DOI: https://doi.org/10.17816/RFD75815

Features of management and vaccination of comorbid patients with rheumatic diseases in a pandemic of a new coronavirus infection

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The review presents the results of scientific studies devoted to the features of the course and outcomes of a new coronavirus infection COVID-19 in patients with immuno-inflammatory rheumatic diseases (IIRD). The risk of developing coronavirus infection in such patients may slightly exceed the population risk in the presence of established factors aggravating its course (old age, obesity, diabetes mellitus, cardiovascular diseases). Patients receiving long-term immunosuppressive therapy and high doses of glucocorticoids may have a long period of positive viral replication and isolation of a viable virus, which requires dynamic monitoring of such patients and correction of anti-rheumatic therapy. The issues of post-COVID-19 joint syndrome, which can occur within the framework of post-viral arthritis or be the debut of an immuno-inflammatory rheumatic disease, are highlighted. The draft recommendations of the All-Russian Public Organization "Association of Rheumatologists of Russia" on the management and temporary recommendations of V.A. Nasonova Research Institute of Rheumatology for vaccination of patients with rheumatic diseases in the conditions of the COVID-19 pandemic are presented.

Keywords: rheumatic diseases; new coronavirus infection; post-COVID-19 joint syndrome.

To cite this article:
Belyaeva IB, Mazurov VI, Sarantseva LE, Trofimov EA. Features of management and vaccination of comorbid patients with rheumatic diseases in a pandemic of a new coronavirus infection. *Russian Family Doctor.* 2021;25(3):17–26. DOI: https://doi.org/10.17816/RFD75815

Received: 07.07.2021 **Accepted:** 06.09.2021 **Published:** 30.09.2021

УДК 616.72-002.77-08:616.988:578.834.1
DOI: https://doi.org/10.17816/RFD75815

Особенности ведения и вакцинации коморбидных пациентов с ревматическими заболеваниями в условиях пандемии новой коронавирусной инфекции

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Данная обзорная статья содержит результаты научных исследований новой коронавирусной инфекции (COVID-19) у пациентов с иммуновоспалительными ревматическими заболеваниями. Риск развития коронавирусной инфекции у таких пациентов может незначительно превышать популяционный риск при наличии установленных факторов, усугубляющих ее течение (пожилой возраст, ожирение, сахарный диабет, сердечно-сосудистые заболевания). Пациенты, получающие иммуносупрессивную терапию и высокие дозы глюкокортикоидов, могут переживать длительный период положительной вирусной репликации и выделения жизнеспособного вируса, поэтому они нуждаются в динамическом наблюдении и коррекции противоревматической терапии. Постковидный суставной синдром может протекать в рамках поствирусного артрита, либо являться дебютом иммуновоспалительного ревматического заболевания. В статье представлен проект рекомендаций Общероссийской общественной организации «Ассоциация ревматологов России» и временные рекомендации НИИ ревматологии им. В.А. Насоновой по ведению и вакцинации пациентов с ревматическими заболеваниями в условиях пандемии COVID-19.

Ключевые слова: ревматические заболевания; новая коронавирусная инфекция; постковидный суставной синдром.

Как цитировать:
Беляева И.Б., Мазуров В.И., Саранцева Л.Е., Трофимов Е.А. Особенности ведения и вакцинации коморбидных пациентов с ревматическими заболеваниями в условиях пандемии новой коронавирусной инфекции // Российский семейный врач. 2021. Т. 25. № 3. С. 17–26. DOI: https://doi.org/10.17816/RFD75815

Рукопись получена: 07.07.2021 **Рукопись одобрена:** 06.09.2021 **Опубликована:** 30.09.2021

ЭКО•ВЕКТОР

INTRODUCTION

In patients with rheumatic diseases, infectious complications are registered increasingly often because of secondary immunodeficiency due to the activity of immunoinflammatory rheumatic diseases (IIRD) and use of immunosuppressive drugs [1–4]. Currently, the general pathogenetic mechanism of organ lesions in coronavirus disease 2019 (COVID-19) and IIRD, called thrombo-inflammation, has been determined. It is associated with the overproduction of proinflammatory cytokines that induce damage to endothelial cells, platelets, and complement system, as well as the formation of neutrophil extracellular traps [5–11]. COVID-19 is accompanied by extrapulmonary clinical manifestations such as arthralgia, myalgia, vasculitis, myocarditis, and antiphospholipid syndrome. Laboratory changes detected in COVID-19, including cytopenia, increased levels of acute-phase proteins, ferritin, D-dimer, proinflammatory cytokines, and antibodies to phospholipids and antinuclear antibodies are also characteristic of IIRD.

CHARACTERISTICS OF THE COVID-19 COURSE IN RHEUMATIC DISEASES

A study provided no unequivocal evidence that rheumatic diseases greatly contributed to the development of COVID-19 [12–14].

The results of a survey of 320 patients with IIRD living in Lombardy, a province in Italy with the highest incidence of COVID-19, have been published [15]. 57% of respondents had rheumatoid arthritis and 43% had spondyloarthritis. Moreover, 52% of the patients received treatment with tumor necrosis factor inhibitors, 40% received other genetically engineered biological drugs (GEBDs), and 8% received targeted disease-modifying antirheumatic drugs (DMARDs). In this group, four patients had confirmed COVID-19 identified through rhinopharyngeal swabs. Another four patients showed clinical symptoms of COVID-19. Five additional patients with reported certain contacts remained asymptomatic at the end of the 2-week observation period. GEBDs or DMARDs were temporarily discontinued in patients with clinical and/or laboratory signs of COVID-19, and antibiotic therapy was prescribed. No patients had severe respiratory complications, lethal outcomes, or relapses of the underlying disease. The authors suggested that in patients with chronic arthritis taking targeted DMARDs or GEBDs, the risk of the life-threatening complications of COVID-19 did not exceed the risk of the general population; therefore, unjustifiable preventive withdrawal of such therapy is not reasonable and may cause a relapse of the main IIRD.

A similar survey was conducted in 162 patients with systemic vasculitis having large-vessel vasculitis (LVV) [16]. Two-thirds of these patients lived in Lombardy. Of these patients, 67 had Takayasu arteritis and 95 had giant cell arteritis. Moreover, 51 patients received methotrexate, 5 received leflunomide, 53 received tocilizumab, 25 received infliximab, and 8 received combination therapy (DMARDs and GEBDs). COVID-19 was confirmed in four respondents, and two of them were hospitalized, recovered, and discharged. COVID-19 was not detected in 12 patients with symptoms of acute respiratory viral infection. The same number of patients had contact with patients having COVID-19 without consequences. Thus, a previous therapy with immunosuppressants in patients with systemic vasculitis caused no significant negative effects on the course of COVID-19. In conclusion, there was no need to suspend immunosuppressive therapy in these patients during the pandemic.

By contrast, another Italian cohort study conducted in a group of patients monitored for one or both diseases and showed that among 1641 patients with rheumatic diseases, the prevalence of COVID-19 was higher than that in patients without IIRD (1.5% and 0.3%, respectively). COVID-19 was more commonly detected in patients with systemic connective tissue disorders and less often in patients with inflammatory arthritis. Moreover, viral infection was registered more often in patients with IIRD who did not take synthetic and targeted DMARDs, GEBDs, and glucocorticoids [17].

According to a multicenter cohort study [17], which assessed clinical outcomes in patients hospitalized for COVID-19 and chronic inflammatory and autoimmune rheumatic diseases, among 456 patients, severe COVID-19 in patients with IIRD was recorded more often to some extent than in other patients (31.6% and 28.1%, respectively). The presence of connective tissue disease, rather than its therapy, was associated with severe COVID-19. Moreover, comorbid conditions occurred with equal frequency both in patients with IIRD and in other patients.

The study conducted at the V.A. Nasonova Scientific Research Institute of Rheumatology (SRIR) revealed that the risk factors of pneumonia in patients with rheumatoid arthritis were high activity of the inflammatory process (odds ratio (OR) 15.5; $p < 0.001$) and the lack of DMARDs (OR 5.6; $p < 0.001$). With a combination of both factors, the risk of pneumonia increased to 19.3. Thus, IIRD activity should be controlled and maintained to reduce the incidence of comorbid infections [18].

We agree with the data of recent studies that the risk of COVID-19 in patients with IIRD may slightly exceed the risk of the general population in the presence of established factors aggravating its course (i.e., old age, obesity, diabetes mellitus, and cardiovascular diseases). In our opinion, patients receiving immunosuppressive therapy and high doses of glucocorticoids can experience a long period of positive viral replication and isolation of a viable virus; therefore, they require case follow-up and correction

with antirheumatic therapy. Consequently, an unfavorable comorbid background, activity of the underlying disease, and high doses of glucocorticoids determine an unfavorable prognosis of IIRD during the COVID-19 pandemic.

POST-COVID SYNDROME IN RHEUMATOLOGY

Another unsolved problem for patients with rheumatic diseases is the management of post-COVID syndrome, which includes signs or abnormal clinical parameters that persist 4 weeks and longer after COVID-19 and are considered long-term consequences. Currently, PubMed has indexed >4104 references to post-COVID syndrome. Thus far, 55 long-term effects of COVID-19 have been identified, and the most significant are fatigue (58%), headache (44%), impaired attention (27%), alopecia (25%), shortness of breath (24%), myalgia (19%), as well as arthralgia and arthritis (15%) [19].

At present, there are no unambiguous data on the nature of undifferentiated arthritis (UA) in COVID-19, which can occur either with post-viral arthritis or represent IIRD onset, such as rheumatoid arthritis, spondyloarthritis, systemic lupus erythematosus, Sjögren syndrome, systemic vasculitis, inflammatory myopathy (Fig. 1). We have revealed that post-viral arthritis develops on average in 35% of patients with UA and is characterized by an early onset of arthritis during specific manifestations of COVID-19 (1–4 weeks). Post-viral arthritis is clinically manifested with mono- and oligoarthritis of the knee, ankle, and proximal and distal interphalangeal joints, swelling of periarticular soft tissues, absence of destructive changes in joints and chronic process, and a good response to non-steroidal anti-inflammatory drugs (NSAIDs) and short courses of glucocorticoids (Fig. 2, 3) [20]. However, post-viral arthritis remains an exception in most cases. Differential diagnostics is performed in patients with sepsis, microcrystalline arthritis, reactive arthritis, and onset of IIRDs, including rheumatoid arthritis, axial spondylitis, and systemic connective tissue disorders. The etiological role of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is confirmed by the absence of signs of another rheumatic disease, namely, increased levels of uric acid, rheumatoid factor, count of antibodies to cyclic citrullinated peptide, antinuclear factor, and presence of the histocompatibility antigen HLA B-27 [21].

Early-onset rheumatoid arthritis is common in patients with UA. Its formation from UA includes signs such as symmetric arthritis, rapid increase in the number of tender and swollen joints (mainly of the knee, wrist, proximal interphalangeal joints of the hands and metatarsophalangeal joints of the feet), seropositivity for rheumatoid factor, and antibodies to cyclic citrullinated peptide. Ultrasound examination of the joints reveals tenosynovitis and osteochondral erosion. Ragocytes are found in the synovial fluid of the affected joints [22].

To determine the diagnostic values of an antinuclear factor (≥1:160 on the Hep 2 cell line) in patients with UA with a history of COVID-19, further clinical and immunological

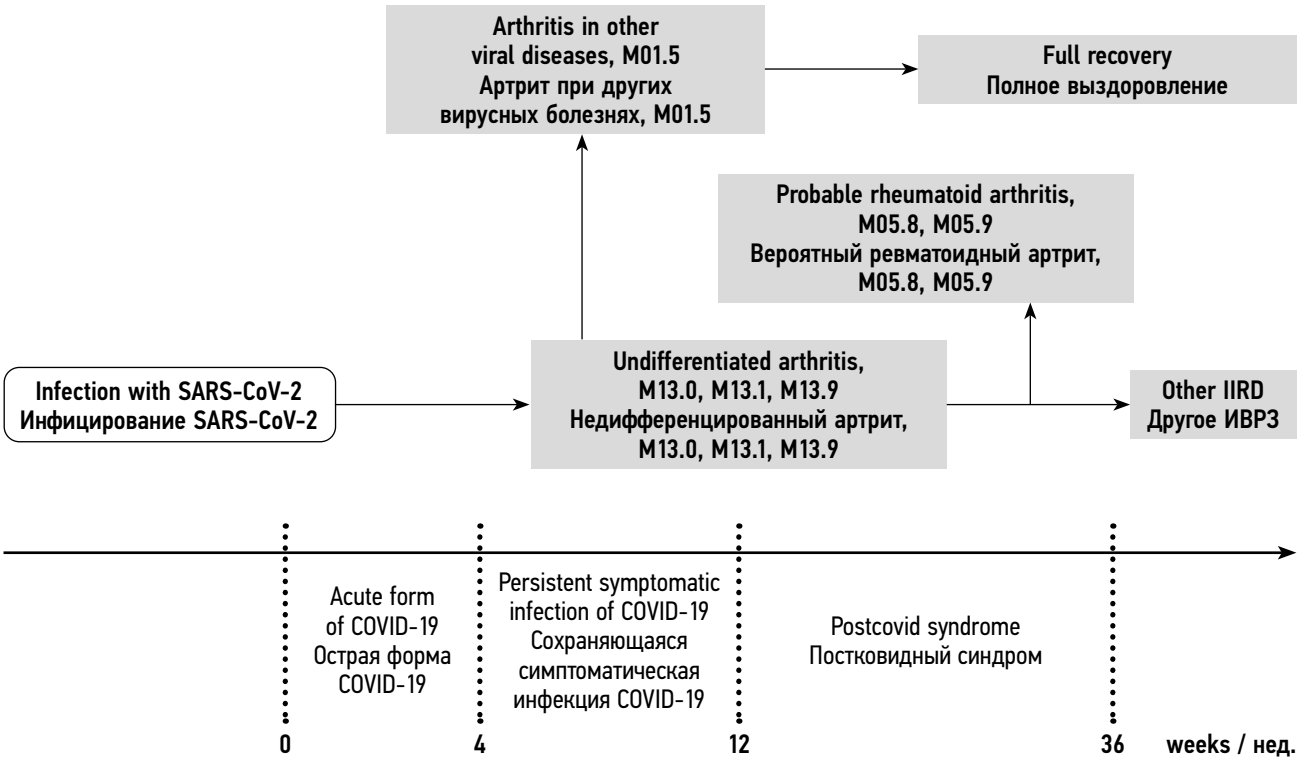

Fig. 1. The scheme of the evolution of the joint syndrome after COVID-19 (own data). IIRD — immuno-inflammatory rheumatic diseases
Рис. 1. Схема эволюции суставного синдрома после COVID-19 (собственные данные). ИВРЗ — иммуновоспалительное ревматическое заболевание

DOI: https://doi.org/10.17816/RFD75815

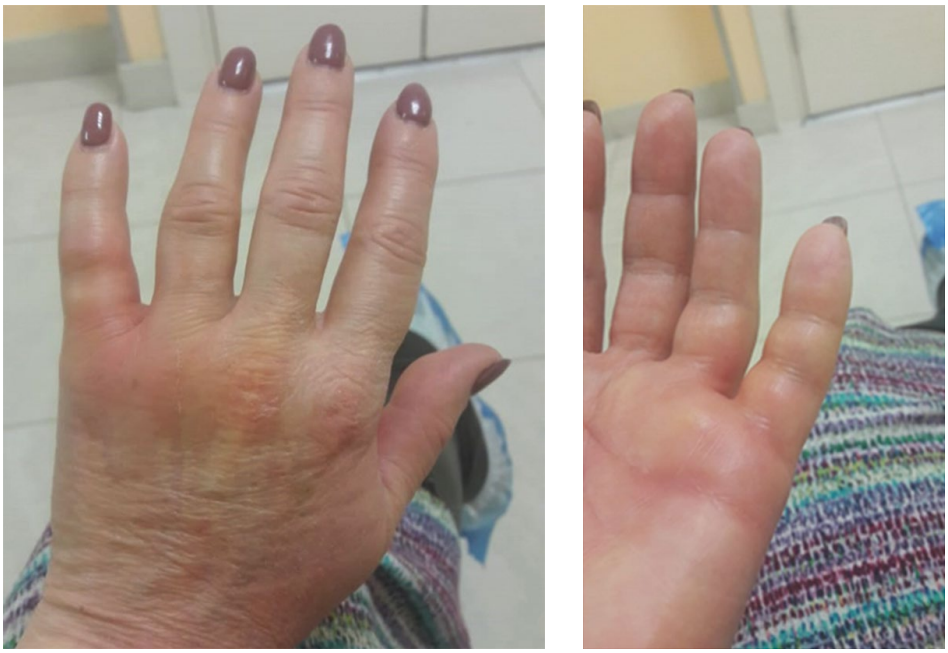

Fig. 2. Arthritis of small joints of the left hand (III, IV metacarpophalangeal; III, IV proximal interphalangeal joints). Involvement of surrounding soft tissues (own data)
Рис. 2. Артрит мелких суставов левой кисти (III, IV пястно-фаланговых; III, IV проксимальных межфаланговых суставов). Вовлечение окружающих мягких тканей (собственные данные)

examination is required to determine the onset of IIRD. However, positivity for antinuclear factor and antibodies to DNA can be a part of an immune-mediated response to viral infection in individuals without IIRD [23], and the diagnosis of UA can be preserved in patients with persistent articular syndrome without characteristic manifestations of any rheumatic diseases [20]. Therefore, the diagnostics should be accompanied by case follow-up.

MANAGEMENT OF PATIENTS WITH RHEUMATIC DISEASES IN A PANDEMIC

In July 2020, the Association of Rheumatologists of Russia issued a draft recommendation "Coronavirus disease 2019 (COVID-19) and immunoinflammatory (autoimmune) rheumatic diseases," which formulated the main provisions for the management of patients with IIRD [24]:

1. Patients with IIRD are at risk for an unfavorable course of COVID-19.
2. SARS-CoV-2 infection (like other viruses) can exacerbate the pathological process in rheumatic diseases.
3. The high incidence of cardiometabolic and pulmonary comorbidity, a characteristic of IIRD, in patients with COVID-19 can reduce the efficiency of a therapy for the underlying disease and complicate the diagnostics of infection (lung damage).
4. A pathology of the immune system in patients with IIRD and concomitant comorbid diseases can aggravate the course of infection and increase the risk of "cytokine storm syndrome."
5. Antirheumatic therapy, including NSAIDs, glucocorticoids, GEBDs, as well as standard and targeted DMARDs, can have multidirectional effects on the course of COVID-19.

Fig. 3. Complete regression of all forms of joint syndrome in patients receiving aceclofenac 200 mg/day for 14 days (own data)
Рис. 3. Полный регресс всех проявлений суставного синдрома на фоне приема ацеклофенака по 200 мг/сут в течение 14 дней (собственные данные)

6. Risk factors for COVID-19 and severe COVID-19 in patients with rheumatic diseases include the following:
- Older age.
- Taking of high doses of antirheumatic drugs.
- Simultaneous administration of several antirheumatic drugs, especially when combined with glucocorticoids.
- High disease activity.
- The presence of concomitant diseases such as arterial hypertension, ischemic heart disease, diabetes mellitus, interstitial lung disease, other lung diseases (such as bronchial asthma, chronic obstructive pulmonary disease, and arterial pulmonary hypertension), glomerulonephritis (especially with renal failure), neutropenia, liver diseases, treatment with cyclophosphamide, and rituximab.
- The role of NSAIDs in increasing the risk of COVID-19 complications has not been fully investigated. NSAIDs can be used in low doses (ibuprofen and ketoprofen) or paracetamol as an antipyretic drug.

7. Interruption of treatment with glucocorticoids is not recommended, but the dose of the drug should be reduced as much as possible.
8. Taking of aminoquinoline drugs (hydroxychloroquine) or to prescribe them in the absence of contraindications was recommended.
9. In the absence of contraindications, immunization with pneumococcal vaccine should be performed.
10. If COVID-19 is detected or suspected, treatment with antirheumatic drugs (with the exception of glucocorticoids, hydroxychloroquine, and sulfasalazine) should be temporarily discontinued, and a rheumatologist should be consulted.
11. The safety in using angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers in patients with IIRD and COVID-19, for appropriate indications, requires further study.
12. During the pandemic, unnecessary hospitalization of patients in a rheumatological hospital and outpatient consultations should be avoided.
13. Virtual methods of communication with patients should be employed as much as possible.
14. Interleukin 6P inhibitors (such as tocilizumab and sarilumab) are effective in the occurrence of a complication of COVID-19, such as acute respiratory distress syndrome in combination with manifestations of the "cytokine storm" syndrome.
15. The possibility of using GEBDs that block the activities of proinflammatory cytokines such as interleukin 1β, gamma-interferons, granulocyte-macrophage colony-stimulating factor, and interleukin 18 for the treatment of cytokine storm syndrome should be discussed.
16. For the prevention and treatment of COVID-19, Janus kinase inhibitors are indicated, including baricitinib, which demonstrates antiviral activity by blocking SARS-CoV-2 endocytosis in the alveolar cells of the lungs and suppresses the synthesis of proinflammatory cytokines involved in the immunopathogenesis of COVID-19.

VACCINATION OF PATIENTS WITH IIRD

During the COVID-19 pandemic, experts of the European League Against Rheumatism strongly recommend vaccination primarily against influenza and pneumococcal infection for the vast majority of patients with IIRD.

This circumstance is due to the significant risk of fatal outcomes caused by respiratory tract infections in patients with rheumatological conditions, especially given the high incidence of respiratory tract damage in COVID-19 [25].

High expectations are set for COVID-19 vaccines; however, their use in patients with IIRD is possible only after several issues have been resolved. It remains unclear how long protective levels of antibodies against COVID-19 persist after recovery. The benefit of immunization against COVID-19 (prevention or reduction in the severity of infection) is expected to far outweigh any vaccine-associated risk. Moreover, no major clinical studies have focused on investigating the efficacy, immunogenicity, and safety of COVID-19 vaccines in patients with IIRD both in Russia and in the world.

Given the lack of sufficient information, temporary recommendations for the vaccination of patients with IIRD were issued at the V.A. Nasonova SRIR on June 11, 2021 [21].

1. The question of administering a COVID-19 vaccine in patients with IIRD should be decided individually, taking into account the epidemiological situation, rheumatic disease activity, therapy given (preferably 4 weeks before the start of treatment with immunosuppressive drugs), and need for informing the patient and obtaining voluntary consent.
2. If a patient with IIRD is already receiving immunosuppressive drugs, during vaccination against COVID-19, to increase the immunogenicity of the vaccine, the following actions are possible:
- Taking of methotrexate, Janus kinase inhibitors, cyclophosphan, and mycophenolate mofetil should be discontinued for 1 week after each dose of vaccine, if possible.
- The administration of subcutaneous abatacept should be discontinued 1 week before and 1 week after the first vaccine dose, while no change is required in the second dose.
- The intravenous administration abatacept should be discontinued 4 weeks before and 1 week after the first vaccine dose, while no change is necessary in the second dose.
- Vaccination should be started at least 5 months after the last injection of rituximab and 4 weeks before the upcoming infusion.

DOI: https://doi.org/10.17816/RFD75815

Discussion of temporary discontinuation of immunosuppressive therapy due to the vaccination is strongly recommended on a case-by-case basis.

3. After COVID-19 vaccination, patients with IIRD should continue practicing general preventive measures, namely, social distancing, wearing masks, and hand hygiene.
4. Family members and other persons in close contact with patients with IIRD should be immunized against COVID-19 to create the effect of a "vaccination cocoon" in the patient's environment.
5. In the context of the COVID-19 pandemic, all patients with IIRD should receive seasonal influenza and pneumococcal vaccination unless contraindicated in accordance with current national guidelines.

Within the next 1–2 months, clinical studies are planned to be started at V.A. Nasonova SRIR to analyze the use of the Russian vaccine CoviVac in patients with rheumatic diseases, produced at the M.P. Chumakov Federal Scientific Center for Research and Development of Immune- and Biological Products of the Russian Academy of Sciences.

CONCLUSION

Patients with IIRD are susceptible to the infectious complications of COVID-19. The short- and long-term effects of COVID-19 on patients with IIRD have not been fully explored; however, we can assume that the low activity of IIRD and adequately selected antirheumatic therapy contribute to the prevention of severe COVID-19.

The problem of post-COVID syndrome treatment in patients with IIRD remains unsolved, including signs or abnormal clinical parameters that persist for 4 weeks and longer after COVID-19 and long-term consequences of the disease. Optimal approaches to the therapy and vaccination against COVID-19 in patients with IIRD have not been developed.

The data presented indicate the need to continue the investigation on the mutual influence of IIRD and COVID-19, including the formation of UA and rheumatic diseases in patients without a history of any rheumatological pathology. The solution of these issues will allow the development of sound algorithms for the management of these patients.

ADDITIONAL INFORMATION

Funding. The study had no external funding.

Conflict of interest. The authors declare no conflict of interest.

All authors made significant contributions to the research and preparation of the article, read, and approved the final version before its publication.

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