Figure 1. Antibody responses (A) Anti spike and anti RBD IgG levels at indicated time points. Blue line represents median ratio in convalescent patients. The red line is the seropositivity threshold: the median antibody level of those that pass both a 1% false positive rate and show ≥3SD from the log means of the negative controls. **(B)** Relative ratio of RBD, spike and NP across time. Black and gray lines indicate median and mean values, respectively. *p≤0.05, **p≤0.01, ***p≤0.001, ****p≤0.0001

Table 1.   Baseline characteristics of study participants

	Control	untreated IMID	Anti-TNF	Anti- TNF +MTX/ AZA	Anti-IL-23	Anti -IL-12/23	Anti -IL-17	MTX/ AZA	p-value
	n=26	n=9	n=44	n=16	n=10	n=28	n=9	n=8	
IMID*	N/A								
IBD		9	30	10	0	27	0	4	
Psoriasis		1	3	1	8	1	2	2	
PA		0	7	3	2	1	7	2	
AS		0	8	3	0	0	1	0	
RA		1	1	0	0	0	1	1	
Age									
median	36	33	38	53	48	34	49	42	
years [IQR]	[26-46]	[27-41]	[30-51]	[44-59]	[45-61]	[28-47]	[46-61]	[31-55]	<0.001^
Sex									
male (%)	16 (62)	5 (56)	18 (41)	8 (50)	5 (50)	13 (46)	6 (67)	4 (50)	0.772~
BMI									
median kg/m2	25	26	22	26	27	22	32	26[25-	0.001^
[IQR]	[23-28]	[22-27]	[24-26]	[24-28]	[24-35]	[21-24]	[26-34]	33]	
Vaccine interval									
median	74	54	60	64	74	62	65	58	0.372^
days [IQR]	[35-84]	[31-64]	[45-69]	[50-72]	[35-84]	[49-69]	[52-75]	[21-97]	

*multiple IMIDs per patient possible

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RELAPSES OF IDIOPATHIC INFLAMMATORY MYOPATHIES AFTER VACCINATION AGAINST COVID19: A REAL-LIFE ITALIAN STUDY

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Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination plays a crucial role as pivotal strategies to curb the coronavirus disease-19 (COVID-19) pandemic. Despite the mass-scale vaccination, literature data about the incidence of disease flares in IIM patients are still not reported as well as the immunological condition.

Objectives: The present study aimed to describe the clinical status of patients affected by IIM after vaccination against COVID19 in order to assess the number of relapses or immune-mediated reactions in a cohort of Italian patients with such disease.

Methods: We included all patients affected by IIM and followed by Myositis Clinic, Rheumatology and Respiratory Diseases Units, Siena University Hospital, Bari University Hospital, Policlinico Umberto I, Sapienza University, Rome, and Policlinico Paolo Giaccone, Palermo. Inclusion criteria were a recent (<3 months) clinical and serological assessment before the survey and a definite diagnosis of dermatomyositis, polymyositis and anti-synthetase syndrome. All patients underwent a telephone survey in order to establish their clinical status and potential relapses after vaccination.

Results: A total of 119 IIM patients (median, IQR 58 (47-66) years; 32 males) were consecutively enrolled. Fifty had a diagnosis of DM, 39 had PM and 30 had ASS. The median months of disease duration was 79.62±83.98. According to number of organs involvement, forty-two had only one, 45 had two organs involvement, 20 had three, 11 had four and one had five. The majority of them received two doses of COVID-19 vaccine, except four patients who refused the vaccination: 94 (78.9%) Cominarty, 16 (13.4%) Moderna, 5 (0.04%) AZ. Seven (0.06%) patients had flare after vaccination, the majority of them were mild except one major with three organs involved and one life-threatening with systemic involvement. In order to understand or predict the effect of demographic and clinical features on the flare development after vaccination, a logistic regression analysis was performed. The goodness-of-fit statistics showed a Chi^2 associated with the Log ratio (L.R.) of 0.045. From the probability associated with the Chi-square tests, the Type II analysis showed the variable that most influences the development of flare was the number of organs involved (p=0.047). Sixty-eight patients received the third dose of COVID-19 vaccination: 51 (75%) Cominarty and 17 (25%) Moderna. Only one (0.01%) patient (the same who had life-threatening flare with systemic involvement after two doses) had flare after third dose and eventually died.

Conclusion: Vaccines against SARS-CoV2 have provided, both in registratory studies and in preliminary real-life evidence, an overall good efficacy and safety. Nevertheless, only scanty data are available for rheumatic patients in general and the ones affected by IIM in particular. To the best of our knowledge, ours represent the largest cohort of IIM patients in which immunogenicity of anti-SARS-CoV2 vaccine was assessed. In line with real-life data from other diseases, we found a non-statistically significant risk of relapse in our patients, which occurred seldom, usually mild and in patients with a more severe and aggressive course of disease.

Disclosure of Interests: None declared