Guidelines

British Society for Rheumatology

Updated recommendations of the German Society for Rheumatology for the care of patients with inflammatory rheumatic diseases in times of SARS-CoV-2—methodology, key messages and justifying information

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Abstract

A few days after the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection was declared a pandemic, the German Society for Rheumatology (DGRh) compiled the first group of recommendations for the care of patients with inflammatory rheumatic diseases in light of SARS-CoV-2/coronavirus disease 2019 (COVID-19). These first recommendations were based on an expert consensus and were largely non-evidence-based. Now that the first scientific data from registries, cross-sectional studies, case reports and case series are available, the DGRh has developed a timely update. This update is based on a literature search of publications available through 15 June 2020 and addresses preventive measures (such as hygiene measures or vaccinations) and the use of immunomodulatory/immunosuppressive drugs. Driven by the commitment to let patients benefit from these new evidence-based recommendations as quickly as possible, the DGRh published the update in German on its homepage and in the *Zeitschrift für Rheumatologie* immediately after completion. Here we report the key recommendations to make them available to the international community, provide the scientific methodology used to develop the recommendations, give additional thoughts and advice for the management of patients with rheumatic diseases during the COVID-19 pandemic and discuss our recommendations in the context of other international recommendations.

Key words: SARS-CoV-2, COVID-19, therapy management, recommendation, inflammatory diseases

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Rheumatology key messages

- Evidence from case series and registries allow the development of recommendations for the management of patients with an IRD in light of SARS-CoV-2.
- Patients with an IRD have no higher risk of contracting SARS-CoV-2.
- Patients with an IRD are recommended to follow the same behavioural and precautionary measures as the general population.
- Anti-rheumatic medication should not be changed solely for fear of SARS-CoV-2 infection.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic has posed particular challenges for patients with inflammatory rheumatic diseases (IRDs) as well as for rheumatologists. The aim of the first recommendations of the German Society for Rheumatology (DGRh) from 30 March 2020 was to provide immediate assistance in the care of patients with an IRD in view of the threat of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [1]. The recommendations at that time were based on an expert consensus and were largely non-evidence-based. With the first scientific data from registries, cross-sectional studies, case reports and case series now available, the DGRh developed an update on their initial recommendations following established scientific paths for the preparation of guidelines [2]. These DGRh recommendations primarily reflect the situation in Germany and may differ from other national or international guidelines.

Methods

Systematic literature review

A literature search was performed by searching the databases MEDLINE, Embase and the Cochrane Library for articles published before 15 June 2020 using the search terms 'IRD', 'inflammatory rheumatic diseases', 'COVID-19', 'SARS-CoV-2', 'therapy' and any combinations of these terms. Studies were included if they were based on an identifiable cohort (by one centre and/or by a defined disease) and dealt with the outcome of patients with an IRD in the context of COVID-19. The literature that met the inclusion criteria and was used for the discussion while formulating the recommendations is provided as Supplementary Table 1, available at *Rheumatology* online. As the current evidence level of publications on the management of patients with an IRD in the context of COVID-19 is at most grade 3 (system of the Oxford Centre for Evidence-Based Medicine of 2011), the present recommendations regarding information that is not covered by corresponding studies on SARS-CoV-2/COVID-19 have been supplemented with analogies from longer-known viral infections and by expert opinion.

Expert panel and steering committee

The expert panel consisted of 16 experienced German rheumatologists representing the board of directors of the DGRh, the members of the Commission for Pharmacotherapy of the DGRh, rheumatologists in private practice with long experience in developing guidelines and a managing director of the DGRh. A steering committee of six rheumatologists (experienced in steering committees relating to general practice and specialty medicine) contributed to study planning and development, reviewed survey results and led scientific discussions. Patients and the public were not involved in the design or conduct of this study.

Modified Delphi process

Statements were collated according to the available evidence and disseminated to the panel members. Questions and drafted statements were reviewed and assessed using a well-established method of consensus building (modified Delphi process). This included two webinars with the entire panel and one round of asynchronous anonymous voting using a voting system.

Statistical analysis

Measures for central tendency and level of dispersion were determined for each statement. For each consensus statement, the mean score and S.D. are reported. Panel members voted on agreement with draft recommendations using a numeric scoring system of 1–10. The level of agreement was provided according to the mean score S.D. A minimum level of 8 was required to keep the recommendation.

Results

Prevention and management: prevention of infections and protective measures

Recommendation 1: With regard to prevention and management to avoid infections, patients with inflammatory rheumatic diseases are recommended to follow the behavioural and precautionary measures for the general population as described by the Robert Koch Institute. This also applies in the case of positive SARS-CoV-2 IgG antibody detection. [Level of evidence (LoE) IV, level of agreement (LoA) 9.94 ± 0.24]

> The basic behavioural and precautionary measures described and regularly updated by the Robert Koch Institute (RKI) [3] and the Federal Centre for Health Education [4] for the general population and for persons at particular risk apply. Special measures beyond

these procedures are not generally recommended, due to lack of evidence.

Patients with an IRD have an increased risk of certain infections under special circumstances [5–7]. The RKI has defined patients under immunosuppression as particularly vulnerable [8]. Data from COVID-19 registries, case series and case reports suggest, however, that patients with an IRD do not have a fundamentally increased risk of infection with SARS-CoV-2 compared with the general population without rheumatic diseases [9–13]. The majority of the current data also show that COVID-19 is not more severe in patients with an IRD than in individuals without an IRD [9–11, 14, 15]. Similarly, there is currently no convincing evidence that, with the exception of glucocorticoids (GCs; see below), anti-rheumatic drug therapy poses a risk of severe COVID-19 progression in patients with an IRD [13].

The current data suggest that the risk of a severe course of an infection is probably increased if the IRD is insufficiently controlled [16, 17]. Since any change in anti-rheumatic therapy entails a potential destabilization of disease control, anti-rheumatic therapy should not be changed or paused in patients with well-controlled disease in a different than usual manner.

Recommendation 2: To interrupt infection chains and contain a new possible wave of infection, patients are recommended to use digital tracking possibilities such as the Corona-Warn-App. (LoE V, LoA 9.31 ± 1.04)

While this recommendation is not different in patients with an IRD than in the general population, digital tracking possibilities for SARS-CoV-2 infections help to quickly identify transmission chains and thus prevent further transmission. They have been developed and are in use in many countries.

Recommendation 3: In the context of the COVID-19 pandemic, inability to work solely on the basis of an assumed risk due to the underlying rheumatic disease and its treatment is generally not justified. (LoE V, LoA 9.94 ± 0.24)

Although it is clear that no two immunosuppressive or immunomodulating drugs may be associated with the same risk, the evidence in the SARS-CoV-2 pandemic for individual drugs and their possible combination is still so scarce (and sometimes even contradictory in individual reports) that the available data do not permit an evidence-based detailed risk assessment of individual medications.
Therefore a certificate may be issued stating that the patient is under current immunomodulatory/immunosuppressive therapy. This allows patients to contact company doctors/official doctors/employers and clarify whether it is necessary to maintain a workplace with contact minimization/avoidance (for a certificate template, see the link at www.dgrh.de).

Recommendation 4: When determining an individual risk, known risk factors should be considered. (LoE IV, LoA 10.0)

It is likely that the known risk factors for infections in patients with an IRD also apply to SARS-CoV-2.
Validated risk factors for infections in patients with an IRD include older age, obesity, multimorbidity (especially pre-existing lung disease, pre-existing cardiovascular disease, diabetes), a history of previous serious infections, long-term therapy with GCs (especially >5 mg/day), therapy with DMARDs and other immunosuppressive drugs (exceptions are hydroxychloroquine, sulfasalazine), high activity of the underlying rheumatic disease, current or previous (up to 8 weeks) therapy with cyclophosphamide and acquired or congenital immunodeficiencies (in particular Ig deficiency <4 g/dl IgG, lymphopenia < 500 cells/μl, CD4 T cell count <200/μl) [1, 11, 18]. It is likely that the known risk factors for severe COVID-19 disease also apply to patients with an IRD [11, 18].

Recommendation 5: At present, the care of patients with inflammatory rheumatic diseases should be in accordance with the rheumatologic standards that apply under normal conditions and should not be changed as a result of the COVID-19 pandemic alone. (LoE IV, LoA 9.75 ± 0.56)

Necessary inpatient treatment should not be delayed.

In accordance with the recommendations of the Standing Committee on Vaccination at the RKI, the vaccination status should be updated (focus: pneumococcal vaccination, influenza vaccination as soon as available for the 2020–2021 season).

Therapy for SARS-CoV-2 infection and COVID-19 independent of IRDs

The treatment of SARS-CoV-2 infection should be managed by the general practitioner (mild cases), an infectiologist, a pneumologist or, if necessary, by an intensive care physician (severe cases). Rheumatologists should always be involved in the decision to maintain, reduce or pause anti-rheumatic therapy.

Among the few studies available that tested the effect of immunomodulatory therapy in non-hospitalized non-IRD patients with SARS-CoV-2 with regard to reducing time to an undetectable viral load, reducing the duration of clinical symptoms or preventing clinical deterioration, none provided evidence of treatment efficacy. Likewise, in hospitalized non-IRD patients with SARS-CoV-2, the vast majority of clinical studies have failed to demonstrate additional clinical benefit of immunomodulatory drugs if added to the standard of care. In a subgroup of patients (e.g. those requiring respiratory support or those >60 years of age), a beneficial effect of dexamethasone has been described [19, 20].

Beyond their potential use in the described subgroups, the task force recommends the application of anti-rheumatic drugs in the context of SARS-CoV-2 only in clinical studies. This should also ensure the availability of DMARDs for the treatment of patients with an IRD.

IRD patients without contact with a SARS-CoV-2-positive person and without signs of infection

Recommendation 6: The initiation or adjustment of anti-rheumatic therapies should not be stopped or delayed due to the COVID-19 pandemic. (LoE IV, LoA 9.94 ± 0.24)

Existing anti-rheumatic therapy

As dose tapering of clinically efficacious anti-rheumatic therapy is associated with the risk of a flare of the underlying rheumatic disease [21] and increased activity of the underlying IRD is associated with an increase risk of infection [1], treatment with NSAIDs, GCs, conventional synthetic DMARDs (csDMARDs), targeted synthetic DMARDs (tsDMARDs), biologic DMARDs (bDMARDs) or immunosuppressive drugs (e.g. azathioprine, cyclophosphamide), if indicated by the IRD, should not be terminated or reduced in dose solely for fear of infection with SARS-CoV-2.

Consider a delay of rituximab (RTX) in indications without potentially life-threatening manifestations (i.e. especially uncomplicated RA) and in cases of sustained remission and persistent B cell depletion and/or hypogammaglobulinemia.

Initiation/adjustment of an anti-rheumatic therapy

Do not discontinue, delay or underdose anti-rheumatic therapy due to the COVID-19 pandemic if the IRD requires such therapy.

Consider the use of medications with a short half-life. A recommendation for a specific DMARD cannot be given at this time for new patients.

Do not disregard RTX for remission induction in ANCA-associated vasculitis (AAV) out of concern about COVID-19.

Prefer established protocols (e.g. giant cell arteritis, AAV) with reduced GC administration [22, 23].

IRD patients with contact with a SARS-CoV-2-positive person but without signs of COVID-19

Recommendation 7: In IRD patients without signs of infection, even with contact with SARS-CoV-2-positive individuals, the existing anti-rheumatic therapy should be continued unchanged. (LoE V, LoA 9.56 ± 1.22)

If symptoms occur, a doctor or rheumatologist should be contacted immediately.

IRD patients with contact with a SARS-CoV-2-positive person and with signs of COVID-19

Perform a PCR from nasopharyngeal/oropharyngeal swabs for SARS-CoV-2 immediately.

Do not change therapy if symptoms are mild and fever is absent.

Pause anti-rheumatic medication if clear signs of infection, and especially fever (>38°C), are present.

Continue any long-term GC therapy <10 mg/day prednisolone.

Prednisone doses ≥10 mg/day are associated with higher odds of hospitalization in patients with an IRD [24]. An individual decision with regard to GC tapering is necessary for patients with an IRD taking prednisone at a dose ≥10 mg/day.

IRD patients who test positive for SARS-CoV-2 (PCR) but without signs of COVID-19

Recommendation 8: In IRD patients who test positive for SARS-CoV-2 by PCR without signs of infection, pausing or delaying tsDMARD or bDMARD therapy for the duration of the mean incubation period (e.g. 5–6 days) should be considered. (LoE V, LoA 9.75 ± 0.43)

Consider pausing or delaying tsDMARD or bDMARD therapy for the duration of the mean incubation period (5–6 days after the smear).

Continue any long-term GC therapy <10 mg/day prednisolone.

Prednisone doses ≥10 mg/day are associated with higher odds of hospitalization in patients with an IRD [24]. An individual decision with regard to GC tapering is necessary for patients with an IRD taking prednisone at a dose ≥10 mg/day.

Do not discontinue csDMARDs.

IRD patients who test positive for SARS-CoV-2 (PCR) and with signs of COVID-19

Recommendation 9: Patients with confirmed, active COVID-19 should pause DMARD therapy. Continuous GC therapy <10 mg/day used for treatment of the underlying inflammatory rheumatic disease should be continued at the same dose. (LoE V, LoA 9.94 ± 0.24)

Continue any long-term GC therapy <10 mg/day prednisolone. Prednisone doses ≥10 mg/day are associated with higher odds of hospitalization in patients with an IRD [24]. An individual decision with regard to GC tapering is necessary for patients with an IRD taking prednisone at a dose ≥10 mg/day.

In general, pause DMARDs. However, consider continuation of bDMARDs and tsDMARDs in individual cases based on available data on their effect in COVID-19.

Consider a washout procedure for leflunomide.

Measures to increase knowledge with regard to SARS-CoV-2 in patients with an IRD

Recommendation 10: Patients with inflammatory rheumatic diseases and a positive test for SARS-CoV-2 (PCR and/or antibodies) should be documented in the COVID19-rheuma.de registry of the DGRh. (LoE V, LoA 10.0)

Efforts are being made worldwide to document the course of SARS-CoV-2 and COVID-19 in patients with IRDs and thus to gain experience about the infection in these patients. This experience is essential for the development of future recommendations for the management of IRD patients in times of SARS-CoV-2/COVID-19. In addition to large national registries, international registries also exist, e.g. those of the EULAR and the Global Rheumatology Alliance. National data sets should be made available to the international databases, but duplication of patients must be carefully avoided.

Discussion

With the use of a well-established consensus method, a modified Delphi process, we developed evidence-based expert consensus statements and provide clinical guidance for the management of patients with an IRD in times of SARS-CoV-2. The update of our first recommendation [1] is based on registry data, cross-sectional studies and case series, which provide important information on SARS-CoV-2/COVID-19 in IRDs despite the short time since the beginning of the pandemic. All of these data sources have limitations: the most important potential bias is the disproportionate number of severe cases that are characteristic of these types of studies; the lack of parallel, regional comparative cohorts without IRD; the regionally different handling of SARS-CoV-2 and the different frequency of infected individuals, as well as the specific differences of individual healthcare systems.

In the DGRh update, aspects of the prevention and management of SARS-CoV-2/COVID-19, risk assessment of IRDs and the use of immunomodulatory/immunosuppressive drugs in these patients are discussed. The recommendations correspond in many aspects with those of American (ACR) [25] and European (EULAR) [26] professional societies, but also differ in some points.

All three professional societies recommend adherence to the behavioural and precautionary measures prescribed by

local authorities for patients with an IRD in the same way as the general population. Any activities beyond these measures are not suggested for patients with an IRD for lack of scientific evidence in any of the recommendations.

Differences exist with regard to contact with physicians controlling the IRD: while the ACR and EULAR suggest selected measures to reduce personal contact—e.g. fewer laboratory tests, use of telemedicine, extended dosage intervals for i.v. drugs and postponement of visits to the rheumatologist—the DGRh recommends against a postponement of regularly scheduled visits but rather asks for 'care as usual as possible' even in the case of controlled disease and stable therapy. This difference is owed to the currently better-controlled infection situation in Germany compared with other European countries and the USA and is driven by the concern for increasing activity of the underlying immunological disease that, if uncontrolled, would be both, disadvantageous for the IRD but also increases the risk of a SARS-CoV-2 infection.

The DGRh recommendation is the only guidance that makes distinct statements on existing *vs* new or escalated therapy. In contrast to the ACR, the DGRh does not comment on anti-rheumatic therapy in individual IRDs on a scientific basis, for the lack of evidence, but rather gives recommendations for anti-rheumatic therapy independent of the underlying IRD. In all three recommendations, it is suggested to perform GC therapy with the lowest possible daily dose. However, since this is the rheumatologic standard, EULAR and the DGRh have explicitly refrained from recommending a reduction in the daily GC dose for fear of a SARS-CoV-2 infection. There is agreement here that ongoing GC therapy in a dosage that is rheumatologically justified should not be abruptly discontinued or reduced.

On the basis of the available data, the DGRh recommends a less restrictive attitude towards delaying, postponing or stopping DMARD therapy compared with the recommendations of the EULAR and the ACR. While the ACR recommends pausing anti-rheumatic treatment with many but not all immunosuppressive therapies upon contact of the IRD patient with a SARS-CoV-2-positive individual, the DGRh recommends this only if there are clear symptoms of infection or a positive SARS-CoV-2 test in the IRD patient. We strongly believe that in light of the available data, which fail to show an increased risk for many of the anti-rheumatic DMARDs for an increased infection with SARS-CoV-2 and for more severe COVID-19, that IRD patients who halt anti-rheumatic therapy would be at risk for flairs and would also have the demand and necessity for frequent visits to the rheumatologist that should be avoided.

These recommendations have been prepared by the Board of Directors of the DGRh and the Commission for Pharmacotherapy of the DGRh (as of 1 July 2020). The text has been published in German as clinical guidance on the homepage of the society and in the *Zeitschrift für Rheumatologie* [27] to allow German-speaking rheumatologists and patients to take advantage of this novel, evidence-based guidance as soon as it was completed. The DGRh will continue to update its recommendations and will publish these and other information on the COVID-19 pandemic on its homepage (www.dgrh.de) on an ongoing basis. It is also recommended that every physician should keep her-/himself informed about new diagnostic and therapeutic developments regarding COVID-19, as this may result in short-term deviations from these recommendations. In individual cases, a deviation from these recommendations may be appropriate.

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Data availability statement

None declared.

Supplementary data

Supplementary data are available at *Rheumatology* online.

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