Epidemiology and outcomes of novel coronavirus 2019 in patients with immune-mediated inflammatory diseases

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Purpose of review
The novel coronavirus 2019 (COVID-19) pandemic is of special concern for patients with immune-mediated inflammatory disease (IMID) and those who care for them because of the potential for worse outcomes. This article analyzes peer-reviewed research on the epidemiology and outcomes of COVID-19 in those with IMID.

Recent findings
Published literature on approximately 1400 patients was included from rheumatology, gastroenterology, and dermatology. Data suggest that those who are older and have comorbidities have poorer outcomes. This is consistent with the reports from the general population of patients with COVID-19. Adjusted analyses from the largest published studies demonstrate independent effects of systemic glucocorticoids, as well as age and comorbidities with poorer COVID-19 outcomes (SECURE-IBD registry, $n = 525$; COVID-19 Global Rheumatology Alliance registry, $n = 600$); biologic or targeted synthetic disease-modifying antirheumatic drug therapy has not been associated with more severe outcomes. These early results will require validation in population-based studies as more data becomes available.

Summary
Current data suggest that similar to the general population, age, and comorbidities are risk factors for poorer COVID-19 outcomes in patients with IMID. Additional research is needed to quantify outcomes and risk across rheumatic disease types, comorbidities, and immunosuppressive drugs.

Keywords
novel coronavirus 2019, epidemiology, outcomes, rheumatology, SARS-CoV-2

INTRODUCTION

The novel coronavirus 2019 (COVID-19) pandemic is the first coronavirus pandemic declared by the WHO. It has touched almost all countries in the world and caused over 6 million infections and over 350 000 deaths. The impact of previous epidemics caused by coronavirus infections like severe acute respiratory syndrome 1 (SARS-1) and middle east respiratory syndrome (MERS) on patients with immune-mediated inflammatory disease (IMID) has scarcely been reported. People with IMID have underlying immune system dysfunction and often take immune-suppressing medications. The potential for poorer outcomes compared with others is a considerable concern. In the face of the uncertainty around outcomes in IMID patients, a number of registries have collected case information to help guide patient management [1–3,4▪▪]. This review discusses published research on patients with IMID who have COVID-19, their outcomes, and future research questions that should be addressed.

CLINICAL FEATURES AND OUTCOMES IN THE GENERAL POPULATION

The characteristics of COVID-19 in IMID patients should be considered in the context of the broader epidemiology of COVID-19 in the general population. Many large case series of patients from areas with high prevalence of COVID-19 have been reported. The large contrast in percentage of hospitalizations, ventilation needs, and death across studies illustrate how estimates can differ depending on the population measured and sampling strategy

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KEY POINTS

- Current data suggest that similar to the general population, age, and comorbidities are a risk factor for poorer COVID-19 outcomes in patients with immune-mediated inflammatory diseases.
- Glucocorticoids may also be associated with severe outcomes in patients with immune-mediated inflammatory diseases and COVID-19.
- More research is needed to further determine whether risk and outcomes of COVID-19 occur across various rheumatic diseases, comorbidities, and immunosuppressive drugs.

used to identify patients, which is important in interpreting findings. However, available estimates provide a foundation for comparing results from disease-specific studies of COVID-19, such as those examining patients with IMID.

One of the first population-based COVID-19 publications explored over 1000 patients from over 500 hospitals across China and found that overall, 5% of patients were admitted to the ICU, 2.3% received invasive mechanical ventilation, and 1.4% died [5]. In an Italian surveillance report of over 62 000 cases from across the nation, researchers found that 15.5% of cases were hospitalized and 9–11% of hospitalized patients were admitted to the ICU [6]. The overall case fatality rate was estimated to be 8.8%, much higher than the study from China. This likely reflects the very high prevalence of disease in a concentrated area (Lombardy region) and the older age structure of the Italian population, which contributed to an overwhelming burden on healthcare systems. In a separate study of patients admitted to the ICU also in the Lombardy region, 88% required ventilation and the mortality rate was estimated to be 26% [7].

Additional studies from the United States mirror these early studies from China and Italy. For example, Richardson *et al.* [8] found that among hospitalized patients in New York City, an area also overburdened by a sudden high prevalence of disease, 14% were admitted to the ICU. Of the cases that were hospitalized, 12.2% required invasive mechanical ventilation and 21% died. In contrast, a report of patients with lab-confirmed COVID-19 in the United States across 14 states found a hospitalization rate of less than 1%, with a higher proportion of patients hospitalized that were older and had underlying medical conditions [9]. The more comprehensive case-finding approach using population-based surveillance across a number of different states with varying degrees of prevalence and testing strategies likely resulted in a much lower hospitalization rate compared with studies conducted in concentrated areas of high prevalence, illustrating the importance of understanding study design when interpreting results.

CLINICAL FEATURES AND OUTCOMES IN IMMUNE-MEDIATED INFLAMMATORY DISEASE

Several studies have examined IMID cases diagnosed with COVID-19 and have noted similarities in clinical features and outcomes compared with the general population (Table 1). Studies largely come from the rheumatic and inflammatory bowel disease fields, likely because of a critical need to understand whether these patients, many of whom take immunomodulatory medications, are at higher risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection or have poorer outcomes from infection. Additionally, information on patients that are long-term users of potential COVID-19 treatments, such as hydroxychloroquine, unexpectedly became the subject of interest for a wide array of COVID-19 researchers and clinicians. Below we highlight peer-reviewed literature examining patients with IMID and COVID-19 for which a substantial sample size was collected ($n > 10$ confirmed cases). For the dermatology field, all published studies were included as only two reports have been published to date.

Rheumatic diseases

Three types of studies have largely provided information on COVID-19 in the rheumatic disease population, including case series, studies utilizing electronic health records of single healthcare systems, and survey-based designs. Although each provides important information in understanding how patients fare during the pandemic, it is important to note the strengths and limitations of each study design.

Case series have been the most common type of study because of their ability to identify and characterize patients diagnosed with COVID-19 at a rapid pace. However, these studies may bias toward severe cases that are more likely to be captured, whereas those who are treated at home, without medical intervention are not included. One of the first case series in the rheumatic disease fields came from a French group that followed 17 systemic lupus erythematosus patients on long-term hydroxychloroquine that developed COVID-19 to understand the severity of illness and outcomes [10▪]. Authors found that most patients (82%) were hospitalized,

Table 1. Studies of patients with immune-mediated inflammatory diseases (IMID) reported with COVID-19

Author	No. IMID patients with COVID-19	Study type	Location	IMID included	Preexisting treatment	COVID-19 outcomes % hospitalized; % ventilated; % died	Main findings
Rheumatology data							
Mathian *et al.* [10▪]	17	Case series	France	SLE	All on hydroxychloroquine	14 hospitalized (82%); 5 ventilated (29%); 2 died (14%)	A majority of SLE patients on long-term hydroxychloroquine treatment and subsequently diagnosed with COVID-19 were hospitalized
Gianfrancesco *et al.* [11▪]	600	Case series	Global	Rheumatoid arthritis, PsA, SLE, axSpA, vasculitis, Sjogren's syndrome, other (total of 21 rheumatic diseases)	csDMARDs, b/tsDMARDs, glucocorticoids	277 hospitalized (46%); ventilation, not reported; 55 died (9%)	Age >65 years, comorbidities, and glucocorticoid dose ≥10 mg/day were associated with hospitalization
Ye *et al.* [12▪]	21	Case series with comparative group	Wuhan, China	Rheumatoid arthritis, SLE, Sjogren's syndrome, axSpA, other	Glucocorticoids, NSAIDs, csDMARDs; no patients on long-term b/tsDMARD	Hospitalization, not applicable (all hospitalized patients); 8 respiratory failure (38%); 2 died (9.5%)	Higher risk of respiratory failure in patients with rheumatic disease and COVID-19 versus nonrheumatic disease COVID-19 patients. No difference in mortality rate between groups
D'Silva *et al.* [13▪]	52	EHR-based, healthcare system	Boston, MA, USA	Rheumatoid arthritis, SLE, polymyalgia rheumatica, seronegative spondyloarthritis, other (total of 10 rheumatic diseases)	csDMARDs, b/tsDMARDs, glucocorticoids	23 hospitalized (44%); 11 ICU admission/mechanical ventilation (21%); 3 died (6%)	Patients with rheumatic disease had similar rates of hospitalization and mortality than matched nonrheumatic disease patients; but higher rates of ICU admission and mechanical ventilation
Haberman *et al.* [14▪]	86	EHR-based, healthcare system	New York City, NY, USA	Psoriasis, PsA, ulcerative colitis, Crohn's disease, axSpA on immunomodulatory therapies	csDMARDs, b/tsDMARDs, glucocorticoids	14 hospitalized (16%); 1 ventilated (1%); 1 died (1%)	Incidence of hospitalization among IMID patients was consistent with that among patients with COVID-19 in general population; baseline use of biologics not associated with worse COVID-19 outcomes
Michelena *et al.* [15▪]	11	Survey and EHR review	Barcelona, Spain	Rheumatoid arthritis, PsA, axSpA, other	All on b/tsDMARD	6 hospitalized (55%); 1 ICU (9%); 0 died (0%)	Adult and pediatric patients treated with b/tsDMARDs are not at higher risk of COVID-19 or more severe outcome compared with general population
Gastroenterology data							
Brenner *et al.* [4▪▪]	525	Case series	Global	Crohn's disease, ulcerative colitis, other	Steroids, bDMARD and oral immune suppressants	161 hospitalized (31%); 37 ICU, ventilated or died (7%); 16 (3%) died	Older age, steroids and co-morbidities and ASA/sulphasalazine were associated with poorer COVID-19 outcomes in patients with IBD
Rodríguez-Lago *et al.* [16▪]	40	Case series	Basque country (Spain)	IBD	Steroids, thiopurines, and bDMARD	21 hospitalized (53%); 0 ventilated (0%); 2 died (5%)	Patients with IBD fared generally well; those that died were over 75 years old
Allocca *et al.* [17▪]	15	Case series	Multicentre (Italy and France)	IBD	Steroids, thiopurines, and bDMARD	5 hospitalized (33%); 0 ventilated (0%); 0 died (0%)	Incidence of COVID-19 in IBD patients was similar to that in the general population of France and Italy; mortality and need for ventilation was much lower
Dermatology data							
Damiani *et al.* [18▪]	22	Case control	Lombardy, Italy	Psoriasis	All b/tsDMARD	5 hospitalized (23%); 0 ICU (0%); 0 died (0%)	Rates of ICU admission and death in psoriasis patients not different to wider Lombardy population
Gisondi *et al.* [19▪]	6	Case series	Multicentre Italy	Chronic plaque psoriasis	All bDMARD	4 hospitalized (67%); 1 ICU (17%); 0 died (0%)	Rates of death and COVID-related interstitial pneumonia in chronic plaque psoriasis patients not different to general Italian population

axSpA, Axial spondyloarthritis; ASA, aminosalicylic acid; b/tsDMARD, biologic or targeted synthetic disease-modifying antirheumatic drug; COVID-19, novel coronavirus 2019; csDMARD, conventional synthetic disease-modifying antirheumatic drug; HER, electronic health records; IBD, inflammatory bowel disease; NSAID, nonsteroidal antiinflammatory drugs; PsA, psoriatic arthritis; SLE, systemic lupus erythematosus; .

including 41% to an ICU. Over half of patients received oxygen therapy (65%). At the time the report was written, half remained hospitalized and two died (14%). These outcomes are more severe than those reported in the general population; however, because the denominator of total lupus patients is not mentioned, it is difficult to make conclusions about risk of COVID-19 in the specific population, as well as capture accurate estimates of hospitalization or death rates.

In the largest case series to date, the COVID 19-Global Rheumatology Alliance (C19-GRA) physician registry collected a total of 600 cases of 21 different rheumatic diseases from 40 countries [11▪]. The registry found that 46% of cases were hospitalized and 9% died. Information regarding ventilation outcomes were not reported. Although case series deriving from physician-reported registries such as the C19-GRA may also bias toward more severe cases and outcomes, over time they may collect less severe cases as well.

Other case series of rheumatic disease patients have been collected with a corresponding nonrheumatic disease population, allowing researchers to compare whether rheumatic disease patients have more severe outcomes than the general population. A retrospective case series in Wuhan, China examined 21 patients with a rheumatic disease from a sample of 2326 patients with COVID-19 who were hospitalized [12▪]. The authors found that age, length of hospital stay and mortality were not different between COVID-19 patients with and without rheumatic disease; however, respiratory failure was more common in those with rheumatic disease (38 versus 10%).

A second type of study includes data using electronic health records (EHR) of patients within a single healthcare system. These studies may also overestimate the severity of COVID-19 in the patient population, as patients with mild or no symptoms will not be captured. Researchers from Boston, MA, examined differences in outcomes of COVID-19 in patients with and without rheumatic disease from a large healthcare system [13▪]. As in the study from Wuhan, China, there was no significant difference in COVID-19 symptoms, age, length of hospitalization, or mortality between the groups; however, there was a higher odds of ICU admission/mechanical ventilation among hospitalized patients with rheumatic disease (48 versus 18%). Although the analysis controlled for disease type and comorbidities, the potential for unmeasured confounding in disease severity or other conditions not captured cannot be ruled out. While the similar findings are intriguing, as they were generated in two very different datasets, additional replication is warranted.

Using records from a health system in New York City, a study with 86 IMID COVID-19 positive patients found that the incidence of hospitalization (16%) was consistent with that among patients with COVID-19 in the corresponding general population (26%) [14▪]. Mortality in this case series was 7%. Fifty percentage of hospitalized patients required supplemental oxygen and 7% needed ICU-level care, mechanical ventilation, or both.

Other types of studies have focused on survey-based designs, identifying patients through telephone or questionnaires from specific centers or cohorts. It is important to note that these studies tend to bias toward low hospitalization and death, favoring those with less severe outcomes who can be reached by phone and/or are healthy enough to respond. In a cohort of adult and pediatric patients with IMID who were treated with targeted biologic and synthetic disease-modifying antirheumatic drugs (DMARDs) at a clinic in Barcelona, Spain, researchers found that the incidence of COVID-19 was similar to that in the general population [15▪]. Interestingly, they found no cases reported in the pediatric cohort. Patients also did not demonstrate more severe disease compared with the general population. In this study, over half were hospitalized (55%), and no one (0%) died.

Gastrointestinal diseases

Within the gastrointestinal field, studies have been mostly case series in design. In the largest case series to date, the Surveillance Epidemiology of Coronavirus Under Research Exclusion for Inflammatory Bowel Disease (SECURE-IBD) registry collected 525 cases from over 30 countries around the world [4▪▪]. The series was mainly composed of patients with Crohn's disease (59%) and ulcerative colitis (39%). Approximately, 30% were hospitalized and 3% of patients died. Researchers found that 7% of patients had severe COVID-19, defined as ICU admission, ventilator use, and/or death. Similar to the studies mentioned above, including the C19-GRA registry, the SECURE-IRB registry may skew toward more severe cases; however, the addition of less severe cases over time may help reduce this potential bias.

Another study from the Basque country (Spain) identified 40 cases out of 9452 positive cases of SARS-CoV-2 infection [16▪]. No patients were admitted to the ICU or needed mechanical ventilation, although two deaths were reported (5%) in patients over 75 years of age. In an attempt to estimate cumulative incidence of COVID-19, researchers from France and Italy calculated the number of COVID-19 cases in two large cohorts of inflammatory bowel disease (IBD) patients, identified through

Table 2. Factors shown in more than one report to be associated with poorer outcomes in patients with IMID

Factor	IMID	Size of effect
Glucocorticoids	Inflammatory bowel disease[a]	Systemic glucocorticoid aOR 6.87 (95% CI 2.30–20.51)
	Rheumatic disease[b]	Prednisone ≥10 mg/day aOR 2.05 (95% CI 1.06–3.96)
Comorbidity	Inflammatory bowel disease[a]	≥Two comorbidities aOR 2.9 (95% CI 1.1–7.8)
	Rheumatic disease[b]	Hypertension or CVD aOR 1.86 (95% CI 1.23–2.81) Lung disease aOR 2.48 (95% CI 1.55–3.98) Diabetes mellitus aOR 2.61 (95% CI 1.39–4.88) Chronic renal impairment aOR 3.02 (1.21–7.54)
Age	Inflammatory bowel disease[a]	Increasing age aOR 1.04 (95% CI 1.01–1.02)
	Rheumatic disease[b]	Age >65 years aOR 2.56 (95% CI 1.62–4.04)

aOR, Adjusted odds ratio; CI, confidence interval; CVD, cardiovascular disease.
[a]Outcome was 'severe COVID-19,' defined as a composite of ICU admission, ventilator use, and/or death (Brenner *et al.* [4▪▪]).
[b]Outcome was hospitalization (Gianfrancesco *et al.* [11▪]).

telemedicine and infusion center visits [17▪]. A total of 15 cases were captured, and the authors found that the incidence of COVID-positive IBD patients (0.0025) was similar to the general population (0.0017 for France and Italy). Authors found a much lower mortality rate and need for intensive care support than in the general population, with no case qualifying for either category; however, similar to the survey-based studies described above, this study likely missed severe cases who could not be reached.

Dermatological diseases

Currently, there is limited data available on dermatology patients; we identified one case-control study and a case series. The single-center case-control study examined psoriasis patients treated with a range of therapies from northern Italy [18▪]. Authors reported that of 1193 patients, only 22 (2%) were infected and none died. The rates of ICU admission and death were not different from the corresponding general population. Additionally, a multicenter retrospective case series from five dermatology departments across Italy reported on 5206 patients with chronic plaque psoriasis treated with biologic therapies [19▪]. Researchers found a total of six patients diagnosed with COVID-19, of which four were hospitalized (67%). No deaths occurred within this study population.

In summary, the aforementioned studies reflect a range of hospitalization from 16 to 82% and death from 0 to 50%. Differences derive, in part, from the study design and sampling strategy used to identify patients, which can result in under or overreporting of COVID-19 disease and severity. It is important to take these differences into account when interpreting results and conclusions.

RISK FACTORS ASSOCIATED WITH NOVEL CORONAVIRUS 2019 OUTCOMES IN IMMUNE-MEDIATED INFLAMMATORY DISEASE

In studies within the general population, older age and comorbidities such as hypertension, obesity, chronic lung disease, diabetes mellitus, and cardiovascular disease are associated with worse COVID-19 outcomes [9]. These findings have also been replicated in IMID populations (Table 2). In the C19-GRA article examining 600 cases, age over 65 years and the most common comorbidities (hypertension/cardiovascular disease, lung disease, diabetes, chronic renal insufficiency/end-stage renal disease) were associated with higher odds of hospitalization, even after adjustment for multiple factors [11▪]. The authors also demonstrated a significant association between prednisone-equivalent glucocorticoids at least 10 mg/day and hospitalization. The large SECURE-IBD registry similarly found that factors associated with severe COVID-19 in adjusted models were older age, at least 2 comorbidities, and glucocorticoids; additionally, the group demonstrated that sulfasalazine or 5-aminosalicylate use was associated with higher odds of severe COVID-19 [4▪▪].

Although the role of age and comorbidities are not surprising given their association with COVID-19 in the general population, significant associations with glucocorticoids across registries provide insight into potentially important risks for IMID patients, information that can guide clinicians in counseling patients as the pandemic evolves. These findings are in line with previous research showing increased risk of infections with higher doses of glucocorticoids [20]. Interestingly, the C19-GRA and SECURE-IBD registries did not find increased odds in hospitalization or severe infection associated with anti-tumor (or tumour) necrosis factor

(TNF), respectively. Because of the risk of unmeasured confounding, this finding needs confirmation in additional studies.

CONCLUSION

Collectively, results suggest that IMID patients are not at higher risk of developing COVID-19 than individuals without IMID and that most patients recover, including those on biologic therapies, which provides reassurance to both patients and providers. However, there is suggestive evidence that patients with rheumatic disease may have a higher likelihood of having severe outcomes, such as requirement for mechanical ventilation. Additionally, glucocorticoid exposure may be associated with more severe outcomes. Owing to this information, IMID patients should continue to take caution and avoid high-risk exposures.

It is important to note that biases may be inherent in all types of study designs. For example, if patients within the IMID population have differential behavioral practices (i.e., be more likely to take preventive measures such as wearing masks, washing hands, and sheltering in place longer) than the general population due to awareness of being at higher risk of developing infections because of their disease or long-term medications, this could potentially lead to an underestimate of risk within the IMID population. Additionally, as testing guidelines and availability differ between and within countries, these factors may also impact findings across studies. In the future, widely available antibody testing in representative samples may provide a more accurate estimate of SARS-CoV-2 infection amongst IMID patients and the general population; however, even then, sampling strategies may result in biased estimates of prevalence. For example, antibody test specificities of 94–96% will produce very poor positive predictive values in areas of low disease prevalence. Therefore, it is important that researchers and the public be cautious when interpreting study findings and making clinical decisions that impact the treatment of patients.

Research examining the risk of SARS-CoV-2 infection in IMID populations is still urgently needed. Several of the studies reviewed were small, not population-based, or lacked control for potential confounders, limiting the validity and generalizability of findings. Large-scale, population-based studies using nationwide registries, especially in countries with uniform COVID-19 reporting systems, may provide a better estimate of risk of COVID-19 in the IMID population, and whether differences in incidence and outcomes are present. Claim-based studies in the United States, or studies in countries with universal health systems or nationwide registers, are most appropriate for these types of questions. However, they will take time to collect and analyze and may not be generalizable outside of the population examined.

Case series, on the other hand, will be useful in countries where national data are not available. They will also allow examination of rare diseases on a large scale, as well as detailed clinical phenotype information that may not be available in large population-based studies (e.g., disease activity assessment), and analyses of country and region-specific differences. Finally, longitudinal cohort studies will allow for the understanding of long-term outcomes of COVID-19 on both the health of patients with infection, and the pandemic in general on disease outcomes in the IMID population, with potential loss of insurance, disruptions to access in care, and ongoing stress. Given the strengths and limitations of each type of study design, it is important that diverse research studies are conducted to answer the questions for which they are best suited, with clear acknowledgement and understanding of their limitations.

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