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Background: The COVID-19 pandemic has impacted the wellbeing of patients with Rheumatic and Musculoskeletal Diseases (RMDs).

Objectives: The aim is to assess emotional well-being and its associated factors in patients with RMDs during the first wave of the COVID-19 pandemic.

Methods: REUMAVID is an international collaboration led by the Health & Territory Research group at the University of Seville, together with a multidisciplinary team including patient organisations and rheumatologists. This cross-sectional study consisting of an online survey gathering data from patients with a diagnosis of 15 RMDs in Cyprus, France, Greece, Italy, Portugal, Spain, and the United Kingdom. 1,800 participants were recruited by patient organisations. Data was collected between April and July 2020. Participants were divided into two groups: 1) Participants with poor wellbeing (World Health Organization-Five Wellbeing Index (WHO-5) ≤ 50), 2) Participants with good wellbeing (WHO-5 >50). The Mann-Whitney and χ^2 tests were used to analyse possible relations between sociodemographic characteristics, lifestyle, and outdoor contact with wellbeing during the first wave of the COVID-19 pandemic. Univariate and multivariate binary logistic regression was used to determine the impact of the independent variables associated with poor wellbeing.

Results: 1,777 patients with 15 different RMDs were included. The mean age was 52.7, 80.2% female, 48.7% had a university degree, and 69.7% were married or in a relationship. The most frequent diagnoses were inflammatory arthritis (75.4%). 49.0% reported poor wellbeing. 57.7% of patients who belonged to a patient organisation reported good wellbeing (vs 46.3% who did not, $p<0.001$). Those who reported poor wellbeing had higher disease activity (51.4% vs 41.3%, $p<0.001$), a higher risk of anxiety (54.3% vs 41.7%, $p<0.001$) and depression (57.0% vs 42.1%, $p<0.001$), and poorer self-perceived health (53.0% vs 41.8%, $p<0.001$), compared to those who did not. A higher proportion of those who engaged in physical activity presented good wellbeing (54.0% vs 46.5%, $p=0.012$). 57.4% of the patients who were unable to attend their appointment with their rheumatologist reported poor wellbeing, compared to 48.2% who did attend ($p=0.027$). Patients who did not walk outside (56.2%) or who lacked elements in their home to facilitate outside contact (63.3%) experienced poor wellbeing ($p<0.001$). The factors associated with poor wellbeing were lack of elements in the home enabling contact with the outside world (OR=2.10), not belonging to a patient organisation (OR=1.51), risk of depression (OR=1.49), and not walking outside (OR=1.36) during the COVID-19 pandemic (Table 1).

Conclusion: Almost half of the patients with RMDs reported poor emotional wellbeing during the first wave of the COVID-19 pandemic. The lack of elements in the home that facilitate outdoor contact, not belonging to a patient organisation, the presence of anxiety, and not walking outside during the pandemic increase the probability of poor emotional well-being. These results highlight the importance of environmental factors and the role of patient organisations in addressing the effects of the pandemic and its containment measures.

Table 1. Logistic regression for poor wellbeing WHO-5 (N=1,104)

	Univariate logistic analysis		Multivariate logistic analysis	
	OR	95% CI1	OR	95% CI1
Patient organisation. Non-member	1.57	1.30, 1.89	1.51	1.18, 1.93
Disease activity (VAS ≥ 4)	1.50	1.21, 1.86	1.16	0.85, 1.56
Risk of anxiety (HADS, 0-21)	1.67	1.38, 2.02	1.20	0.92, 1.58
Risk of depression (HADS, 0-21)	1.83	1.51, 2.21	1.49	1.12, 1.99
Self-reported health. Fair to very bad	1.58	1.30, 1.91	1.26	0.94, 1.68
Change in health status. Worse	1.27	1.06, 1.53	1.05	0.80, 1.38
Physical activity. No	1.35	1.07, 1.71	1.08	0.83, 1.40
Talked with rheumatologist during the pandemic. No	1.45	1.04, 2.03	1.04	0.68, 1.61
Walk outside during COVID-19 pandemic. No	1.47	1.19, 1.83	1.36	1.02, 1.81
Element in home with outdoor contact. No	1.93	1.42, 2.62	2.10	1.41, 3.15

¹95% CI for test H_0 : OR = 1

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POS1214

THE DYNAMICS OF INFLAMMATORY MARKERS IN COVID-19 PATIENTS TREATED WITH LEVILIMAB

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Background: Levilimab (LVL) is a novel anti-IL6R monoclonal antibody against IL6R α . Cytokine release syndrome plays the key role in the pathogenesis of a range of life-threatening conditions including the acute respiratory distress syndrome in severely ill COVID-19 patients. Thus, the use of LVL could be considered as anti-cytokine therapy with a potency to prevent the complications and progression of respiratory failure in COVID-19.

Objectives: We analyzed the changes in the serum concentrations of inflammatory markers (Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and IL-6) in patients treated with LVL or placebo as part of a phase III multicenter randomized double-blind placebo-controlled adaptive-design CORONA clinical study aimed to evaluate the efficacy and safety of LVL in subjects with severe COVID-19 (NCT04397562).

Methods: A total of 217 patients were enrolled in the study, 206 patients were randomized, and 204 patients received the investigational product (IP, LVL or placebo).

Study included men and non-pregnant women aged ≥ 18 years, hospitalized for severe COVID-19 pneumonia, receiving standard therapy according to the national guidelines. Patients with acute respiratory failure with the need in invasive respiratory support, septic shock, multiple organ failure or life expectancy

less than 24 hours could not participate in the study. The use of other monoclonal antibodies and glucocorticoids for the treatment of COVID-19 were not allowed. Subjects were stratified according to the CRP level (CRP $\leq$ 7 mg/L; CRP $>$ 7 mg/L) and then randomized (1:1) into 2 groups to receive LVL 324 mg or placebo. LVL/placebo were administered as a single subcutaneous injection, investigator and patients were unaware of the received therapy.

Among secondary endpoints of the study changes from baseline in ESR, CRP and IL-6 concentrations were assessed. CRP level and ESR were measured before the IP administration and on Days 3, 5, 7, 14, 21, 29 and 30. Blood samples for the measurement of IL-6 concentration were obtained before the IP administration and then every day for 2 weeks after administration.

Results: We observed the pronounced decrease of ESR in LVL group compared to Placebo group. The difference was statistically significant on Days 3 and 7: the median ESR change from baseline was -3 mm/h and +3 mm/h on Day 3, -11 mm/h and -3.1 mm/h on Day 7, in LVL and Placebo groups, respectively ($p=0.0319$ and $p=0.0110$, Days 3 and 7). The statistically significant difference in the change of CRP level was detected between the groups on Day 3: -26.6 $\pm$ 41.9 mg/L and -19.2 $\pm$ 58.2 mg/L in LVL and Placebo groups, respectively ($p=0.0241$). Numerically the same dynamics of ESR and CRP was observed over entire study period.

The dynamics of IL-6 serum concentrations in LVL and Placebo groups was strikingly different. After LVL administration we detected the rapid significant increase in IL-6 concentration due to IL-6 receptors inhibition. Maximum change from baseline was observed on Day 3 (+91.9 $\pm$ 117.7 pg/mL), on Day 14 the value was +31.9 $\pm$ 62.7 pg/mL.

In the Placebo group, the IL-6 concentration increased slightly until Day 4 (+5.1 $\pm$ 76.5 pg/mL), and then decreased significantly (-39.2 $\pm$ 55.1 pg/mL on Day 14) due to clinical improvement in this group.

Conclusion: The significant differences in the dynamics of ESR, CRP and IL-6 after LVL administration compared to placebo confirmed the pharmacodynamic effect and its potency to prevent the excessive release of inflammatory substances in severely ill COVID-19 patients.

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POS1215

INFLUENCE OF CONFINEMENT CARRIED OUT BY PATIENTS WITH AUTOIMMUNE AND IMMUNE-MEDIATED INFLAMMATORY DISEASE WITH BIOLOGICAL TREATMENT ON COVID-19 INFECTION

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Background: The disease caused by SARS-CoV-2 is a potentially serious infection. The autoimmune and immune-mediated inflammatory disease (AI/IMID) itself, its activity, the immunosuppression and the presence of comorbidities are associated with an increased risk of serious infections. At this moment the literature shows a similar risk of infection and severity compared to the general population. Some reports noted that these patients might adopt stricter measures of self-care protection than general population which could contribute to an incidence of infection lower than expected.

Objectives: To assess the incidence and clinical presentation of SARS-CoV-2 infection in our cohort of patients with AI/IMID treated with biological agents (BA) or Janus Kinase (JAK) inhibitors. To analyse the association of the incidence and the type of confinement between the AI/IMID group and the general population.

Methods: A case-control study nested within a retrospective observational study was conducted from March 13th until April 23th, 2020 in Althaia, Xarxa Assistencial Universitària de Manresa. Subjects: cohort of AI/IMID patients followed by Rheumatology (inflammatory arthritis), Dermatology (psoriasis) and Digestology (inflammatory bowel disease) treated with BA/JAK inhibitors. Controls were selected from our Primary Care Centers. Main outcome: Type of confinement: strict: $<$ 1 outing / week with safety measures (SM), regular (2-3 outings with SM), lax ($>$ 3 outings or face-to-face work with SM) and without confinement (without SM). Secondary outcome: SARS-CoV-2 infection: confirmed (PCR and/or positive serology), probable (severe illness requiring admission without PCR/serology or mild/moderate with epidemiological contact) and possible (mild infection without microbiological check nor epidemiological contact); as well as severity according to the WHO.

Results: 367 patients and 193 controls were included. 45.2% of patients were men, with a mean age of 52 (SD 14.6). 47.4% were patients with rheumatologic disease, 25.3% from dermatology and 27.2% from digestive. 95.6% received a BA (66.6% anti-TNF and 33.4% non-anti-TNF) and the remaining 4.4% received JAK inhibitors. 43.3% patients had at least a risk factor compared to 37.8% in the control group ($p=0.761$). The Table 1 shows the incidence of COVID divided into confirmed and cumulative cases (confirmed and possible), with no significant differences. One patient (0.3%) in the case group and 3 patients (1.6%) in the control group required hospital admission ($p=0.121$). In relation to the type of confinement we had significant differences ($p=0.013$) within the AI/IMID group versus the control group in lax confinement. There were no differences in the incidence of COVID between the different confinement types.

Table 1.

	Case (n=367)	Control (n=193)	p-value	
SARS-CoV-2 infection				
Cumulative COVID	10.1 (7.2-13.6)	13.5 (9.0-19.1)	0.228	
Confirmed COVID	3.3 (1.7-5.6)	5.7 (2.9-10.0)	0.169	
Probable	2.2 (0.9-4.2)	3.1 (1.1-6.6)	0.572	
Possible	4.6 (2.7-7.3)	4.7 (2.1-8.7)	0.987	
Type of confinement				OR (95% CI)
Strict	59.1 (53.8-64.2)	50.3 (43.0-57.5)	0.059	1.40 (0.99-1.99)
Regular	15.4 (11.8-19.5)	14.4 (9.9-20.3)	0.813	1.06 (0.65-1.73)
Lax	25.0 (20.6-29.4)	34.7 (28.0-41.9)	0.013	0.62 (0.42-0.91)
No confinement	0.5 (0.1-1.9)	0.5 (0.01-0.03)	1.000	1.05 (0.09-11.7)

CI: confidence interval; OR: Odds ratio

Conclusion: The incidence of COVID-19 infection in our cohort is similar to that reported in other series of AI/IMID patients and in general population, both for confirmed cases (3.3% vs 5.7%) as well as for cumulative cases (10.1% vs 13.5%). None of our patients developed a severe form of the infection. We observed that strict confinement was predominant in both groups, being higher in the AI/IMID patients (59.1% vs 50.3%). Furthermore, lax confinement was more frequent in the control group. Although the difference was not statistically significant, the incidence of infection was higher in the control group, especially in the subjects who performed lax confinement.

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POS1216

SYMPTOM RATES, ATTITUDES AND MEDICATION ADHERENCE OF RHEUMATIC AND MUSCULOSKELETAL DISEASE PATIENTS DURING THE SARS-CoV2 PANDEMIC

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Background: SARS-CoV2 has caused over two million deaths globally. The relationship between rheumatic and musculoskeletal disease (RMDs), immunosuppressive medications and COVID-19 is unclear.

Objectives: This study explores the rates of COVID-19 symptoms and positive tests, DMARD adherence and attitudes to virtual clinics, amongst RMD patients.

Methods: An online population survey was disseminated via the Arthritis Ireland website and social media channels.

Results: There were 1381 respondents with RMD, 74.8% were on immunosuppressive medication. COVID-19 symptoms were reported by 3.7% of respondents of which 0.46% tested positive, no different from the general population at that timepoint. The frequency of COVID-19 symptoms was higher for respondents with spondyloarthritis [odds ratio (OR) 2.06, 95% CI: 1.14, 3.70] and lower in those on immunosuppressive medication (OR 0.48, 95% CI: 0.27, 0.88), and