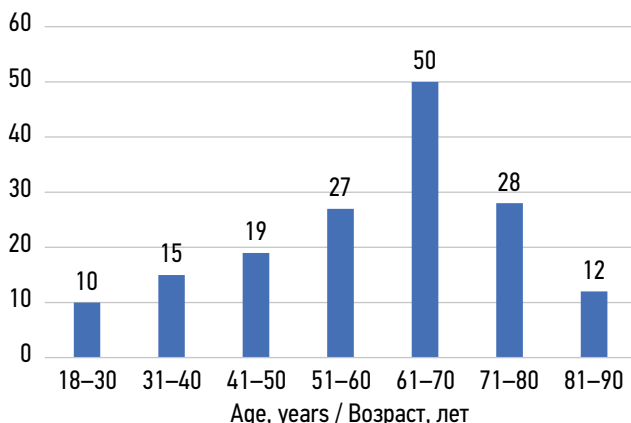


Fig. 3. Distribution of the vaccinated patients with systemic autoimmune rheumatic diseases by age

Рис. 3. Распределение вакцинированных пациентов с системными заболеваниями соединительной ткани по возрасту

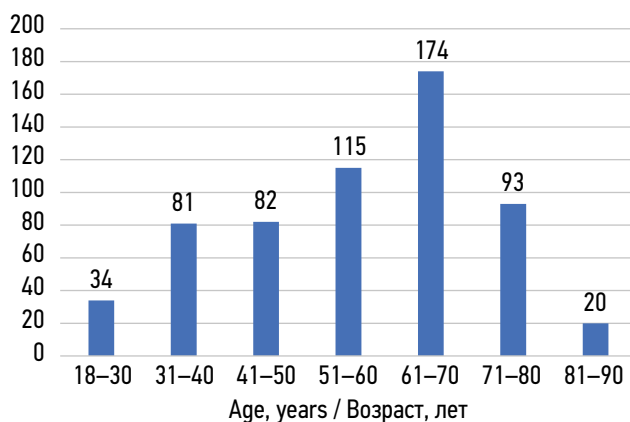


Fig. 2. Distribution of the vaccinated patients with inflammatory arthritis by age

Рис. 2. Распределение вакцинированных пациентов с воспалительными артритами по возрасту

women. When analysing the distribution of patients by age, 311 (51.4%) patients aged <61 years prevailed (Fig. 2).

Reportedly, 61 patients with inflammatory arthritis were vaccinated after contracting COVID-19, and 18 patients contracted COVID-19 after vaccination. Of these patients, 13 fell ill within 1 month of vaccination.

Among 161 vaccinated patients with systemic rheumatic diseases (systemic lupus erythematosus, systemic sclerosis, Sjögren's syndrome and inflammatory myopathies), 28 (17%) were men and 133 (83%) were women. The age distribution was the same as that of patients with degenerative diseases: patients (90 people) aged >61 years accounted for 56% (Fig. 3).

By contrast, in patients with microcrystalline arthritis ($n = 126$), most were men (112 people [89%]). The distribution of patients by age is shown in Fig. 4.

Among 126 patients with microcrystalline arthritis, 20 had COVID-19 before vaccination and 2 had COVID-19 after vaccination, one of whom fell ill within 1 month after the vaccination.

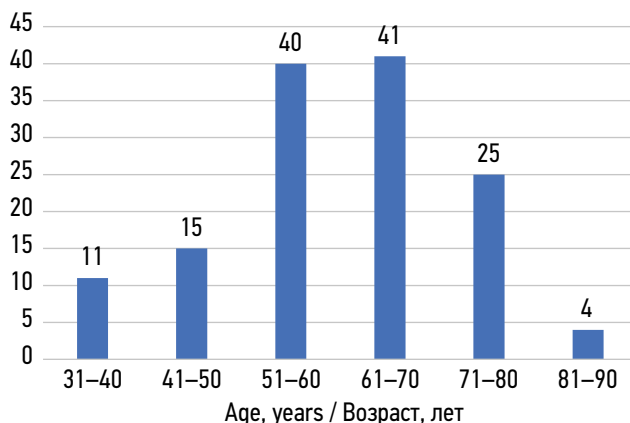


Fig. 4. Distribution of the vaccinated patients with microcrystalline arthritis by age

Рис. 4. Распределение вакцинированных пациентов с микрокристаллическими артритами по возрасту

Thus, the distribution by nosological composition, age and sex of patients with rheumatic diseases who had COVID-19 and those vaccinated against COVID-19 was comparable and did not differ from the corresponding distribution in the general population.

Efficacy of vaccination in the short term. Within 6 months after vaccination, only 42 patients with rheumatic diseases (0.25% of those vaccinated) contracted COVID-19. In all patients, the infectious process was mild, and no deaths were recorded. In the unvaccinated group, 4,268 (26.2%) patients were infected during the year, and 148 (3.47%) cases resulted in death.

Safety of vaccination in the short term. No severe adverse reactions were observed in the group with rheumatic diseases ($n = 2134$) after vaccination. In 12% of cases, patients reported local soreness and hyperaemia at the injection site and low-grade fever accompanied by transient myalgia and arthralgia. In 11 cases, short-term febrile fever with the need for additional antipyretics was recorded. The following reactions were demonstrated by patients mostly of young age (28 ± 4.4 years): four patients with rheumatoid arthritis, three patients with ankylosing spondylitis and one patient in each case of psoriatic arthritis, Sjögren's syndrome, systemic lupus erythematosus and post-traumatic osteoarthritis. Fever over 38°C lasting 1–6 days was noted in six patients, whereas subfebrile fever persisted for 2–12 weeks lasting up to 6 months in one patient. Moreover, fever in all patients was accompanied by arthralgia and myalgia. This reaction necessitated antipyretics or nonsteroidal anti-inflammatory drugs. Three patients had an increase in serum creatine phosphokinase to three upper limits. These values normalised at 3, 8 and 12 weeks. No systemic immunosuppressive therapy was used. In 12% of the cases, patients had exacerbations of the underlying rheumatic disease, which was treated according to the Federal Clinical Guidelines developed by the Association of Rheumatologists of Russia. The analysis of the medical records of these patients showed that the doctors considered these responses to be post-vaccination reactions.

An additional questionnaire was administered to 300 patients aged 18–84 years (76% were women and 24% were men) to clarify the social and medical aspects of rheumatology vaccination. The distribution of the respondents depending on the diagnosis was as follows: rheumatoid arthritis, psoriatic arthritis and undifferentiated arthritis (45%), osteoarthritis (28%), osteoporosis (9%), ankylosing spondylitis (6%), gouty arthritis (5%), systemic scleroderma (2%), overlap syndrome (2%), systemic lupus erythematosus (1%), Still's disease (1%) and rheumatic polymyalgia (1%).

In assessing the activity of rheumatic diseases during vaccination, among 135 patients with inflammatory

arthritis, 55% were vaccinated in remission, 29.6% had low disease activity and 20% had moderate/high disease activity. Among those surveyed, 8% had COVID-19 before vaccination, whereas 19.97% were vaccinated against COVID-19 in total.

A study of patient routing determined that patients were vaccinated against COVID-19 on the recommendation of a general practitioner/physician or rheumatologist or decided to vaccinate upon media recommendations ($n = 48$ [16.5%], $n = 24$ [8.2%] and $n = 219$ [75.3%], respectively).

Before vaccination, 78 (26%) respondents were tested for IgG antibodies to SARS-CoV-2. Testing was performed upon doctor's or friends' recommendations or for other reasons ($n = 33$ [43.4%], $n = 42$ [55.5%] and $n = 3$ [3.9%], respectively). Notably, 33% of the respondents believed that testing for antibodies to SARS-CoV-2 before vaccination against COVID-19 was necessary, 17% said it was not necessary, whereas 50% of respondents failed to answer.

Thus, the above data indicate that COVID-19 vaccination of patients with rheumatological diseases is quite safe in the short term.

DISCUSSION

The analysis of Russian and foreign papers allows for concluding that the register created at the Clinical Rheumatology Hospital No. 25 includes the number of vaccinated patients with rheumatic diseases, which is comparable with the indices of leading international centres (among 16,262 patients with rheumatic diseases, 2134 were vaccinated by 1 September 2021).

According to the register, one in four patients with rheumatic diseases (26.2%) had COVID-19 by 1 September 2021. The incidence of COVID-19 among patients with individual rheumatic diseases corresponds to the incidence of COVID-19 in the population. Previously published data (June 2020) showed that patients with systemic lupus erythematosus, systemic scleroderma and systemic vasculitis had a more severe disease course with COVID-19, especially in the presence of irreversible organ damage [1, 5, 6, 12, 16–19]. This position was confirmed by international studies [17, 18]. The demographic characteristics of patients with rheumatological diseases who contracted COVID-19 (regardless of vaccination status) correspond to the typical age and sex distribution for individual rheumatic diseases.

The rates of patients vaccinated against COVID-19 among those with rheumatic diseases were 13.2% (according to the register of the Clinical Rheumatology Hospital No. 25) and 19.97% (according to the online survey). In Russia, 30.11% of the population were vaccinated as of 1 September 2021; of these, 25.52% were fully vaccinated (the difference in the number of vaccinated patients with rheumatological diseases corresponds to $p < 0.05$).

The only way out of this situation can be active vaccination of patients with rheumatological diseases against COVID-19. This is confirmed by the analysis of the register data from the Clinical Rheumatology Hospital No. 25. Thus, COVID-19 affected only 0.25% among 2,134 vaccinated patients and 25.6% of the unvaccinated. No patients from the vaccinated group died of COVID-19. Importantly, the vast majority of vaccinated patients fell ill in the first month after vaccination (36 of 42 people), when a strong post-vaccination immunity has not yet been formed, and it was inadmissible to lose vigilance and violate epidemiological rules after vaccination. All cases of post-vaccination COVID-19 were mild and did not need hospitalisation.

Almost all patients (96%) included in the St. Petersburg register received the Sputnik-V vaccine; therefore, the data presented in this study on the efficacy and safety of vaccination apply mostly to this vaccine.

Remarkably, the vast majority (75.2%) of patients were vaccinated voluntarily, whereas the smallest number (8.2%) of patients was referred for vaccination by a rheumatologist. These data confirm the timeliness of recommendations developed by the Association of Rheumatologists of Russia for COVID-19 vaccination of patients with rheumatic diseases.

Special attention should be paid to post-vaccination exacerbations of rheumatic diseases. Their number, according to patient questionnaires, did not exceed 12%. Importantly, the analysis of patient records showed that distinguishing an exacerbation from a post-vaccination reaction was extremely difficult for the patient, and most exacerbations were reclassified by doctors as post-vaccination reactions. All such reactions were corrected according to the recommendations for the treatment of the corresponding diseases. Possibly, these exacerbations were due both to the effect of the vaccine and correction of basal and anti-inflammatory therapy administered before and after vaccination. Data from a recently published Hong Kong register suggest that post-vaccination exacerbations of rheumatic diseases are not dependent on the type of disease-modifying antirheumatic treatment [10]. In the database analysed, no information was available on the treatment of patients at the time of and after vaccination, which implies the need for further research.

In addition, some vaccination problems in patients with rheumatological diseases are subject to further research. The most important of these problems is to determine the timing and optimal approaches to revaccination and duration of the maintenance of intense post-vaccination immunity. The determination of IgG levels against COVID-19 may help in resolving this issue [29]. The survey showed that a substantial number of patients had antibody levels determined before and after vaccination, comparing it with the previous indicator.

Thus, the above data from a wide range of literature sources and the analysis of materials from the register of patients with rheumatic diseases of the Clinical Rheumatology Hospital No. 25 suggest that COVID-19 vaccination of patients with rheumatological diseases is effective, safe and necessary. Vaccination can be refused if the rheumatic disease is moderate or severe (vaccination is possible after remission or low rheumatic disease activity), in the case of polyvalent allergies (vaccination must be decided after consulting an allergologist), acute infections (vaccination is possible after recovery) and individual intolerance to the vaccine (a vaccine with a different composition of active ingredients must be used).

CONCLUSIONS

Although the COVID-19-associated morbidity (26.2%) and mortality (3.47%) of patients with rheumatic diseases does not exceed the population rate, patients in this profile show a threefold lower rate of COVID-19 vaccination (13.2% versus 31.8% in the population). The analysis of data from 2,134 patients with rheumatological diseases who were vaccinated by 1 September 2021 showed a 0.25% reduction in the incidence of COVID-19 compared with unvaccinated patients (25.6%) with no fatal outcomes among those vaccinated. Only 8.2% of the patients were vaccinated on the recommendation of a rheumatologist and not by their initiative.

The register data show a high safety of vaccination of patients with rheumatological diseases (12% of post-vaccination reactions of mild and moderate severity) and justify the necessity to observe epidemiological safety measures after vaccination.

The question of the timing and necessity of revaccination, as well as its long-term efficacy and safety, is currently unresolved. The determination of COVID-19 antibody levels may be used in the development of individual vaccination plans for patients with rheumatological diseases in the present setting.

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Author contributions. *V.I. Mazurov* — development of the concept of the study, organization of the study, analysis of the results, preliminary and final editing of the text of the article; *E.L. Nasonov* — improvement of the concept of the article, preliminary and final editing of the text of the article; *A.M. Lila* — improvement of the concept and final version of the article; *I.Z. Gaydukova* — development

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All authors made a significant contribution to the study and preparation of the article and read and approved the final version before its publication.

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Этика исследования. Исследование одобрено комитетом по этике Клинической ревматологической больницы № 25

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