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Outcomes in patients with sarcoidosis and COVID-19

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Abstract. *Background and aim:* The effect of COVID-19 in patients with sarcoidosis has not been fully explored. The aim was to conduct a retrospective cohort study investigating outcomes in patients with sarcoidosis who were hospitalized with COVID-19. *Methods:* We included patients who had diagnoses of sarcoidosis and COVID-19 between January 1, 2020, and February 28, 2021. Primary outcomes included development of critical COVID-19; need for supplemental oxygen, noninvasive ventilation, and invasive ventilation; and death. Association of comorbidities and immunosuppression therapy with outcomes were analyzed. Multiple logistic regression analysis was used to assess risk factors associated with critical COVID-19. *Results:* Of 1198 patients with COVID-19, 169 had sarcoidosis (14.1%) and 1029 (85.9%) did not (control group). Of the 169 patients with sarcoidosis and COVID-19, 84 (49.7%) were hospitalized (study group: mean age 62.4 years; 61.9% women; and 56.0% Black). The study group required supplemental oxygen (81% vs 62%; $p = 0.001$) and noninvasive ventilation (33.3% vs 6.4%; $p < 0.001$) more often and had lower mortality (15.5% vs. 30.4%; $p = 0.004$) than the control group. In patients hospitalized with COVID-19, sarcoidosis was not associated with critical COVID-19 (odds ratio, 0.77; 95% CI, 0.46-1.29; $p = 0.317$), but having sarcoidosis while taking immunosuppression therapy was associated with decreased risk of critical COVID-19 (odds ratio, 0.45; 95% CI, 0.31-0.65; $p < 0.001$). *Conclusions*: Patients with sarcoidosis may not be at increased risk of critical illness or death from COVID-19, and immunosuppression therapy in these patients may reduce the risk of critical COVID-19.

Key words: sarcoidosis, COVID-19, immunosuppression therapy

Introduction

Sarcoidosis is a multisystem inflammatory disease that manifests with lung involvement in more than 90% of patients, often requiring treatment with immunosuppressive medications (1). SARS-CoV-2, responsible for the recent pandemic of COVID-19, disproportionately affects patients with comorbidities and raises a concern for increased risk in immune compromised patients (2). There is a paucity of data on the clinical course of patients who have sarcoidosis and COVID-19, and even less is known about how immunosuppressive agents may affect the manifestation of COVID-19 in these patients.

Expert guidance on adjustment of sarcoidosis management during the COVID-19 pandemic stressed the importance of minimizing the dose of immunosuppression therapy because of the known risk of infection associated with immunosuppressive treatment (3). On the other hand, patients with chronic arthritis who were being treated with immunosuppression therapies did not show an increased risk of pulmonary complications from SARS-CoV-2 infection (4). Therefore, in this retrospective cohort

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study, we asked whether comorbidities and use of immunosuppression therapy in patients with sarcoidosis and COVID-19 would be associated with development of critical COVID-19; the need for supplemental oxygen, invasive mechanical ventilation, or noninvasive ventilation; and in-hospital mortality. Understanding the ways in which SARS-CoV-2 infection affects patients with sarcoidosis is critical for implementing optimal treatment strategies during the ongoing pandemic.

Methods

Study design

This study was approved by the [BLINDED FOR REVIEW] Institutional Review Board (Protocol: 14756). We conducted a single-center, retrospective cohort study of patients who had sarcoidosis and COVID-19 at [BLINDED FOR REVIEW] between January 1, 2020, and February 28, 2021. Data were collected through the electronic health record (Epic, Epic Systems Corporation, Verona WI). Diagnoses of COVID-19 and sarcoidosis were based on International Classification of Disease, Tenth Revision, diagnosis parameters. COVID-19 diagnosis was confirmed by a positive reverse transcriptase-polymerase chain reaction test by nasopharyngeal swab. Sarcoidosis diagnosis was confirmed on chart review per diagnostic criteria of the American Thoracic Society guidelines (5).

Demographic data included age, sex, self-reported race, body mass index, and comorbidities (active tobacco smoking, diabetes mellitus, hypertension, chronic kidney disease, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, asthma, cancer, and venous thromboembolism). Sarcoidosis organ involvement and immunosuppressive sarcoidosis treatment regimens (on medication for at least 1 month and within 7 days of COVID-19 diagnosis) were based on documentation by the patient's primary medical provider and the patient's medication list. Systemic medications used for the treatment of COVID-19 were also collected.

We assessed the following primary outcomes in the subset of patients with sarcoidosis who were hospitalized with COVID-19 (study group): development of critical COVID-19 (defined as admission to the intensive care unit, requiring vasopressors for septic shock, invasive mechanical ventilation, or death), use of supplemental oxygen, need for heated high-flow oxygenation/noninvasive ventilation, need for invasive mechanical ventilation, and death. Control groups included patients consecutively admitted for COVID-19 during the study period: the control group was also subdivided into a first pandemic surge (March–May 2020) and a delta surge (February–July 2021) to investigate possible differences in outcomes based on initiation of the COVID-19 vaccine (December 2020) as a confounding variable. Patients 18 years or older with positive SARS-CoV-2 polymerase chain reaction test results, symptoms of COVID-19 within 7 days of hospitalization, and no history of sarcoidosis were included in the control groups. Patients with missing data or who were transferred from outside hospitals were excluded.

Statistical analysis

Continuous variables were reported as mean with standard deviation for normally distributed data or median with interquartile range for data that did not have a normal distribution. Categorical variables were reported as frequencies and percentages. Univariate analysis was performed to determine the association of risk factors with all outcomes.

We compared the study group with the control group as one sum cohort (COVID-19 without sarcoidosis) using the Mann-Whitney U test or t test for continuous variables and chi-square or Fisher's exact tests for categorical variables. One way analysis of variance was performed with subsequent post hoc Tukey Honestly Significant Difference testing to evaluate the differences between the 3 groups for characteristics/outcomes that had a statistically significant analysis of variance result. Multivariable logistic regression modelling was used to generate odds ratios (OR) with 95% CIs to evaluate risk factors associated with development of critical COVID-19 in hospitalized patients. Variables included in the multivariable logistic regression model were those risk factors that demonstrated statistical significance on univariate analysis. A p value of < 0.05 was considered statistically significant.

Results

Based on the inclusion criteria, a total of 1198 patients with COVID-19 within the study period

were identified. Of this group, 169 patients (14.1%) carried a diagnosis of sarcoidosis, while 1029 patients (85.9%) had been diagnosed with COVID-19 but did not have a history of sarcoidosis (control group). Of the patients who did not have sarcoidosis, 646 were in the first COVID-19 surge, and 383 were in the delta surge. Baseline characteristics of patients with sarcoidosis and COVID-19 are in Table 1. In this group, the mean age was 59.9 (standard deviation, 12.0) years, 107 (63.3%) patients were female, 85 (50.3%) were Black, and the median body mass index was 32.8 kg/m^2 (interquartile range, 28.1-39.5). Regarding sarcoidosis-related organ involvement, 120 patients (71.4%) had pulmonary, 27 (16.1%) had pulmonary fibrosis, 30 (17.9%) had skin, and 12 (7.1%) had ocular involvement. At the time of COVID-19 diagnosis, 42 patients (24.9%) were on corticosteroids, 11 (6.5%) were on methotrexate, and 7 (4.1%) were on tumor necrosis factor inhibitors for the treatment of sarcoidosis (Table 1).

Of the 169 patients with sarcoidosis and COVID-19, 84 (49.7%) were hospitalized for COVID-19 (study group); of which 52 (61.9%) were female and 47 (56.0%) were Black. The mean age of the study group was 62.4 (standard deviation, 22.7) years, and the mean body mass index was 32.0 kg/m^2 (interquartile range, 26.0–39.9). Diabetes mellitus, congestive heart failure, and history of thromboembolic disease were significantly more common in the study group than in the control group (all $p < 0.05$) (Table 2). Univariate analysis comparing the study group to the total control group (n = 1029) showed that the study group required supplemental oxygen (81% vs. 62%; $p = 0.001$) and high-flow oxygen or noninvasive ventilation (33.3% vs 6.4%; $p < 0.001$) more often than patients in the control group. Patients in the study group had significantly lower mortality (15.5% vs 30.4%; $p = 0.004$) than the control group (Table 2). While fewer patients in the study group required invasive mechanical ventilation than patients in the control group, the association was not statistically significant (17.9% vs. 27.7%; $p = 0.051$). Subgroup and other analyses are presented in Table 2.

Multivariate logistic regression analysis revealed that diabetes mellitus (OR, 1.36; 95% CI, 1.05-1.77; $p = 0.019$) and congestive heart failure (OR, 2.88; 95% CI, 2.02-4.05; $p < 0.001$) were associated with development of critical illness in patients who were hospitalized with COVID-19 (Table 3). Having a diagnosis of sarcoidosis was not associated with critical COVID-19 illness (OR, 0.77; 95% CI, 0.46-1.29; $p = 0.317$), and having sarcoidosis managed

Table 1. Characteristics of patients with sarcoidosis and COVID-19.

	Sarcoidosis + COVID-19 (*N*=169)
Age, mean (SD), years	59.9 (12.0)
Female sex, *n* (%)	107 (63.3)
Race, *n* (%)	
Black	85 (50.3)
Other	16 (19.5)
White	68 (40.2)
BMI, kg/m^2, median (IQR)	32.8 (28.1-39.5)
Comorbidities, *n* (%)	
Active smoker	12 (7.1)
Asthma	37 (21.9)
Diabetes	62 (36.7)
Cancer	21 (12.4)
Chronic kidney disease	30 (17.8)
COPD	29 (17.2)
Congestive heart failure	33 (19.5)
Coronary artery disease	24 (14.2)
Hypertension	110 (65.1)
Venous thromboembolism	25 (14.8)
Organ involved, *n* (%)	
Fibrosis	27 (16.1)
Heart	9 (5.4)
Liver	6 (3.6)
Lymph nodes	94 (56.0)
Neurological	9 (5.4)
Ocular	12 (7.1)
Pulmonary	120 (71.4)
Renal	6 (3.6)
Skin	30 (17.9)
Sarcoidosis treatment, *n* (%)	
Azathioprine	3 (1.8)
Corticosteroids	42 (24.9)
Hydroxychloroquine	10 (5.9)
Methotrexate	11 (6.5)
Mycophenolate	1 (0.6)
Tumor necrosis factor inhibitor	7 (4.1)

BMI, body mass index; COPD, chronic obstructive pulmonary disorder; IQR, interquartile range; SD, standard deviation.

Table 2. Characteristics and outcomes of patients hospitalized with COVID-19 with and without a history of sarcoidosis.

Characteristic	Sarcoidosis + COVID-19 Group A (*N*=84)	First Surge Control Group B (*N*=646)	Delta Surge Control Group C (*N*=383)	Univariate Analysis* *p* value	ANOVA *p* value	Tukey HSD Test† *p* value		
						A vs B	A vs C	B vs C
Age, mean (SD), year	62.4 (11.7)	64.2 (16.3)	55.2 (18.2)	0.425	<0.001	0.622	0.001	0.001
Female sex, *n* (%)	52 (61.9)	319 (49.4)	209 (54.6)	0.062	0.047	0.077	0.443	0.241
Race, *n* (%)				0.919	<0.001	0.220	0.001	0.001
Black	47 (56.0)	451 (69.8)	126 (32.9)					
Other	11 (13.1)	27 (4.2)	25 (6.5)					
White	26 (31.0)	126 (19.5)	198 (51.7)					
BMI, kg/m^2, median (IQR)	32.0 (26.0-39.9)	31.0 (26.6-37.2)	30.7 (26.7-37.8)	0.196	0.417	-	-	-
Comorbidities, *n* (%)								
Active smoker	6 (7.1)	219 (33.9)	134 (35.0)	<0.001	<0.001	<0.001	<0.001	0.899
Asthma	15 (17.9)	75 (11.6)	59 (15.4)	0.211	0.103	-	-	-
Cancer	12 (14.3)	86 (13.3)	12 (3.1)	0.160	<0.001	0.899	0.005	0.001
Chronic kidney disease	24 (28.6)	316 (48.9)	66 (17.2)	0.115	<0.001	0.001	0.100	0.001
COPD	22 (26.2)	137 (21.2)	55 (14.4)	0.093	0.006	0.522	0.034	0.019
Coronary artery disease	17 (20.2)	112 (17.3)	47 (12.3)	0.248	0.051	-	-	-
Congestive heart failure	26 (31.0)	109 (16.9)	35 (9.1)	<0.001	<0.001	0.002	0.001	0.002
Diabetes mellitus	41 (48.8)	269 (41.6)	97 (25.3)	0.015	<0.001	0.396	0.001	0.001
Hypertension	61 (72.6)	481 (74.5)	170 (44.4)	0.086	<0.001	0.899	0.001	0.001
Immunosuppression therapy	39 (46.4)	39 (6.0)	107 (27.9)	<0.001	<0.001	0.001	0.001	0.001
Venous thromboembolism	12 (14.3)	55 (8.5)	20 (5.2)	0.022	0.012	0.151	0.014	0.137
Outcomes, *n* (%)								
Critical COVID-19	29 (34.5)	298 (46.1)	117 (30.5)	0.296	<0.001	0.098	0.754	0.001
Supplemental oxygen	68 (81.0)	395 (61.1)	244 (63.7)	0.001	0.002	0.001	0.008	0.669
HHF/noninvasive ventilation	28 (33.3)	7 (1.1)	59 (15.4)	<0.001	<0.001	0.001	0.001	0.001
Invasive mechanical ventilation	15 (17.9)	210 (32.5)	75 (19.6)	0.051	<0.001	0.011	0.899	0.001
Mortality	13 (15.5)	225 (34.8)	88 (23.0)	0.004	<0.001	0.001	0.352	0.001

ANOVA, analysis of variance; BMI, body mass index; COPD, chronic obstructive pulmonary disease; HHF, heated high-flow oxygenation; HSD, Honestly Significant Difference test; IQR, interquartile range; SD, standard deviation.
All data shown as number (%) unless otherwise noted.
*Univariate analysis of patients with sarcoidosis + COVID-19 (Group A) compared to those with COVID-19 and no prior history of sarcoidosis (Groups B and C)
†Tukey HSD only performed for statistically significant ANOVA results with $p < 0.05$

with immunosuppression therapy was associated with decreased risk of critical illness (OR, 0.45; 95% CI, 0.31-0.65; $p < 0.001$) in patients hospitalized with COVID-19 (Table 3).

Discussion

In this retrospective study, we examined a large cohort of patients with sarcoidosis who were

Table 3. Multivariate logistic regression analysis of risk factors associated with development of critical illness in patients hospitalized with COVID-19.

Variable	Odds Ratio (95% CI)	*p* value
Active smoking	1.15 (0.88-1.50)	0.302
Congestive heart failure	2.88 (2.02-4.05)	<0.001
Diabetes mellitus	1.36 (1.05-1.77)	0.019
Immunosuppression therapy*	0.45 (0.31-0.65)	<0.001
Venous thromboembolism (history)	1.56 (0.98-2.46)	0.059
Sarcoidosis	0.77 (0.46-1.29)	0.317

*Patients with sarcoidosis who were being treated with immunosuppression therapy.

hospitalized with COVID-19 and compared outcomes to a control group of patients without sarcoidosis from two different pandemic surges. Our results did not show a significant association between sarcoidosis and development of critical illness or mortality from COVID-19. However, patients with sarcoidosis were found to have an increased risk of requiring supplemental oxygen and high-flow oxygen or noninvasive ventilation, which may likely be explained by the significant pulmonary organ involvement and pulmonary fibrosis in this cohort. Additionally, immunosuppression therapy in patients with sarcoidosis was negatively associated with developing critical disease. Previous studies of patients with sarcoidosis who were diagnosed with COVID-19 have reported a similar rate of hospitalization and mortality as in our study, ranging from 19% to 78% and 1.2% to 16.2%, respectively. These studies have also reported a similar high comorbidity burden in this patient group (6-9), and our study specifically observed that diabetes mellitus and heart failure were risk factors associated with critical illness from COVID-19 in hospitalized patients.

In this study, we stratified our control group of patients diagnosed with COVID-19 without a history of sarcoidosis into two surges in order to account for possible differences caused by the introduction of the COVID-19 vaccine. While we had almost twice as many patients from the first pandemic surge than from the post-vaccination delta surge, we saw a predictable and significant reduction in development of critical COVID-19, the need for invasive mechanical ventilation, and death in patients who got sick later in the pandemic. These differences may also be explained by an improved understanding of the critical COVID-19 disease course and development of better treatment protocols throughout the pandemic surges.

Interestingly, we observed that patients with sarcoidosis who were on immune suppression at the time of COVID-19 diagnosis tended to have lower odds of developing critical COVID-19 illness. The protective effect of immunosuppression seen in our study, which may initially have seemed counter-intuitive, might be explained by the modulation of the aberrant innate and adaptive immune responses as well as hyperinflammation, seen in the immune dysregulation phase of severe COVID-19 illness that induces multi-organ dysfunction (10, 11). Similarly, studies in patients with interstitial lung disease diagnosed with COVID-19 have not shown immune suppression as a risk factor for worse outcomes (12-14). This effect of immune suppression is also consistent among patients with rheumatologic diseases who have been hospitalized with COVID-19 (15). While our study did not look at risks associated with specific doses of corticosteroids, two physician-reported registries suggest that patients with rheumatologic disease and COVID-19 who have been treated with long-term corticosteroids of <10 mg have lower risk of in-hospital admission and death than those treated with >10 mg daily (16, 17). The overall benefit of steroids for treating COVID-19 has been well demonstrated in a clinical trial of 6000 patients, where dexamethasone showed a mortality benefit (22.9% vs 25.7%, $p < 0.001$) relative to standard of care in the treatment of patients hospitalized with COVID-19, with the largest benefit among those who required invasive mechanical ventilation (18).

One of the biggest strengths of our study is that it is one of the largest retrospective cohort studies to assess COVID-19 related critical illness among patients with multi-system sarcoidosis. This study also has several limitations. Because this is a retrospective study, it is subject to recall bias, leading to a possible over-selection of severe cases of COVID-19 among patients with sarcoidosis. Also, since we included only patients who were diagnosed with COVID-19 in the medical record, there is a possibility that many patients with COVID-19 and sarcoidosis were missed, leading to an overestimation of the risk of COVID-19. Our cohort data were also collected from a single tertiary medical center in a large urban city; thus, generalizability of these findings across all populations may be limited. Additionally, our study

is partial in its viewpoint due to missing pulmonary function data and the unknown effect of lung impairment severity on outcomes. In this analysis, 16.1% of sarcoidosis patients diagnosed with COVID-19 had pulmonary fibrosis, which may have increased the risk of hypoxic respiratory failure and critical illness. Due to a majority of patients with absent or inaccurate vaccination status, this study also did not analyze the effect of COVID-19 vaccination on the risk of critical illness in patients with sarcoidosis. COVID-19 vaccination was introduced at our institution in December, 2020, which may have reduced the risk of hospitalization and severe illness.

Conclusion

Our study suggests that patients who have sarcoidosis may not be at an increased risk of critical illness or death from COVID-19 relative to those who do not have sarcoidosis, although patients with sarcoidosis may require oxygen and noninvasive ventilation more often within the context of COVID-19. Furthermore, our study highlights that patients with sarcoidosis who are being treated with immune suppression could have an even lower risk of critical illness from COVID-19, but larger prospective studies will be needed to confirm this finding. Our study contributes to the scarce data available on the clinical course of patients with sarcoidosis and COVID-19 and may help guide development of more effective disease management strategies during the ongoing pandemic.

Conflict of Interest: Author 1: Novartis Pharmaceutical: CMK389 versus placebo in chronic sarcoidosis. All funds to institution. Author 4: Novartis Pharmaceutical: CMK389 versus placebo in chronic sarcoidosis. All funds to institution. Authors 5: Novartis Pharmaceutical: CMK389 versus placebo in chronic sarcoidosis. All funds to institution. Sanofi Pharmaceutical: Dupilumab versus placebo to reduce exacerbations of COPD. All funds to institution. PICORI (Federal): Azithromycin versus Roflumilast to reduce exacerbations of COPD. All funds to institution. Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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