1206 EVALUATION OF SARS-COV-2 IGG ANTIBODY REACTIVITY IN A MULTI-RACIAL/ETHNIC COHORT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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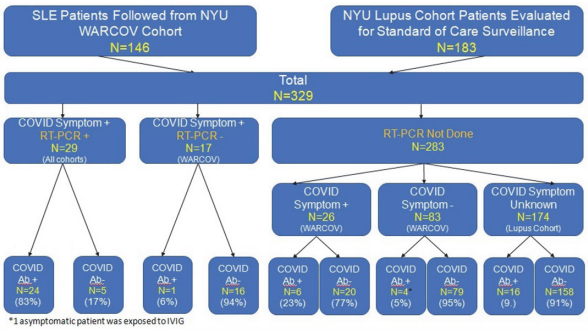
Background Patients with Systemic Lupus Erythematosus (SLE) represent a unique population at risk for COVID-19 due to underlying immune abnormalities and regular use of immunosuppressant medications. This study was initiated to evaluate for the presence of SARS-CoV-2 IgG antibodies in SLE patients with and without prior COVID-19-related symptoms or COVID-19 RT PCR testing.

Methods A total of 329 patients with SLE from two cohorts, one serially monitored for COVID-19 in Spring 2020 (the Web-based Assesment of Autoimmune, Immune-Mediated and Rheumatic Patients (WARCOV) and one undergoing routine surveillance (NYU Lupus Cohort) were tested for SARS-CoV-2 IgG via commercially available immunoassays processed through hospital or outpatient laboratories between April 29, 2020 and February 9, 2021.

Results Overall, 16% of 329 patients had a reactive SARS-CoV-2 IgG antibody test. Seropositive patients were more likely to be Hispanic. Other demographic variables, lupus-specific factors and immunosuppressant use were not associated with reactivity. Of the 29 patients with prior RT-PCR confirmed COVID-19, 83% developed an antibody response despite 62% being on immunosuppressants. Six percent of patients who had symptoms suspicious for COVID-19 but negative concurrent RT-PCR testing developed an antibody response. Twenty-three percent of patients who had COVID-19-related symptoms but no RT-PCR testing and 5% of patients who had no symptoms of COVID-19 developed an antibody response. Among patients initially SARS-CoV-2 IgG positive, the majority maintained reactivity serially. In COVID-19-confirmed patients high percentages had antibody positivity beyond 30 weeks from disease onset, 88% up to 10 weeks, 83% up to 20 weeks, and 80% up to 30 weeks.

Conclusions Most patients with SLE and confirmed COVID-19 were able to produce a serologic response despite use of a variety of immunosuppressants. These findings provide reassurances regarding the efficacy of humoral immunity and possible reinfection protection in patients with SLE.



Abstract 1206 Figure 1 SARS-CoV-2 IgG in SLE

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1300 – SLE diagnosis

1301 EFFECT OF ATTRIBUTION ON EXTERNAL VALIDATION OF THE EULAR/ACR SLE CLASSIFICATION CRITERIA

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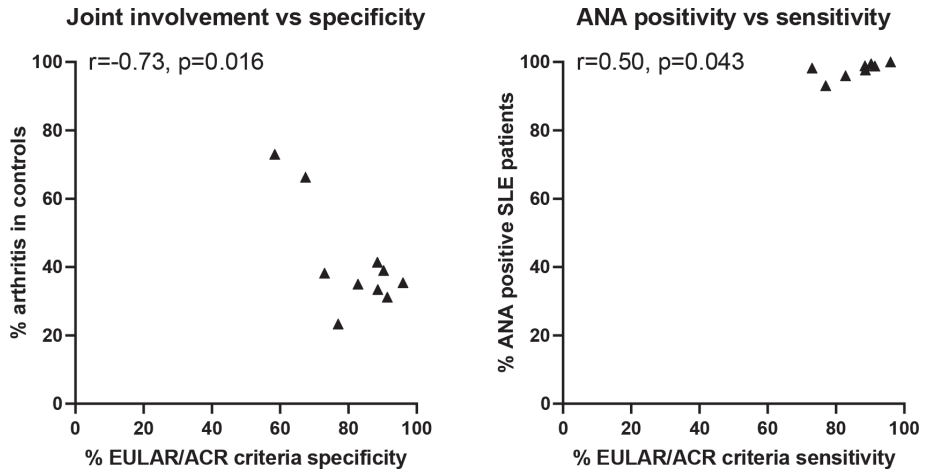
Background With their new structure of ever positive antinuclear antibodies (ANA) as an obligatory entry criterion and weighted specific criteria with a cut-off of $\geq$ 10, the European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) 2019 classification criteria for systemic lupus erythematosus (SLE) has a sensitivity of 96.1% and a specificity of 93.4% in the validation cohort.[1,2] An analysis of the performance of the individual criteria items

Abstract 1301 Table 1

Publication	Population	EULAR/ACR criteria		Arthritis controls	ANA positive
		Sensitivity	Specificity		
Adamichou et al 2019	Early SLE	88.6%	97.3%	37.2%	93.6%
Aljaberi et al 2020	Pediatric SLE	84.8%	82.8% *	35%	96%
Aringer et al 2019 (1,2)(validation)	SLE	96.1%	93.4%	—	99.3%
Aringer et al (derivation)	SLE	98.%	96%	—	99.6%
Batu et al 2020	Pediatric SLE	91.6%	88.5% *	41.4%	98.9%
Dahlström & Sjöwall 2019	SLE	93%	73%*	38.2%	98.2%
Gegenava et al 2019	NPSLE	87%	74%	16.7%	96.3%
Lee et al 2020	SLE	97.6%	91.4% *	31.2%	98.8%
Levinsky et al 2021	Pediatric SLE	96%	89%*	35.4%	100%
Ma et al 2020	Pediatric SLE	97.4%	98.4%	58%	100%
Petri et al 2020	SLE	90.8%	88.6% *	33.4%	97.7%
Rodrigues Fonseca et al 2019 (BL)	Pediatric SLE	89.3%	67.4% *	66.3%	NR
Rodrigues Fonseca et al (one year)	Pediatric SLE	95.1%	58.4% *	73%	NR
Rubio et al 2020	SLE	94.9%	NA	NA	96.3%
Smith et al 2021	Pediatric SLE	94%	77%*	23.3%	93.1%
Suda et al	SLE	92%	NA	NA	92%
Teng et al 2020	SLE	96.5%	90.3% *	39%	99.5%
Wang et al 2021	LN	95.2%	NA	37.2%	95.2%
Whittall Garcia et al 2021	SLE	95.7%	NA	35%	97.1%

Arthritis controls: % non-SLE control population with joint diseases, NR not reported, NA not applicable, * included into specificity analysis. LN lupus nephritis.



Abstract 1301 Figure 1

found that the specificity of joint involvement was 90.9%, but would drop to 57.6% if the attribution rule was not applied.[3] The attribution rule states that only those items should be counted towards classification that have no alternative explanation more likely than SLE. The new criteria have been externally validated in a number of studies. From many of the external validation studies, it is not clear whether this attribution rule was followed

Methods A literature search was performed for „lupus criteria'. Titles and abstracts were screened for studies that (i) referred to the EULAR/ACR criteria (even if using different terms) and (ii) indicated sensitivity and/or specificity estimates. The association between criteria specificity and frequency of joint involvement in the non-SLE control group and association between ANA positivity and criteria sensitivity were evaluated.

Results Operating characteristics of the SLE classification criteria have been evaluated in 19 studies. The external validation studies reported a sensitivity range of 84.8-97.6% and specificity range of (58.4-97.3%) (table 1).

Specificity was evaluated in 14 studies. In 3 of the studies appropriate use of the attribution rule was apparent. One study was excluded for focusing on neuropsychiatric manifestations. For the remaining 10 populations, there was a significant negative correlation between specificity and joint disease in the non-SLE control population. ($r=-0.73$, $p=0.016$), as depicted in figure 1 (left panel). Sensitivity estimates are reported in 19 studies, and the percentage of ANA positive SLE patients was reported for 17 of these. There was a positive correlation between ANA positivity and criteria sensitivity ($r=0.50$, $p=0.043$). (figure 1, right panel)

Conclusions Specificity of the EULAR/ACR criteria is dependent on the correct use of the attribution rule. Higher percentages of patients with joint involvement in the non-SLE control populations is associated with a lower EULAR/ACR criteria specificity. Since joint involvement is particularly vulnerable to not using attribution, this suggests that the lower specificity in some external validation studies in part is due to not fully applying the attribution rule. Sensitivity was high throughout the analyzed studies. It is therefore crucial to differentiate between classification and diagnosis and keep in mind that not fulfilling SLE classification criteria is no valid argument against diagnosing SLE in an individual patient.

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1302 UTILIZATION OF A CLINICAL DATA RESEARCH NETWORK TO ASSESS SYSTEMIC LUPUS INTERNATIONAL COORDINATING CLINICS

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Background SLE, characterized by a heterogenous clinical phenotype, may present differently over time and between patients, creating challenges for identification and treatment of individuals seen at multiple facilities. Clinical data research networks (CDRN) aim to pool electronic health records (EHR) to provide more complete clinical information for patients shared across care centers. We determined whether algorithms to identify Systemic Lupus International Coordinating Clinics (SLICC) classification criteria attributes, using structured EHR data, could be applied to a CDRN to describe people with SLE.

Methods Published algorithms to identify SLICC classification criteria were adapted to the PCORnet Common Data Model used by the Chicago Area Patient Centered Outcomes Research Network (CAPriCORN). Initial patient selection required satisfying $\geq$1 criteria from the SLICC classification criteria as determined by diagnosis (ICD-9/10), procedure (CPT), medication (RX-NORM) and lab codes (LOINC) identified 1,231,130 unique patients. Next, persons with and without SLE were defined by 3+ or 0 instances of a SLE diagnosis by ICD 9/10 code, and the rates of each SLICC criterion was compared using Pearson Chi-squared test at the 95% confidence level. Patient records were assessed for the presence of SLICC criteria and whether they satisfied one SLICC rule for 'Definite SLE' fulfilling 4 total criteria with at least one from the clinical and immunologic domains.

Results The attribute identification frequency of SLICC criteria are represented in table 1. We identified 6,488 persons $\geq$ 3