Assessing the Risk and Outcome of COVID-19 in Patients with Psoriasis or Psoriatic Arthritis on Biologic Treatment: A Critical Appraisal of the Quality of the Published Evidence

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The need to rapidly spread information about the risk of COVID-19 in patients with psoriasis and psoriatic arthritis on biologics may have hampered the methodological rigor in published literature. We analyzed the quality of papers dealing with the risk and outcomes of COVID-19 in patients with psoriasis and psoriatic arthritis receiving biologic therapies. The Newcastle-Ottawa Scale was used to estimate the quality of the published studies. Moreover, to better contextualize results, specific internal and external validity items were further considered, that is, case definition, modality of COVID-19 assessment, evidence for self-selection of participants, percentage of dropout/nonparticipants, and sample size calculation. A total of 25 of 141 papers were selected. The median Newcastle-Ottawa Scale score was 47% for psoriasis and 44% for psoriatic arthritis, indicating an overall high risk of bias. A total of 37% of psoriasis and 44% of psoriatic arthritis studies included patients with suspected COVID-19 without a positive swab. No studies provided a formal sample size calculation. A significant risk of bias in all the published papers was found. Major issues to be considered in future studies are reduction of ascertainment bias, better consideration of nonresponse or participation bias, and provision of formal statistical power calculation.

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INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic spreads globally since early 2020 with major health and economic consequences. After a considerable amount of time, there is still some concern among dermatologists regarding a potentially increased risk of infection and/or worse outcome among patients with COVID-19 on biologic therapy for psoriasis (Pso) or psoriatic arthritis (PsA).

Indeed, the available data point to an increased risk of respiratory infections in patients being treated with antagonists of IL-17 and TNF-α (Ford and Peyrin-Biroulet, 2013; Wan et al., 2020). In contrast, in patients with COVID-19, uncontrolled inflammatory innate responses and impaired adaptive immune responses may lead to tissue damage, both locally and systemically. Many inflammatory cytokines appear to be involved in this phenomenon, including TNF and IL-17 (Feldmann et al., 2020; Pacha et al., 2020).

Overall, whether biologics enhance the risk or protect from the development of severe COVID-19 or whether Pso/PsA per se is associated with a more severe course of infection is yet to be ascertained.

Several papers have been published aiming to elucidate the risk of patients with Pso or PsA being treated by biologics during the COVID-19 pandemic.

However, the need to rapidly spread information to the dermatological community may have hampered the methodological rigor in the currently published literature.

In this study, we analyzed the quality and possible limitations of published studies on the risk and outcome of COVID-19 in patients with Pso or PsA receiving biologic therapies and make suggestions for future research studies.

RESULTS

The initial database search yielded a total of 141 items from PubMed and 53 from Embase (187 records after duplicate removal). A total of 134 studies were further excluded on the basis of abstract review because they did not match the inclusion criteria. After screening the full text of the remaining 53 articles, 25 studies were eligible for the final qualitative assessment (Figure 1).

The characteristics of the selected studies and the respective quality scores according to the Newcastle-Ottawa Scale (NOS) scale are summarized in Table 1. Further details are included in Supplementary Table S1 for Pso and Supplementary Table S2 for PsA.

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Abbreviations: NOS, Newcastle-Ottawa Scale; PsA, psoriatic arthritis; Pso, psoriasis; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

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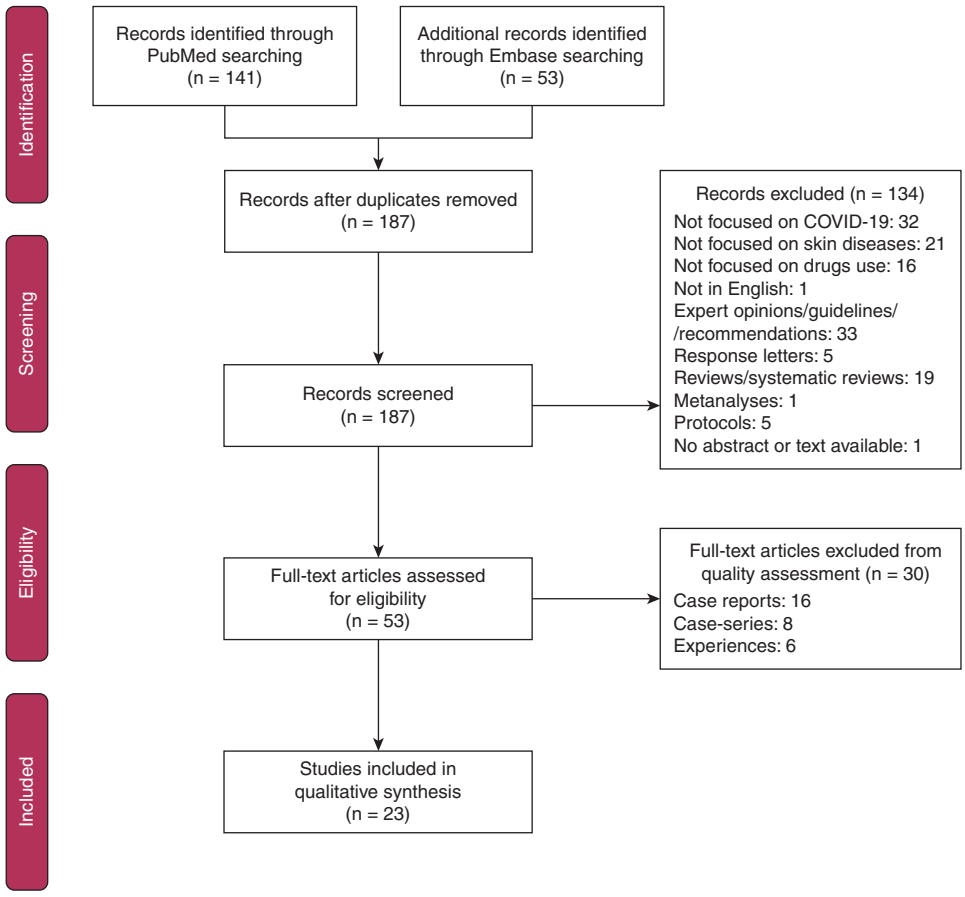

Figure 1. Flow diagram of the study selection procedure.

The median NOS score was 47.2% (interquartile range = 39.7–55.6) for Pso and 44.4% (interquartile range = 40.0–55.6) for PsA, indicating an overall high risk of bias. No study reached a score ≥75%. In particular, no study satisfied the comparability items (study controls for the most important factors or for any additional factor), and in cross-sectional studies, a sample size was never justified, and response rates were provided in 0% of Pso studies and 22.2% of PsA studies.

Two of 16 (12.5%) papers providing data on Pso combined the dermatological condition with other diseases. Seven (43.7%) studies on Pso did not include a control group. Six (37.5%) studies included patients with reported or suspected COVID-19 without a positive swab (Table 2). A total of 13 of 16 (81%) studies collected data on a group of patients from a target population (typically the cohort of patients followed in one or more reference centers for Pso) and not according to self-selection by the patient (e.g., internet-based surveys), but only two studies (12.5%) reported the rate of nonparticipants or dropouts (Table 2).

All of the papers on PsA also included patients with other rheumatologic conditions, and only in one paper we could clearly distinguish the data regarding patients with PsA from the other groups of patients. Two of nine (22.2%) studies on PsA did not include a control group.

Four of nine (44.4%) studies enrolled patients with reported or suspected COVID-19 without a positive swab. Two (22.2%) of the studies collected data on the basis of self-selection by the patient, and one of these reported a 54% rate of nonparticipants or dropouts (Table 2).

No studies on Pso or PsA provided a statement concerning the power of the statistical tests used or a formal sample size calculation for incidence or prevalence estimates.

A detailed description of the studies according to the additional elements described in the Materials and Methods is summarized in Supplementary Tables S3 and S4 for Pso and PsA, respectively.

DISCUSSION

In this comprehensive meta-research comprising 25 studies on the risk and outcomes of COVID-19 in patients with Pso and PsA, we found a high risk of bias in all of the published papers. No study reached a NOS score ≥75%.

Lack of a comparator group and floating numerators

One common flaw was the lack of a suitable comparator group. Seven of 16 (43.7%) studies on Pso did not consider any control group. This prevented a proper evaluation of the risk of COVID-19 associated with the disease or its treatment.

One major problem in 7 of 25 (28%) studies, particularly registries, which collected data on patients with COVID-19 and compared the proportion of patients who were hospitalized or died according to different treatments received for their underlying disease, was the lack of a reference to the underlying at-risk population, that is, the population of patients treated by different medications from which the

Table 1. Synthesis of Studies Focused on Pso and PsA

Authors	Study Design	Number of Studied Patients	Number of SARS-CoV-2–Positive Patients	NOS Score/Total (%)
Psoriasis				
Baniandrés-Rodríguez et al. (2021)	Multicenter prospective cohort	2,329 Pso	Pts: 73 (36 possibile, 16 probabile, 21 PCR+, 13 hospit, 1 ICU, 1 death)	5/9 (56)
Brazzelli et al. (2020)	Cross-sectional	180 Pso	33 probable	4/10 (40)
Damiani et al. (2020)	Case-control	1,193 Pso	Pts: 22 (17 quarantined at home, 5 hospit, 0 deaths) Ctrs: 54,801	3/9 (33)
de Wijs et al. (2021)	Cross-sectional	264 Pso 347 AD	Pts: 270 with symptoms (3 PCR+) Ctrs: 0.3%	3/10 (30)
Fougerousse et al. (2020)	Multicenter cross-sectional study	1,418 Pso	54 probable (12 PCR+, 5 hospit, 0 deaths)	4/10 (40)
Georgakopoulos et al. (2020a)	Multicenter retrospective cohort	1,390 Pso	0	3.5/9 (39)
Georgakopoulos et al. (2020b)	Multicenter retrospective cohort	2,095 Pso	0	3.5/9 (39)
Gisondi et al. (2020a)	Multicenter retrospective cohort	5,206 Pso	Pts: 6 (4 hospit, 0 deaths) Ctrs: 110,574	5/9 (56)
Gisondi et al. (2020b)	Retrospective cohort (Pso + renal tx)	Pso: 980 Renal tx: 247	Pts with Pso: …[1] Ctrs: 3,199	5.5/9 (61)
Gisondi et al. (2021)	Multicenter retrospective cohort	6,501 Pso	Pts: 18 hospit, 2 deaths Ctrs: 68,099	5.5/9 (61)
Lima et al. (2020)	Retrospective cohort (COVID-19 only)	104 Pso	104 (41 hospit, 13 ICU, 9 deaths)	5/9 (56)
Mahil et al. (2021)	International registry Psoprotect (clinician report) PsoprotectMe (patient report)	Psoprotect: 374 (147 F, 227 M) PsoprotectMe: 1,626 (1,041 F, 583 M)	Psoprotect: 374 (172 PCR+, 77 hospit, 9 deaths) PsoprotectMe: 150 (15 PCR+)	4/10 (40)
Piaserico et al. (2020)	Multicenter prospective cohort	1,830 Pso	Pts: 6 (4 hospit, 0 deaths) Ctrs: 19,154	6/9 (67)
Pirro et al., 2020	Retrospective cohort (telephone survey)	226 Pso	0	4.5/9 (50)
Rodríguez-Villa Lario et al., 2020	Retrospective cohort (telephone survey)	146 Pso	19 clinical diagnosis (6 PCR+, 3 hospit)	5/9 (56)
Vispi et al. (2020)	Multicenter prospective cohort	246 Pso	Pts: 1 Ctrs: 1,075	4/9 (44)
Psoriatic Arthritis				
Costantino et al. (2021)	Cross-sectional (e-mail survey)	52 PsA 129 RA 474 SpA	Pts: 4 suspected, 1 PCR+ Ctrs: 4.4%	6/10 (60)
Favalli et al. (2020)	Cross-sectional survey	203 PsA 531 RA 181 SpA 40 CTD, vasculitis, or autoinflammatory diseases	Pts: 0 PCR+ Ctrs: 57,592	4/10 (40)
Ferri et al. (2020)	Multicenter retrospective cohort (telephone survey)	208 PsA 695 RA 35 AS 438 SSc 76 SLE 64 UCTD 19 PM/DM 18 SJö 88 others	Pts: 11 PCR+ 14 highly suspected (1 hospit, 1 death) (overall) Ctrs: 349/100,000	4/9 (44)

(continued)

Table 1. Continued

Authors	Study Design	Number of Studied Patients	Number of SARS-CoV-2–Positive Patients	NOS Score/Total (%)
Fredi et al. (2020)	Case-control (COVID-19 only)	20 (PsA + SpA) 37 RA 12 SLE	Pts: 20 suspected or PCR+ (3 deaths) Ctrs: 62 suspected or PCR+ (6 deaths)	3/9 (33)
Gianfrancesco et al. (2020)	International registry	230 RA 85 SLE 74 PsA 48 SpA 44 Vasculitis 28 SJö 21 other inflammatory arthritis 20 inflammatory myopathy 19 Gout 16 Ssc 12 polymyalgia rhematica 10 sarcoidosis 28 other	548 PCR+, 52 suspected (277 hospit, 55 deaths)	4/10 (40)
Hasseli et al. (2020)	Cross-sectional (registry, COVID-19 only)	19 PsA (approximate) 47 RA 10 AS 5 SSc <5 Others	Pts: 19 Ctrs: 152,438 (5,500 deaths)	3/10 (30)
Mena Vázquez et al. (2021)	Cross-sectional	1,754 PsA 2,480 RA 786 SpA	Pts: 5 (5 PCR+, 0 deaths) Ctrs: 1,532	6/10 (60)
Montero et al. (2020)	Retrospective cohort (COVID-19 only)	16 (PsA + SpA) 20 RA 4 Other inflammatory 9 SLE 13 Other CTD	Pts: 16 (1 death)	5/9 (56)
Pablos et al. (2020)	Multicenter retrospective matched cohort (COVID-19 only)	35 PsA 65 RA 36 SpA 92 CTD	Pts (Psa + SpA): 71 (43 hospit, 3 deaths) Ctrs: 228	5/9 (56)

Abbreviations: AD, atopic dermatitis; AS, ankylosing spondylitis; CTD, connective tissue disease; Ctr, control; F, female; ICU, intensive care unit; Hospit, hospitalized; M, male; PCR+, PCR confirmation; PM/DM, polymyositis/dermatomyositis; PsA, psoriatic arthritis; Pso, psoriasis; Pt, patient; RA, rheumatoid arthritis; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; Sjö, Sjögren syndrome; SLE, systemic lupus erythematosus; SpA, axial spondyloarthritis; SSc, systemic sclerosis; Tx, transplant recipients; UCTD, undifferentiated connective tissue diseases.

[1]Unknown.

Table 2. Synthesis of Studies Focused on Psoriasis and Psoriatic Arthritis

Paper	Case Definition	COVID-19 Assessment	Voluntary Self-Selection	Dropout/ Nonparticipants (%)	Sample Size Estimate
Psoriasis					
Baniandrés-Rodríguez et al. (2021)	Clearly identifiable	anamnestic assessment without validation	yes	no	no
Brazzelli et al. (2020)	Clearly identifiable	anamnestic assessment without validation	no	unclear	no
Damiani et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	unclear	no
de Wijs et al. (2021)	mixed up with other conditions	anamnestic assessment without validation	yes	yes (56)	No
Fougerousse et al. (2020)	Clearly identifiable	anamnestic assessment without validation	no	not applicable	no
Georgakopoulos et al. (2020a)	Clearly identifiable	anamnestic assessment with validation	no	unclear	no
Georgakopoulos et al. (2020b)	Clearly identifiable	unclear/other	no	unclear	no
Gisondi et al. (2020a)	Clearly identifiable	anamnestic assessment with validation	no	No	no
Gisondi et al. (2020b)	Clearly identifiable	anamnestic assessment with validation	no	No	no
Gisondi et al. (2021)	Clearly identifiable	anamnestic assessment with validation	no	No	no
Lima et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	not applicable	no
Mahil et al. (2021)	Clearly identifiable	anamnestic assessment without validation	no	not applicable	no
Piaserico et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	No	no
Pirro et al., 2020	Clearly identifiable	anamnestic assessment without validation	no	unclear	no
Rodríguez-Villa Lario et al., 2020	Clearly identifiable	anamnestic assessment with validation	no	yes (53)	no
Vispi et al. (2020)	Clearly identifiable	anamnestic assessment with validation	yes	unclear	no
Psoriatic Arthritis					
Costantino et al. (2021)	mixed up with other conditions	anamnestic assessment with validation	yes	yes (54)	no
Favalli et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	yes (2)	no
Ferri et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	unclear	no
Fredi et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	No	no
Gianfrancesco et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	No	no
Hasseli et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	yes	not applicable	no
Mena Vázquez et al. (2021)	Clearly identifiable	direct assessment	no	unclear	no
Montero et al. (2020)	mixed up with other conditions	direct assessment	no	unclear	no
Pablos et al. (2020)	mixed up with other conditions	direct assessment	no	No	no

COVID-19 cases originated. This flaw is sometimes referred to as floating numerators. It can be easily demonstrated, for example, that similar proportions can originate from underlying populations with largely divergent risks (Naldi and Cazzaniga, 2020). Hence, the lack of information on the appropriate denominator (i.e., the source population) for COVID-19 cases does not allow for calculating the proper incidence rates and risks.

Lack of specificity and mixed reference populations

In 40% of the studies, patients with suspected COVID-19 were included without a positive test or a definite diagnosis. When assessing the incidence rate of a disease with a low number of collected cases, this could determine a substantial impact on the analysis.

A common problem in PsA studies was the pooling of different rheumatologic conditions together, including PsA.

Rheumatoid arthritis, lupus erythematosus, or scleroderma are completely different conditions from PsA, with distinct comorbidities and treatments. Mixing them up can either dilute or amplify risks.

Potential for selection bias

Regrettably, only 16% of the studies reported the percentage of responders on the overall group of potential participants. This may represent a relevant issue (nonresponse or participation bias), especially in telephone- and web-based studies.

Web-based nonresponse might be related to technological difficulties. Because internet access tends to be correlated with age and COVID-19 severity is markedly greater in elderly people, web-based data could provide biased results.

In contrast, also a telephone-based collection of data may severely bias the analysis of data in an opposite way. If the surveys were conducted during business hours, active workers would be less likely at home than elderly retired individuals.

This potential mismatch between the characteristics of respondents in a nonrandom sample and those of the general population can lead to severe issues in assessing the outcome of interest. We acknowledge that removing nonresponse bias from a study may be an impossible effort. Regardless, researchers should declare the response rate of the overall population.

Furthermore, studies were mostly conducted in referral hospital centers, and no population-based studies were published (selection bias). Patients with Pso seen in referral centers are likely to have more healthcare exposure than the general population (ascertainment bias). In addition, unmeasured confounders from the physician (e.g., collecting only a portion of patients of COVID-19) or patient (e.g., greater application of social distancing measures and personal protection strategies compared with that of the general population) may also have biased the analysis.

Statistical power issues

It should be recognized that several studies were well-constructed, with a proper calculation of the incidence rate of COVID-19 infection and COVID-19–related hospitalization and death, but none of them performed a sample size estimation and were most likely underpowered to detect any difference between patients with Pso and the control group (type II error). For example, the study which included the largest available cohort of patients with Pso for COVID-19 outcomes was able to reach a maximum power of only 64% (exact binomial test). This was largely due to relatively low incidence rates in both the population and the study cohort (Gisondi et al., 2021).

Our results in the context of COVID-19 studies in the general literature

Our observations are in line with similar data from quality surveys in other clinical areas. A study showed that the quality of papers published in the *New England Journal of Medicine*, *Lancet*, and *JAMA* was lower in the first months of 2020 than in the same period in 2019 and that the decline could be attributed to COVID-19 (Stefanini, 2020). Fewer studies were randomized in 2020 than in 2019 (29.2% vs. 41.4%; OR = 0.58; 95% CI = 0.41–0.82). In addition, according to GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) criteria used in the paper, just 13.7% of 2020 studies were considered high quality, compared with 27.6% of studies published in 2019 (OR = 0.41; 95% CI = 0.27–0.63). In a sensitivity analysis that excluded COVID-19 research, no difference was found between the quality of original research published in 2020 and the quality of those published in the year before.

Another study confirmed that COVID-19–related research in the same journals (i.e., the *New England Journal of Medicine, Lancet,* and *JAMA*) was of lower quality than research on other topics in the same journals for the same period of time, with a great effect size (Zdravkovic et al., 2020). Interestingly, the number of publications on COVID-19 alone was almost the same as the number of publications on all other topics.

There are many reasons that could explain the high frequency of biased published studies. COVID-19 is (still) an unknown disease, and there was an urgent need to collect and publish some data. Everybody agreed on the fact that little, even flawed, data were better than no data.

Against this backdrop, the traditional peer-review system has been stressed by the enormous number of COVID-19–related manuscripts (Bauchner et al., 2020).

Several studies were similar, and redundancy in COVID-19 studies may have led to lost time and energy for research teams, scientific journals, and reviewers (London and Kimmelman, 2020).

Limitations of our study

Our study is not without limitations. We evaluated the methodological quality (i.e., internal quality) of existing studies using NOS, a well-established and widely used score system but not completely appropriate in case of studies lacking a formal design. Indeed, NOS has been criticized by some authors (Hartling et al., 2013; Stang, 2010). In particular, low agreement (with $k < 0.50$ for 8 of the 9 questions) between two independent reviewers when using the NOS has been documented in some surveys. Tool's decision rules and some interpretative questions (e.g., whether exposed cohorts are somewhat or truly representative of the average exposed person in the community) may appear vague and difficult to use (Hartling et al., 2013). Furthermore, NOS gives equal weight to each question, which sometimes may not be appropriate.

In combination with NOS, we designed a questionnaire aimed at assessing crucial aspects of papers for data generalizability in clinical practice. This questionnaire was based on study reporting and may not reflect how the study was actually conducted.

Moreover, our analysis included early publications on COVID-19, and an improvement in the quality of related studies has to be expected as the number of cases increases and better-designed studies, which take longer to design and conduct, will be possibly published. Accordingly, it is likely that over time, research quality will improve.

Suggestions for future studies

It is our impression that many of the problems we have pointed to were determined by a lack of coordination

between different researcher groups and a lack of multidisciplinary collaboration. A larger, possibly multicountry collaboration and the involvement of researchers in different areas, including epidemiologists and biostatisticians, would increase the size of the studied populations and allow refined analyses and higher quality results.

Such a collaboration would be of paramount importance when assessing the safety and immunogenicity of the vaccines against SARS-CoV-2.

The following issues should be carefully considered in future studies:

1. Always consider a comparator group. The comparator could be either the general population, for population-based studies, or an independent group of patients with similar characteristics as cases, for hospital-based studies.
2. Analyze separately different populations of patients (e.g., PsA separated from rheumatoid arthritis).
3. Exclude probable cases of COVID-19 (without a positive test) from the analysis, especially when making comparisons with the general population. These cases are typically not included in the data available from the general population, which only consider a patient with COVID-19 the one who has been tested positive.
4. Formally evaluate the sample size required to document a given incidence or prevalence rate or an expected difference among study groups, looking at confidence intervals and not assuming negative results as proof of a lack of difference in underpowered studies.
5. Analyze treatments by within class (i.e., do not compare all biologics with all oral medications).
6. Plan a priori subanalyses in high-risk patient groups such as older patients or those with comorbidity.
7. It is even more important to establish multicenter collaboration, prioritizing quality in data collection. A system to rapidly activate formal epidemiological studies and registries when confronted with global health crises should be considered, with an international study coordination and data sharing, as, for example, Psoprotect is (Mahil et al., 2021).

Our study is not intended as criticism to the journals or the authors who genuinely provided a service to the scientific community but rather a reminder for readers to be careful when they read new COVID-19 papers. During a pandemic, one should be more cautious when incorporating evidence from new studies into personal clinical decision making.

In conclusion, considering the currently published data, no definite statement can be made on the risk of COVID-19 among patients with Pso or PsA treated with biologics. At the moment, a cautious approach is still recommended. Better designed robust studies taking into account a suitable comparator, a proper sample size calculation, and a confirmed ascertainment of incident cases are needed to reliably define the incidence and the outcome of COVID-19 in these patients.

The tremendous hunger for data by the public and medical community and the understandable desire of providing swift information should not, in the future, lower the quality of research.

MATERIALS AND METHODS

Literature search strategy

The database of Pubmed and Embase, from pandemic inception (January 1, 2020) to November 18, 2020, were queried with the following search string (COVID-19 OR SARS-CoV-2) AND psor* AND (biologic* OR treatment* OR therap*) under all fields.

Inclusion criteria

Studies meeting the following selection criteria were accepted for evaluation: (i) data on COVID-19 prevalence and clinical outcomes; (ii) patients with Pso or PsA; (iii) patients treated with biologic medications; and (iv) observational studies.

Exclusion criteria

After duplicate removal, articles were excluded on the basis of titles and abstracts if they included any of the following criteria: (i) letters, review/systematic review articles, meta-analysis, protocols, and expert opinions/recommendations/guidelines; (ii) articles not focused on COVID-19, on selected skin diseases, or on drug use; and (iii) articles not in English or not available.

Articles that remained after the initial screening underwent a full-text review for inclusion consideration. For the quality assessment of studies, case reports were excluded. The detailed search strategy is displayed in Figure 1.

Data extraction and quality assessment

All data were independently abstracted by two authors. For each of the selected studies, data on first author, study design, country, period of observation, sample size, presence of a control group, age and sex, number of SARS-CoV-2–positive subjects, type of medications, and COVID-19 clinical outcomes were collected.

The NOS was used to estimate the internal validity of the included studies. The NOS is a tool developed jointly by the University of Newcastle (Newcastle, Australia) and the University of Ottawa (Ottawa, Canada) with the purpose of assessing the quality of non-randomized studies to be used in systematic reviews. It consists of a star system in which a study is judged on three broad perspectives: the selection of the study groups, the comparability of the groups (of case and controls in case-control studies, of cohorts in cohort studies), and the assessment of the outcome (in case-control studies) or exposure (in cohort studies) (Wells et al., 2013). For cross-sectional studies, a modified version of the NOS was adopted (Herzog et al., 2013).

The NOS score for case-control and cohort studies ranges from 0 to 9, whereas the score for cross-sectional study ranges from 0 to 10, with higher scores indicating a better quality of the study. The NOS can also be normalized as a percentage score. NOS scores $\geq$75% are considered as high-quality studies (with a low risk of bias).

In this work, four authors were involved in the rating process, with two blinded assessors rating in parallel each Pso and PsA study, respectively. If there was any disagreement between the assessors' ratings, the discrepancy was further discussed. In case the disagreement could not be solved, the average of paired raters' scores was considered as the final result.

In addition, to provide a better appreciation of the internal validity and the external validity according to the Quality Criteria for Nontherapeutic Studies of the Agency for Healthcare Research and Quality, two independent raters assessed the following aspects of the studies: case definition, modality of COVID-19 assessment, evidence for self-selection of participants, existence of dropout/

nonparticipants and their percentages, and adequate sample size estimate (Dekkers et al., 2010; Shamliyan et al., 2011). Any discrepancy in judgment by the two independent raters was resolved by discussion within the whole study group.

A detailed description of the generalizability criteria is presented in Supplementary Table S5.

Outcome assessment

This work seeks to evaluate the quality of the selected studies through the NOS and some additional points to establish the robustness and reliability of the data published during the pandemic period. A further goal was to draw attention to the necessity of having specific and shared criteria in studies conduction. The main outcomes of interest of the papers selected were incidence and severity, in terms of hospitalization, intensive care unit admission, and mortality from SARS-CoV-2 infection in patients with Pso treated by biologics.

Medications considered were conventional synthetic disease-modifying antirheumatic drugs, biological disease-modifying antirheumatic drugs, targeted synthetic disease-modifying antirheumatic drugs for PsA and anti-TNF, anti-IL23 anti-IL12/IL23, anti-IL17, anti-IL23p19, conventional systems, apremilast, and dimetilfumarate for Pso.

Besides assessing the quality of the selected studies through the NOS and generalizability criteria, we proposed recommendations for the conduction of future studies in this area.

Data availability statement

No datasets were generated or analyzed during this study.

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CONFLICT OF INTEREST

SP received consultation fees from Abbvie, Almirall, Celgene, Janssen, Leopharma, Eli Lilly, Novartis, Sandoz, and UCB as a speaker and/or participants in advisory boards. PG received consultation fees from Abbvie, Almirall, Amgen, Eli Lilly, Janssen, Leo Pharma, Novartis, Sanofi, Sandoz, and UCB as a speaker and/or participants in advisory boards. LN received consultation fees from Abbvie, Amgen, Boehringer Inghelheim, Celgene, Eli Lilly, IBSA, Menarini, Janssen, Novartis, and Sanofi. The remaining authors state no conflict of interest.

AUTHOR CONTRIBUTIONS

Conceptualization: SP, PG, SC, LN; Data Curation: SC, SDL; Formal Analysis: SP, PG, SC, SDL, LN; Methodology: SP, PG, SC, LN; Project Administration: LN; Supervision: LN; Validation: SC, LN; Visualization: SP; Writing - Original Draft Preparation: SP, PG, SC, SDL, LN; Writing - Review and Editing: SP, PG, SC, SDL, LN

SUPPLEMENTARY MATERIAL

Supplementary material is linked to the online version of the paper at www.jidonline.org, and at https://doi.org/10.1016/j.jid.2021.04.036.

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SUPPLEMENTARY MATERIALS

SUPPLEMENTARY REFERENCES

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Supplementary Table S1. Synthesis of Studies Focused on Psoriasis

Authors	Study Design	Country	Period of Observation	Number of Patients with Pso	Number of Ctrs	Age of Patients with Pso (y)	Number of SARS-CoV-2–Positive Patients	Therapies for Pso	COVID-19–Related Outcomes	NOS Score/ Total (%)
Baniandrés-Rodríguez et al. (2021)	Multicenter prospective cohort	Spain	Mar? – Jul 6	2,329	General population	Median (IQR) (COVID-19 Pts) = 51.8 (39.6–60)	Pts: 73 (36 possibile, 16 probable, 21 PCR+, 13 hospit, 1 ICU, 1 death) Ctrs:?	Conventional systemics Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19 Apremilast Dimetifumarate	Incidence Hospitalization ICU Death rates	5/9 (56)
Brazzelli et al. (2020)	Cross-sectional	Italy	Jan 1 – May 31	180 (82 F, 98 M)	—	Mean ± SD = biologics: 53.8 ± 12 topicals: 56.6 ± 14.8	33 probable	Anti-TNF, Anti-IL17 Anti-IL12/23 Anti-IL23 Topicals	Prevalence and clinical course	4/10 (40)
Damiani et al. (2020)	Case-control	Italy	Feb 21 – Apr 9	1,193 (382 F, 811 M)	10,060,574 inhabitants	Mean ± SD = 55 ± 12.7	Pts: 22 (17 quarantined at home, 5 hospit, 0 deaths) Ctrs: 54,801 (16,042 quarantined at home, 11,796 hospit, 1,236 ICU, 10,222 deaths)	Anti-TNF, Anti-IL17 Anti-IL12/23 Anti-IL23 Apremilast Dimetifumarate	Quarantined at home Hospitalization ICU Death rates	3/9 (33)
de Wijs et al. (2021)	Cross-sectional	The Netherlands	May 28 – Jun 23	264 Pso 347 AD	General population	Median (IQR) = 45 (29–55) (overall)	Pts: 270 with symptoms (3 PCR+) Ctrs: 0.3%	Systemic treatments	Incidence and clinical course	3/10 (30)
Fougerousse et al. (2020)	Multicenter cross-sectional study	France	Apr 27 – 7 May	1,418 (619 F, 797 M)	—	?	54 probable (12 PCR+, 5 hospit, 0 deaths)	Conventional systemics Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19 Apremilast	Hospitalization and death rates	4/10 (40)
Georgakopoulos et al. (2020a)	Multicenter retrospective cohort	Canada	Feb 1- Apr 15	1,390	—	≥18	0	Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19	Treatment discontinuation Incidence rates	3.5/9 (39)
Georgakopoulos et al. (2020)	Multicenter retrospective cohort	Canada	Feb 1 – Jun 1	2,095	—	≥18	0	Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19	Treatment discontinuation Incidence rates	3.5/9 (39)
Gisondi et al. (2020a)	Multicenter retrospective cohort	Italy	Feb 20 – Apr 1	5,206 (2,383 F, 2,823 M)	60,359,546 inhabitants	Mean ± SD = 53.2 ± 11.2	Pts: 6 (4 hospit., 0 deaths) Ctrs: 110,574 (49,285 hospit, 13,155 deaths)	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Hospitalization and death rates	5/9 (56)

(*continued*)

Supplementary Table S1. Continued

Authors	Study Design	Country	Period of Observation	Number of Patients with Pso	Number of Ctrs	Age of Patients with Pso (y)	Number of SARS-CoV-2–Positive Patients	Therapies for Pso	COVID-19–Related Outcomes	NOS Score/ Total (%)
Gisondi et al. (2020b)	Retrospective cohort (Pso + renal tx)	Italy	Feb 20 − Apr 10	Pso: 980 (412 F, 568 M) Renal tx: 247	257,353 inhabitants	Mean ± SD = Pso: 56.4 ± 12.4 Renal tx: 57.7 ± 13.1	Pso pts: 0 Ctrs: 3,199 (589 hospit, 227 deaths)	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Hospitalization and death rates	5.5/9 (61)
Gisondi et al. (2021)	Multicenter retrospective cohort	Italy	Feb 20 − May 1	6,501 (2,885 F, 3,616 M)	19,978,806 inhabitants	Mean ± SD = 53.4 ± 11.0	Pts: 18 hospit., 2 deaths Ctrs: 68,099 hospit., 22,013 deaths	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Hospitalization and death rates	5.5/9 (61)
Mahil et al. (2021)	International registry Psoprotect (clinician report) PsoprotectMe (patient report)	International	Psoprotect: Mar 27 − Jul 1 PsoprotectMe: May 4 − Jul 3	Psoprotect: 374 (147 F, 227 M) PsoprotectMe: 1,626 (1,041 F, 583 M)	— 1476	Median (IQR) = Psoprotect: 50 (41 −58) PsoprotectMe: 48 (36−59)	Psoprotect: 374 (172 PCR+, 77 hospit,9 deaths) PsoprotectMe: 150 (15 PCR+)	Anti-TNF Anti-IL17 Anti-IL23 Nonbiologic systemic agents	COVID-19 Hospitalization related to clinical and demographic factors Risk-mitigating behaviors	4/10 (40)
Lima et al. (2020)	Retrospective cohort (COVID-19 only)	Brazil	Mar? − May?	104 (43F, 61 M)	—	Mean ± SD = systemic: 55.1 ± 16 no-systemic: 57.4 ± 18.4	104 (41 hospit., 13 ICU, 9 deaths)	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Hospitalization, ICU admission, intubation and/or death	5/9 (56)
Piaserico et al. (2020)	Multicenter prospective cohort	Italy	Feb 20 − Jun 1	1,830 (622 F, 1,208 M)	4,905,854 inhabitants	Mean ± SD = 55 ± 14.8	Pts: 6 (4 hospit, 0 deaths) Ctrs: 19,154	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Incidence, hospitalization and deaths rates	6/9 (67)
Pirro et al., 2020	Retrospective cohort (telephone survey)	Italy	Mar 9 − May 3	226 (88 F, 138 M)	—		0	Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19	Disease worsening related to: -Drug withdrawal -Anxiety -Depression -Resilience -perceived stress -work activity	4.5/9 (50)
Rodríguez-Villa Lario et al., 2020	Retrospective cohort (telephone survey)	Spain	?	146 (64 F, 82 M)	—		19 clinical diagnoses (6 PCR+, 3 hospit)	Anti-TNF Anti-IL17 Anti-IL12/23 Anti-IL23	Incidence rates Psychological impact	5/9 (56)
Vispi et al. (2020)	Multicenter prospective cohort	Italy	Mar 1 − May 12	246 (104 F; 142 M)	534,423 inhabitants	Mean (range) = 56 (21−90)	Pts: 1 Ctrs: 1,075	Anti-TNF Anti-IL12/IL23 Anti-IL17 Anti-IL23p19	Incidence rates	4/9 (44)

Abbreviations: AD, atopic dermatitis; Apr, April; Ctrs, controls; F, female; Feb, February; Hospit, hospitalizations; ICU, intensive care unit; IQR, interquartile range; Jan, January; Jun, June; Jul, July; M, male; Mar, March; PCR+, PCR confirmation; Pso, psoriasis; Pts, patients; Tx, transplant recipients.

Supplementary Table S2. Synthesis of Studies Focused on PsA

Authors	Study Design	Country	Period of Observation	Number of Pts with PsA	Number of Ctrs	Age of Pts with PsA (y)	Number of SARS- CoV-2–Positive Pts	Therapies for PsA	COVID-19–Related Outcomes	NOS Score/ Total (%)
Costantino et al. (2021)	Cross-sectional (e-mail survey)	France	Apr 18 − May 21	52 (30 F, 22 M) PsA 129 RA 474 SpA	General population	Mean ± SD = 54.1 ± 13.8	Pts: 4 suspected, 1 PCR+ Ctrs: 4.4%	csDMARDs bDMARDs tsDMARDs	Incidence rates Predictive factors	6/10 (60)
Favalli et al. (2020)	Cross-sectional survey	Italy	Feb 25 − Apr 10	203 (104 F, 99 M) PsA 531 RA 181 SpA 40 CTD, vasculitis, or autoinflammatory diseases	8,687,083 inhabitants	Mean ± SD = 52 ± 12	Pts: 0 PCR+ Ctrs: 57,592	csDMARDs bDMARDs tsDMARDs	Severity and Incidence rates Coping strategies	4/10 (40)
Ferri et al. (2020)	Multicenter retrospective cohort (telephone survey)	Italy	Mar 15 − Apr 25	208 (124 F, 84 M) 695 RA 208 PsA 35 AS 438 SSc 76 SLE 64 UCTD 19 PM/DM 18 SJö 88 miscellany	General population	Mean ± SD = 56 ± 11	Pts: 11 PCR+ 14 highly suspected (1 hospit, 1 death) (overall) Ctrs: 349/100,000	csDMARDs bDMARDs tsDMARDs	Incidence rates	4/9 (44)
Fredi et al. (2020)	Case-control (COVID-19 only)	Italy	Feb 24 − May 1	20 (PsA + SpA) 37 RA 12 SLE	62	Median (IQR) = 68 (55−76) (overall COVID-19 pts)	Pts: 20 suspected or PCR+ (3 deaths) Ctrs: 62 suspected or PCR+ (6 deaths)	csDMARDs bDMARDs	Incidence rates	3/9 (33)
Gianfrancesco et al. (2020)	International registry	International	Mar 24 − Apr 20	230 RA 85 SLE 74 PsA 48 SpA 44 Vasculitis 28 SJö 21 other inflammatory arthritis 20 inflammatory myopathy 19 Gout 16 Ssc 12 polymyalgia rhematica 10 sarcoidosis 28 other	—		548 PCR+, 52 suspected (277 hospit, 55 deaths)	csDMARD b/tsDMAR Antimalarial NSAIDs Prednisone	Hospit related to demographic and clinical factors	4/10 (40)

(*continued*)

Supplementary Table S2. Continued

Authors	Study Design	Country	Period of Observation	Number of Pts with PsA	Number of Ctrs	Age of Pts with PsA (y)	Number of SARS- CoV-2–Positive Pts	Therapies for PsA	COVID-19–Related Outcomes	NOS Score/ Total (%)
Hasseli et al. (2020)	Cross-sectional (registry, COVID-19 only)	Germany	Mar 30 − Apr 25	19 PsA (approximate) 47 RA 10 AS 5 SSc <5 Others	General population	Median (range) = 56 (23−87) (overall)	Pts: 19 Ctrs: 152,438 (5,500 deaths)	csDMARDs bDMARDs None	Incidence and severity rates	3/10 (30)
Mena Vázquez et al. (2021)	Cross-sectional	Spain	Mar 13 − Apr 12	1,754 PsA 2,480 RA 786 SpA	300,802	Mean ± SD = 60.8 ± 13.5 (overall COVID-19 Pts)	Pts: 5 (5 PCR+, 0 deaths) Ctrs: 1,532 (515 PCR+, 60 deaths)	csDMARDs bDMARDs tsDMARDs	Incidence and case fatality rates	6/10 (60)
Montero et al. (2020)	Retrospective cohort (COVID-19 only)	Spain	Mar 4 − Apr 24	16 (PsA + SpA) 20 RA 4 Other inflammatory 9 SLE 13 Other CTD	—	Mean ± SD = 60.9 ± 13.9 (overall)	Pts: 16 (1 death)	csDMARDS bDMARDs	Hospitalization and severity rates	5/9 (56)
Pablos et al. (2020)	Multicenter retrospective matched cohort (COVID-19 only)	Spain	? − Apr 17	35 PsA 65 RA 36 SpA 92 CTD	228	Median (IQR) = 63 (54-78) (overall)	Pts (Psa + SpA): 71 (43 hospit, 3 deaths) Ctrs: 228 (175 hospit, 30 deaths)	csDMARDs bDMARDs tsDMARDs	Hospitalization Invasive ventilation ICU Mortality rates	5/9 (56)

Abbreviations: Apr, April; AS, ankylosing spondylitis; bDMARD, biological disease-modifying antirheumatic drug; csDMARD, conventional synthetic disease-modifying antirheumatic drugs; CTD, connective tissue diseases; Ctr, control; F, female; Feb, February; Hospit, hospitalization; ICU, intensive care unit; IQR, interquartile range; M, male; Mar, March; NSAID, non-steroidal anti-inflammatory drug; PCR+, PCR confirmation; PM/DM, polymyositis/dermatomyositis; PsA, psoriatic arthritis; Pt, patient; RA, Rheumatoid Arthritis; Sjö, Sjögren syndrome; SLE, systemic lupus erythematosus; SpA, axial spondyloarthritis; SSc, systemic sclerosis; tsDMARD, targeted synthetic disease-modifying antirheumatic drugs; UCTD, undifferentiated connective tissue diseases.

Miscellany includes mixed connective tissue disease, Behçet's disease, idiopathic juvenile arthritis, enteropathic arthritis, sarcoidosis, polymyalgia rheumatica, systemic vasculitis, and undifferentiated inflammatory arthritis.

Supplementary Table S3. Synthesis of Studies Focused on Psoriasis

Paper	Case Definition	COVID Assessment	Voluntary Self-Selection	Dropout/ Nonparticipants	% Dropout/ Nonresponders	Sample Size Estimate
Baniandrés-Rodríguez et al. (2021)	Clearly identifiable	anamnestic assessment without validation	yes	no	—	No
Brazzelli et al. (2020)	Clearly identifiable	anamnestic assessment without validation	no	unclear	—	No
Damiani et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	unclear	—	No
de Wijs et al. (2021)	mixed up with other conditions	anamnestic assessment without validation	yes	yes	56	No
Fougerousse et al. (2020)	Clearly identifiable	anamnestic assessment without validation	no	not applicable	—	No
Georgakopoulos et al. (2020a)	Clearly identifiable	anamnestic assessment with validation	no	unclear	—	No
Georgakopoulos et al. (2020b)	Clearly identifiable	unclear/other	no	unclear	—	No
Gisondi et al. (2020a)	Clearly identifiable	anamnestic assessment with validation	no	no	—	No
Gisondi et al. (2020b)	Clearly identifiable	anamnestic assessment with validation	no	no	—	no
Gisondi et al. (2021)	Clearly identifiable	anamnestic assessment with validation	no	no	—	no
Lima et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	not applicable	—	no
Mahil et al. (2021)	Clearly identifiable	anamnestic assessment without validation	no	not applicable	—	no
Piaserico et al. (2020)	Clearly identifiable	anamnestic assessment with validation	no	no	—	no
Pirro et al., 2020	Clearly identifiable	anamnestic assessment without validation	no	unclear	—	no
Rodríguez-Villa Lario et al., 2020	Clearly identifiable	anamnestic assessment with validation	no	yes	53	no
Vispi et al. (2020)	Clearly identifiable	anamnestic assessment with validation	yes	unclear	—	no

Abbreviations: BJD, *British Journal of Dermatology*; JAAD, *Journal of the American Academy of Dermatology*; JACI, *The Journal of Allergy and Clinical Immunology*; JCMS, *Journal of Cutaneous Medicine and Surgery*.

Supplementary Table S4. Synthesis of Studies Focused on Psoriatic Arthritis

Paper	Case Definition	COVID Assessment	Voluntary Self-Selection	Dropout/ Nonparticipants	% Dropout/ Nonresponders	Sample Size Estimate
Costantino et al. (2021)	mixed up with other conditions	anamnestic assessment with validation	yes	yes	54	no
Favalli et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	yes	2	no
Ferri et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	unclear	—	no
Fredi et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	no	—	no
Gianfrancesco et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	no	no	—	no
Hasseli et al. (2020)	mixed up with other conditions	anamnestic assessment without validation	yes	not applicable	—	no
Mena Vázquez et al. (2021)	Clearly identifiable	direct assessment	no	unclear	—	no
Montero et al. (2020)	mixed up with other conditions	direct assessment	no	unclear	—	no
Pablos et al. (2020)	mixed up with other conditions	direct assessment	no	no	—	no

Supplementary Table S5. Description of Additional Points Identified by the Authors

Crucial Points	Description
Case definition	Whenever it is not possible to consider data concerning a given disease entity because these data are combined with those of other conditions, the answer is mixed up.
COVID-19 assessment	It refers to the means by which COVID-19–related conditions are assessed.
Voluntary self-selection	This applied when people are offered participation on a voluntary basis (e.g., by providing a link to a web questionnaire).
Dropout/ nonparticipants	Usually, samples from a target population are identified, contacted, and recruited. If not all contacted people participate or participants are lost to follow-up, then there are nonparticipants or dropouts. If such a recruiting process is not clear, then the response unclear is applied.
% of dropout/ nonparticipants	It indicates the number without decimals.
Sample size estimate	For a yes answer, a statement concerning statistical power or formal sample size calculation should be found in the paper.