Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Journal of Autoimmunity 132 (2022) 102868

Contents lists available at ScienceDirect

Journal of Autoimmunity

journal homepage: www.elsevier.com/locate/jautimm

COVID-19 outcomes in giant cell arteritis and polymyalgia rheumatica *versus* rheumatoid arthritis: A national, multicenter, cohort study

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A R T I C L E I N F O

Keywords:
Giant cell arteritis
Polymyalgia rheumatica
Rheumatoid arthritis
COVID-19
SARS-CoV-2

A B S T R A C T

Objectives: To determine whether giant cell arteritis and polymyalgia rheumatica (GCA/PMR) represent independent risk factors for worse outcomes in COVID-19.
Methods: Observational, national, French, multicenter cohort (NCT04353609) comprising patients aged ≥18 years with confirmed diagnoses of either GCA, PMR or rheumatoid arthritis (RA) having presented COVID-19; those under rituximab were excluded. Primary endpoint was COVID-19 severity in GCA/PMR patients as compared to RA. We also aimed to describe the evolution of GCA/PMR patients following COVID-19. Multinomial logistic regression models were performed, with and without adjustment on pre-specified confounding factors (i.e., age, sex, body mass index, arterial hypertension, diabetes and cardiovascular disease). Unadjusted and adjusted multinomial odds-ratio (OR/aOR) and their 95% confidence intervals (CIs) were calculated as effect size using RA as reference group.
Results: Between April 15, 2020, and August 20, 2021, 674 patients [45 (6.6%) GCA, 47 (7.0%) PMR, 582 (86.4%) RA; 62.8 years, 73.2% female] were included. Compared to RA patients, those with GCA/PMR were older and more frequently presented hypertension, diabetes and cardiovascular disease. Severe COVID-19 and death occurred in 24 (26.1%) and 16 (17.8%) patients with GCA/PMR, respectively. Unadjusted analyses revealed higher odds of severe COVID-19 [OR = 3.32 (95% CI 1.89–5.83; $p < 0.001$)] and death [OR = 3.20 (95%CI 1.67–6.13; $p < 0.001$)] for GCA/PMR compared to RA. After model adjustment, these odds were attenuated.
Conclusion: Patients with GCA/PMR were more likely to have severe COVID-19 and higher mortality compared to those with RA. This worse prognosis is mostly due to well known risk factors for the general population rather than vasculitis *per se*.

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https://doi.org/10.1016/j.jaut.2022.102868
Received 10 May 2022; Received in revised form 7 July 2022; Accepted 8 July 2022
Available online 20 July 2022

1. Introduction

Throughout the course of the COVID-19 pandemic, many concerns have been raised regarding the impact of SARS-CoV-2 outbreak among patients with inflammatory rheumatic and musculoskeletal diseases (iRMD) [1]. The pandemic's effects on these patients range from mental health issues (e.g., more anxiety and depression due to social isolation and healthcare system disruption) [2] to their underlying iRMD management, with inadvertent treatment discontinuation and disease flares being described [1]. Patients with giant cell arteritis (GCA) – the most common systemic vasculitis in Western countries, often associated with polymyalgia rheumatica (PMR) – are particularly susceptible considering their advanced age, comorbidity profile, vascular inflammation effects and the burden of immunosuppressive therapies [2]. Their aggregated pandemic morbidity goes further, with the reluctance to seek medical assistance having led to an increased rate of bilateral blindness, a complication as feared as it is preventable [3].

In the opposite direction, the iRMD effects on COVID-19 have also been studied, with worse outcomes within some subsets of this diverse group being described [1,4–6]. The poor prognostic factors in COVID-19 described for the general population – namely older age and comorbidities such as hypertension, cardiovascular disease, obesity and diabetes – were progressively reproduced in the iRMD population [5–7]. Many of these comorbid conditions are associated with vascular dysfunction and abnormal endothelial cell metabolism [8]; in turn, SARS-CoV-2 infection *per se* can also lead, among other immune-mediated phenomena, to endothelial dysfunction [8,9]. Particularly, large-vessel inflammation has been described within the spectrum of COVID-19 clinical presentation, either by direct viral action or as a trigger for an immune-mediated inflammation [8]. These aspects raised the question about the impact that underlying iRMDs evolving with vascular inflammation could have on COVID-19 prognosis.

Determining high-risk profiles in COVID-19 is crucial in vaccination strategy design, and some studies observed worse outcomes in patients with primary systemic vasculitis compared with those with chronic inflammatory arthritis [4,6]. One could wonder that vascular inflammation from COVID-19 combined with that of vasculitis could contribute to this poorer prognosis. Within this highly heterogeneous group of diseases, the typically elderly patient profile with multiple comorbidities that characterizes GCA/PMR raises particular concern. Early data on the COVID-19 course in patients with large-vessel vasculitis were restricted to small monocentric case series, limiting the extent of their findings [10,11]. In a recent COVID-19 Global Rheumatology Alliance study aiming to describe the COVID-19 presentation in systemic vasculitis, higher mortality rates in patients with GCA were described in comparison to patients with other vasculitis [7]. Sattui and colleagues emphasized the need for additional studies directed at better understanding the reason for this worse prognosis.

So far and to the best of our knowledge, no study has specifically evaluated the COVID-19 outcomes in patients with GCA or PMR and its inherent risks in this setting. This study primarily aimed to determine whether GCA/PMR represents independent risk factors for worse outcomes in COVID-19 by comparing these patients to those with rheumatoid arthritis (RA), the prototype of chronic inflammatory arthritis.

2. Methods

2.1. Study design and patients

The French RMD COVID-19 cohort (ClinicalTrials.gov identifier: NCT04353609) is an observational, national, multicenter study comprising patients aged 18 years or older with iRMD and having presented either highly suspected or confirmed COVID-19, further detailed elsewhere [6]. This study selected patients with confirmed diagnoses of GCA, PMR and RA within the French RMD COVID-19 cohort; because this database allowed only one diagnosis per patient, there were no cases of overlapping GCA and PMR. Given the known potential deleterious effect of rituximab for iRMD patients in the setting of COVID-19 [12], those under this specific therapy were excluded from analyses to mitigate this potential confounder.

The study was performed in compliance to the Declaration of Helsinki and informed consent was obtained from patients. Ethical approval was not required according to French law [13]; the study was performed according to the research methodology MR-004 [14], received permission from Lille University Hospital, and was declared to the Commission Nationale de l'Informatique et des Libertés (reference DEC20-107).

2.2. Data collection

All cases of highly suspected/confirmed COVID-19 were reported retrospectively. Individual data regarding demographics, comorbidities, iRMD features, current disease activity, rheumatic treatments, and COVID-19 outcomes were registered by physicians via a national data entry portal. Further details obtained from patients' medical records were described in detail previously [6].

The cutoff for dataset lock was on Aug 20, 2021; before that, missing data were tracked in an effort to retrieve them, COVID-19 evolution was validated, duplicate or erroneous reports were removed, and data was checked for consistency. All participants were followed up to the worst COVID-19 outcome upon blocking of the dataset.

2.3. Outcomes

The primary aim of the study was to assess the COVID-19 severity in patients with GCA or PMR as compared to RA ones. Severity was classified according to the level of care received during COVID-19 as follows: mild, when the patient was managed on an outpatient basis; moderate, when on an inpatient basis but without the need for critical care; and severe, when the patient was admitted to an intensive care unit or when death occurred. As secondary objectives, we aimed to describe the evolution of patients with GCA/PMR following COVID-19 diagnosis, notably regarding mortality, also in comparison to RA patients.

2.4. Statistical analysis

Categorical variables were expressed as numbers (percentage), and quantitative variables as mean (± standard deviation, SD). Comparison in outcomes between GCA/PMR (pooled together) and RA groups were made using multinomial logistic regression model. To consider the potential confounding factors, comparisons were done with and without adjustment on pre-specified variables (namely age, sex, body mass index, arterial hypertension, diabetes and cardiovascular disease). Unadjusted and adjusted multinomial odds-ratio (OR/aOR) and their 95% confidence intervals (CIs) were calculated as effect size using RA group as reference. Comparisons in outcomes were further investigated by considering GCA and PMR separately. To avoid case deletion in analyses, missing data for outcomes and pre-specified confounding factors were imputed by simple imputation using the regression-switching approach. The imputation procedure was performed under the missing-at-random assumption, with predictive mean-matching method for continuous variables and logistic regression (binary, ordinal, or multinomial) models for categorical variables. All statistical tests were performed at the two-tailed α level of 0.05 using SAS software (v.9.4).

3. Results

3.1. Patients' characteristics

Between April 15, 2020, and August 20, 2021, 674 patients (mean age 62.8 years ±14.7) following eligibility criteria and with available data on COVID-19 severity were included, 92 (13.6%) of whom diagnosed with GCA (n = 45) or PMR (n = 47), separately described in

Supplementary Table 1. Patients' characteristics for the overall study population and according to GCA/PMR and RA groups are shown in Table 1. Overall, 493 (73.2%) were female, and 498 (74.0%) had at least one comorbidity, the most common being arterial hypertension (33.1%). Compared to RA patients, those with GCA/PMR were numerically older (74.9 ± 9.5 *vs*. 60.9 ± 14.4 years) and more frequently presented hypertension (50.0% *vs*. 30.5%), diabetes (17.4% *vs*. 11.2%) and cardiovascular disease (27.2% *vs*. 12.2%).

3.2. COVID-19 severity and evolution

The outcomes of COVID-19 in GCA/PMR and RA groups are summarized in Table 2. As for severity, 26.1% of patients with GCA/PMR had severe COVID-19, while this occurred in 12.4% of those with RA. In the unadjusted analysis, the GCA/PMR group had 3.32 more odds (95% CI 1.89–5.83; p < 0.001) of having a severe COVID-19 course compared to the RA one. On multivariate adjustment for age, sex, hypertension, diabetes, cardiovascular disease and body mass index, these odds equalized (aOR = 0.98, 95%CI 0.50–1.92; $p = 0.94$).

Concerning COVID-19 evolution, 16.7% and 18.1% of patients with GCA/PMR and RA recovered from the infection while developing sequelae, respectively. A total of 52 patients (7.9%) died from COVID-19, i.e., 16 (17.8%) with GCA/PMR and 36 (6.4%) with RA. Taking severity and evolution together, approximately one in three GCA/PMR patients requiring intensive care due to COVID-19 survived, as opposed to half of RA patients in the same setting. The OR for death was 3.20 (95%CI 1.67–6.13; p < 0.001) for GCA/PMR compared to RA patients. In the model adjusted for confounding factors, the odds were no longer statistically significant (aOR = 0.78, 95%CI 0.36–1.69; $p = 0.52$).

Multinomial logistic regression models were also performed separately for GCA and PMR as compared to RA (Supplementary Tables 2 and 3, respectively). Overall, the unadjusted analyses in GCA revealed even more significant results for severe COVID-19 (OR = 4.23, 95%CI 1.96–9.08; $p < 0.001$) and death (OR = 4.33, 95%CI 2.00–9.35; $p < 0.001$), but with the respective aORs being also equalized after adjusting for confounding factors. This pattern was observed in PMR for severe COVID-19 as well (OR = 2.64, 95%CI 1.23–5.66; $p = 0.012$); regarding death, although numerically higher in the PMR group, the statistical significance level was not reached (OR = 2.04, 95%CI 0.74–5.58; $p = 0.17$).

Considering older age (and potentially greater comorbidity associated with it) as a traditional poor prognostic factor, the distribution of COVID-19-related outcomes has been depicted with respect to age groups in Supplementary Table 4 for each disease. The proportions of outcomes observed appear more evenly balanced when considering matched age groups.

4. Discussion

Within this national, multicenter, iRMD cohort – the first specifically looking at COVID-19 outcomes in patients with GCA/PMR – these were more likely to have severe COVID-19 and higher mortality rate compared to those with RA. These odds, however, were attenuated when corrected for previously known COVID-19 poor prognostic factors, mitigating the potential direct deleterious effect that this large-vessel vasculitis could play in COVID-19-related outcomes.

Advanced age and multiple comorbidities have been highlighted as factors associated with a COVID-19 poor prognosis since the pandemic began. In addition, the immunological phenomena and vascular inflammation seen in COVID-19 [8,9] provided a rationale for worse outcomes in patients with GCA/PMR. In the first COVID-19 Global Rheumatology Alliance study, there was a higher proportion of patients with systemic vasculitis among hospitalized than non-hospitalized patients [4]. Thereafter, adjusted analyses from the first French iRMD cohort study revealed a 2.25-fold increased risk of severe COVID-19 in patients with vasculitis compared with those with chronic inflammatory

Table 1
Overall patients' characteristics and according to groups.

	Overall (n = 674)	Giant cell arteritis or polymyalgia rheumatic (n = 92)	Rheumatoid arthritis non-treated by Rituximab (n = 582)
Age (years)			
18–54	194 (28.8)	3 (3.3)	191 (32.8)
55–64	150 (22.3)	9 (9.8)	141 (24.2)
65–74	179 (26.6)	33 (35.9)	146 (25.1)
≥75	151 (22.4)	47 (51.1)	104 (17.9)
Mean ± SD	62.8 ± 14.7	74.9 ± 9.5	60.9 ± 14.4
Female sex	493 (73.2)	61 (66.3)	432 (74.2)
Comorbidities[1]			
Respiratory disease	94 (14.0)	12 (13.0)	82 (14.1)
Interstitial lung disease	22 (3.3)	2 (2.2)	20 (3.4)
COPD	44 (6.5)	9 (9.8)	35 (6.0)
Asthma	35 (5.2)	1 (1.1)	34 (5.9)
Cardiovascular disease	96 (14.3)	25 (27.2)	71 (12.2)
Coronary heart disease	78 (11.6)	21 (22.8)	57 (9.8)
Stroke	26 (3.9)	6 (6.5)	20 (3.4)
Diabetes	81 (12.0)	16 (17.4)	65 (11.2)
BMI (kg/m^2)			
<30	445 (75.9)	61 (73.5)	384 (76.3)
30–39.9	121 (20.6)	18 (21.7)	103 (20.5)
≥40	20 (3.4)	4 (4.8)	16 (3.2)
Hypertension	223 (33.1)	46 (50.0)	177 (30.5)
Cancer	32 (4.8)	2 (2.2)	30 (5.2)
Smoking	61 (9.1)	7 (7.6)	54 (9.3)
Chronic renal failure	25 (3.7)	6 (6.5)	19 (3.3)
No. of patients with at least 1 comorbidity	498 (74.0)	74 (80.4)	424 (73.0)
Disease activity[2]			
Remission	156 (49.5)	24 (52.2)	132 (49.1)
Mild	91 (28.9)	13 (28.2)	78 (29.0)
Moderate	52 (16.5)	4 (8.7)	48 (17.8)
Severe	16 (5.1)	5 (10.9)	11 (4.1)
Rheumatic treatments			
Corticosteroids	241 (35.8)	78 (84.8)	163 (28.0)
Dose ≥ 10 mg	80 (33.5)	41 (52.6)	39 (24.2)
NSAIDs	39 (5.8)	0	39 (6.7)
Hydroxychloroquine	20 (3.0)	0	20 (3.4)
Methotrexate	394 (58.5)	20 (21.7)	374 (64.3)
Leflunomide	48 (7.1)	0	48 (8.2)
Salazopyrine	7 (1.0)	0	7 (1.2)
Targeted biologic or synthetic therapies			
Anti-TNF	135 (20.0)	1 (1.1)	134 (23.0)
Anti-IL6	67 (9.9)	14 (15.2)	53 (9.1)
Abatacept	40 (5.9)	0	40 (6.9)
JAK inhibitor	61 (9.1)	0	61 (10.5)
Other biologics	6 (0.9)	0	6 (1.0)

Values are presented as frequency (percentage) unless otherwise indicated.
Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; JAK, janus kinase; NSAIDs, non-steroidal anti-inflammatory drugs; SD, standard deviation; TNF, tumor necrosis factor.

[1] missing values for comorbidities except for BMI where 88 values are missing (Giant cell arteritis and polymyalgia rheumatic, n = 9; Rheumatoid arthritis non-treated by Rituximab, n = 79).
[2] 359 missing values.

arthritis [6]; even though these findings were not consistently reproduced in other studies [1,5]. Herein, the higher risk profile of GCA/PMR patients was confirmed as they had a roughly 3-fold greater odds of both developing severe COVID-19 or death in unadjusted analyses as compared to those with RA. However, these odds balanced when adjusting the models for age, sex, body mass index, hypertension, diabetes and cardiovascular history. In the recent Global Alliance study evaluating the COVID-19 outcomes in systemic vasculitis, older age was a consistent worse prognostic factor among patients with GCA or PMR, those with GCA also having higher mortality [7]. Although not aiming to compare different vasculitis, these study's findings meet ours in supporting the high-risk profile for severe COVID-19 in patients with GCA/PMR.

Profiling high risk subjects aids in pandemic vaccination strategies. International guidelines are not unanimous about the higher risk of COVID-19 severe forms in the iRMD group compared to the general population, although they do converge in placing this heterogeneous patient population as a vaccination priority [15,16]. The substantial variability in risk factors for poor COVID-19 outcomes observed in patients with iRMD – both related to the underlying disease and their treatments – may indeed confer them additional risks [15]. Although we have not documented GCA/PMR as independent poor prognostic factors in COVID-19, the occurrence of disease flare and the need for high corticosteroid doses may confer them an extra risk [1,4,5,7], beyond older age and multiple comorbidities. Overall, the safety profile of SARS-CoV-2 vaccines in iRMD patients is reassuring [17]. However, vaccine response, particularly in those receiving systemic immunomodulatory therapies, is likely to be impaired as compared to the general population [15]. This has recently been illustrated in GCA, with the immunogenicity of the first (but not the second) dose of the BNT162b2 COVID-19 vaccine being significantly impaired, notably for those patients on corticosteroids $\geq$ 7.5 mg/day or methotrexate [18]. These findings reinforce the need for a full vaccination regimen in these patients; furthermore, in the absence of longer-term data, booster doses throughout the pandemic course should be considered. Hence, either due to their baseline high-risk profile or to their lower early vaccine response, patients with GCA/PMR become critical within public health strategies.

Some limitations must be acknowledged in the present study. In addition to well-known limitations from retrospective observational studies, selection bias from physician-entry database-based studies may have impacted the study population profile. Also, missing data – especially concerning disease activity degree – did not allow us to assess its influence on the COVID-19-related outcomes for both groups, even if multiple imputations were used to handle it. Another possible limitation concerns the lack of adequate statistical power in detecting significant differences as there was no formal initial sample size calculation. Finally, there may have been disparities in the quality and availability of healthcare between different regions where these patients were assisted, which could not be weighted in the analyses.

We conclude that patients with GCA/PMR are indeed at a higher risk of poorer COVID-19 outcomes as compared to RA ones, mostly because of known risk factors for the general population rather than the vasculitis *per se*. Our data provide a new perspective on these patients' risk stratification towards the pandemic, underlining the attention and planning that should be given to these patients, but minimizing the concern of direct deleterious effects of this vasculitis on SARS-CoV-2 infection.

Author's contributions

MV, **CC** and **PC** conceptualized the study. **MV, CC, JL, AM, DS, CR, RMF, EH**, **ED** and **PC** were involved in data collection and analysis. **ED** and **JL** did the statistical analysis. **MV**, **CC**, **ED**, **JL** and **PC** verified the underlying data. **MV** wrote the initial draft of the manuscript. **CC**, **AM**, **DS**, **CR**, **RMF**, **EH** and **PC** critically contributed to the article. All authors revised and approved the submitted version. PC had the final responsibility for the decision to submit for publication.

Funding

This study was not supported by research funding, but FAI2R is funded by the French Ministry of Social Affairs and Health.

Ethical approval information

Not required.

Patient and public involvement

Patients and/or the public were not involved in the design, or

Table 2
Comparison of COVID-19 outcomes between groups.

Outcomes	Giant cell arteritis or polymyalgia rheumatic (n = 92)	Rheumatoid arthritis non-treated by Rituximab (n = 582)	Unadjusted		Adjusted	
			OR (95% CI)	p-value	OR (95% CI)	p-value
Severity				<0.001		0.98
Mild	40 (43.5)	398 (68.4)	1.00 (ref.)	–	1.00 (ref.)	–
Moderate	28 (30.4)	112 (19.2)	2.49 (1.47–4.21)	<0.001	1.04 (0.58–1.87)	0.89
Severe	24 (26.1)	72 (12.4)	3.32 (1.89–5.83)	<0.001	0.98 (0.50–1.92)	0.94
Evolution[1]				0.002		0.40
Recovery without sequelae	59 (65.6)	425 (75.5)	1.00 (ref.)	–	1.00 (ref.)	–
Recovery with sequelae	15 (16.7)	102 (18.1)	1.06 (0.58–1.94)	0.85	0.65 (0.34–1.24)	0.19
Death	16 (17.8)	36 (6.4)	3.20 (1.67–6.13)	<0.001	0.78 (0.36–1.69)	0.52

Values are presented as frequency (percentage).
Adjusted odds-ratio and p-values were calculated after handle missing data by simple imputation.
Odds-ratio were calculated using Rheumatoid arthritis non-treated by Rituximab group as reference.
[1] 21 missing values for evolution (2 GCA/PMR and 19 RA patients).

conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not required.

Declaration of competing interest

The authors have declared that no conflict of interest exists.

Data availability

Data will be made available on request.

Acknowledgments

We thank all patients and all physicians involved in the care of the patients. We thank the pro-bono support of SANOÏA Digital Contact Research Organization (Aubagne, France) team, who provided outstanding electronic case report forms, agile data visualization, and extensive project support.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jaut.2022.102868.

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