Conclusion: Our data show that patients with SpA do not face a worse prognosis of COVID-19 than subjects without rheumatic/autoimmune diseases and that demographic and clinical features did not influence the course of the disease.
Disclosure of Interests: None declared
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POS1254 RISK FACTORS FOR SEVERE COVID-19 INFECTION AMONG PATIENTS WITH AUTOIMMUNE INFLAMMATORY RHEUMATIC DISEASES (AIRD) AND THE IMPACT OF VACCINATIONS - AN ISRAELI, MULTI-CENTER EXPERIENCE

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Background: AIRD patients (pts) may be more susceptible to severe COVID19.
Objectives: To determine the risk factors for severe COVID19 and the effect of vaccinations among AIRD pts followed at dedicated rheumatology clinics.
Methods: At the onset of the pandemic, we established a national registry of AIRD pts, diagnosed with COVID19, based on voluntary reporting by the treating rheumatologist. 12 centers from Israel participated in the study. COVID19 was confirmed by a positive SARS CoV2 PCR. The indications for PCR testing were clinical symptoms or close contact with an infected person. Severe illness was defined by SpO_2 <94% in room air, respiratory rate of >30 breaths/min, PaO_2/FiO_2 <300 mm Hg, or lung infiltrates >50% on imaging. The registry included demographic data, AIRD diagnosis and duration, visceral involvement, co-morbidities, immunomodulatory treatment, date of diagnosis and severity of COVID19 disease, management, complications, duration of hospitalization, the dates of the mRNA vaccinations, lab results and outcome. We analyzed data from 1.3.2020 to 30.11.2021
Results: During the study period we experienced 4 outbreaks of COVID19 infection. Initially social distancing, followed by a lockdown were imposed. The low number of cases led to relaxation of the measures. Two more severe outbreaks followed, which triggered 2 new lockdowns. The 3rd outbreak ended almost 2 months after vaccination started (BNT162b2 mRNA COVID19 vaccine). From March 1st 2020 to April 30, 2021, 298 AIRD pts (70.8% females, mean (SD) age 53.3(15.3)) with confirmed COVID19 infection were included. 43.3%(129) had visceral involvement due to the AIRD. 58.7%(175 pts) were on conventional synthetic disease modifying drugs (csDMARDs), 44.6% (133) on biologic/targeted DMARDs and 40% (120) on prednisone. Almost 2/3 of pts had at least one comorbidity.
In a multivariate logistic regression analysis age, AIRD with pulmonary involvement, diabetes and treatment with prednisone, mycophenolate mofetil or JAK inhibitors were associated with hospitalization. Older age, renal and vascular involvement due to the AIRD, and congestive heart failure were associated with higher mortality.
The 4th outbreak occurred 6 months after the introduction of vaccines, with spreading of the delta variant: 110 AIRD pts with COVID19 were recorded. Demographic data, clinical AIRD's characteristics, immunomodulatory treatment and comorbidities were similar to the previous outbreaks. However, during the 4th outbreak, the proportion of pts with severe COVID19, the hospitalization and mortality rate were significantly lower as compared to the first 3 outbreaks (15% vs 24%, 27% vs 53%, 6.7% vs 9.1%, respectively). Among COVID19 pts, 25% received a 3rd vaccine dose (booster), 56% contracted infection more than 5 months after the 2nd vaccine dose and 24% were unvaccinated. Most of the pts who received the booster contracted the disease within a week of vaccination. The odds ratio for hospitalization in vaccinated pts compared to unvaccinated was 0.11 (0.01 – 0.63 95% CI, p=0.041) in those vaccinated within the previous 1-5 months, and 0.38 (0.21-0.67 95% CI, p=0.001) in those vaccinated more than 6 months ago. 9 pts died, 5 were more than 6 months after the 2nd mRNA vaccine, 2 were unvaccinated and 1 patient received the booster on the same day of COVID19 diagnosis.
Conclusion: Before the vaccination campaign, the hospitalization and mortality rate in our cohort were similar to the data reported by other registries. COVID19 tends to be more severe, with increased mortality in patients with active AIIRD and visceral involvement (pulmonary, cardiac, renal), advanced age and co-morbidities. The delta outbreak occured 6 months after the implementation of vaccinations and was associated with significantly lower hospitalization and mortality rates, despite the increased aggressiveness of the variant. Vaccination of AIIRD pts with 3 doses of mRNA vaccines protects from severe COVID19 disease, hospitalization, and death.
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POS1255 SAFETY OF THE PFIZER/BIONTECH AND SINOVAC/CORONAVAC VACCINES AMONG PATIENTS WITH BEHCET'S SYNDROME AND FAMILIAL MEDITERRANEAN FEVER

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Background: Since first emerged in December 2019, the COVID-19 pandemic has resulted in a death toll surpassing 5.5 million worldwide and had severe consequences on the global economy, environment, public health and social life [1, 2]. Multiple potential vaccines against COVID-19 have been developed swiftly and as shown in several phase 3 clinical trials, they demonstrated considerable efficacy without an unusual safety signal in healthy individuals.
Objectives: In this study, we aimed to evaluate vaccine reactivity and disease flare following vaccination with either Sinovac/CoronaVac or Pfizer/BioNTech among BS and FMF patients compared with patients with various diagnosis of RD and healthy controls.
Methods: Only those patients and healthy controls who rece,ved at least one single shot of either CoronoVac or BioNTech against COVID-19 were included in the study. We tried to contact all of these patients and controls consecutively by telephone and attempted to make interviews with the eligible ones.
Results: We studied the efficacy, side effects and disease flares after COVID-19 vaccination in 256 patients with Behcet's syndrome (BS), 247 with familial Mediterranean fever (FMF), 601 with rheumatic diseases (RD) and 612 healthy controls (HC). Study participants were vaccinated either with CoronaVac (BS:109, FMF: 90, RD: 343, and HC: 334) or BioNTech (BS: 147, FMF:157, RD: 258 and HC: 278). BioNTech ensured a significantly better efficacy than CoronaVac against COVID-19 in all patient groups (BS: 1.4% vs 10.1%; FMF: 3.2% vs 12.2%, RD:2.7% vs 6.4%). Those with at least one adverse event (AE) were significantly more frequent among those vaccinated with BioNTech than those with CoronaVac (BS: 86.4% vs 45%; FMF: 83.4% vs 53.3%; RD: 83.3% vs 45.5% and HC: 86.3% vs 52.1%). The majority of AEs were mild to moderate and transient and this was true for either vaccine. There were also AEs that required medical attention in all study groups following CoronaVac (BS:5.5%, FMF:3.3%, RD:2.9% and HC:3.3%) or BioNTech (BS:5.4%, FMF:1.9%, RD:4.7% and HC:4.7%). The main causes for medical assistance were disease flare, and cardiovascular events. Disease flares after vaccination were significantly more frequent among BS (41/256; 16.0%) and FMF (43/247; 17.4%) patients compared to patients with RD (36/601; 6.0%). This was true for both CoronaVac (BS: 11.0%, FMF: 24.4% and RD: 5.2%, p<0.001) and BioNTech (BS: 19.7%, FMF: 13.4% and RD: 7.0%, p=0.001)(Table 1).

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Table 1. Flares among patients with Behçet's syndrome, familial Mediterranean fever, rheumatic diseases after vaccination with CoronaVac and BioNTech

CoronaVac		
Behçet's syndrome, n=109	Familial Mediterranean Fever, n=90	Rheumatic diseases, n=343
Flares, n (%) 12 (11.0)	Flares, n (%) 22 (24.4)	Flares, n (%) 18 (5.2)
BioNTech		
Behçet's syndrome, n=147	Familial Mediterranean Fever, n=157	Rheumatic diseases, n=258
Flares, n (%) 29 (19.7)	Flares, n (%) 21 (13.4)	Flares, n (%) 18 (7.0)

RA, Rheumatoid Arthritis; BS, Behçet's syndrome; FMF, Familial Mediterranean Fever

Conclusion: Our study demonstrates that BS and FMF patients vaccinated with either CoronaVac or BioNTech demonstrated almost similar AE profile and frequency compared to RD patients and HC. AEs that required physician consultation or hospitalization occurred in all study groups after either CoronaVac or BioNTech. Caution should be required when monitoring these patients after vaccination. Increased frequency of flares in BS and FMF compared to that seen in RD might reflect defects in innate immunity and deserves further investigation.

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POS1256

RISK FACTORS FOR SHORT-TERM ADVERSE EVENT IN PATIENTS WITH IMMUNE-MEDIATED INFLAMMATORY DISEASES

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Background: Many countries are promoting booster SARS-CoV-2 vaccination campaigns as the COVID-19 pandemic continues. Incremental short-term adverse events after two SARS-CoV-2 vaccinations have been reported in healthy individuals.[1,2] However, data on incremental short-term adverse events in patients with various immune-mediated inflammatory diseases (IMIDs) after repeated SARS-CoV-2 vaccination is scarce.

Objectives: We report risk factors for short-term adverse events in IMID patients after SARS-CoV-2 vaccination.

Methods: Self-reported daily questionnaires on adverse events in the first seven days after SARS-CoV-2 vaccination were obtained from individuals participating in an ongoing prospective multi-arm multicenter cohort study on SARS-CoV-2 vaccination in patients with various IMIDs in the Netherlands (T2B! immunity after SARS-CoV-2). Clinically relevant adverse events were defined as systemic adverse advents lasting longer than two days or hindering daily activities. Adjusted relative risks for developing clinically relevant adverse events were calculated using a logistic mixed-effects model.

Results: Data of 2081 patients and 178 healthy controls were obtained. Inflammatory bowel disease (N:480), Multiple sclerosis (N:343) and Rheumatoid arthritis (N:266) were the largest disease groups. Adjusted relative risks for relevant adverse events are presented in Figure 1. Third vaccination was not associated with increased risk on adverse events when compared to a second vaccination (aRR: 0.93 95% CI: 0.84-1.02). Patients with IMIDs were at increased risk for developing adverse events after vaccination when compared to controls (aRR: 1.16 95% CI: 1.01-1.34). Female sex (aRR 1.43 95% CI: 1.32-1.56), age below 50 (aRR 1.14 95% CI: 1.06-1.23) and a preceding SARS-CoV-2 infection (aRR: 1.14 95% CI: 1.01-1.29) were also associated with increased risk of adverse events following vaccination. Allergic reactions and hospital admission were uncommon (0.67% and 0.19% respectively); 7.4% and 6.8% of patients reported adverse events impacting daily life on day seven after second and third vaccination, respectively. Data on increase in disease activity of the IMID following vaccination are currently being investigated.

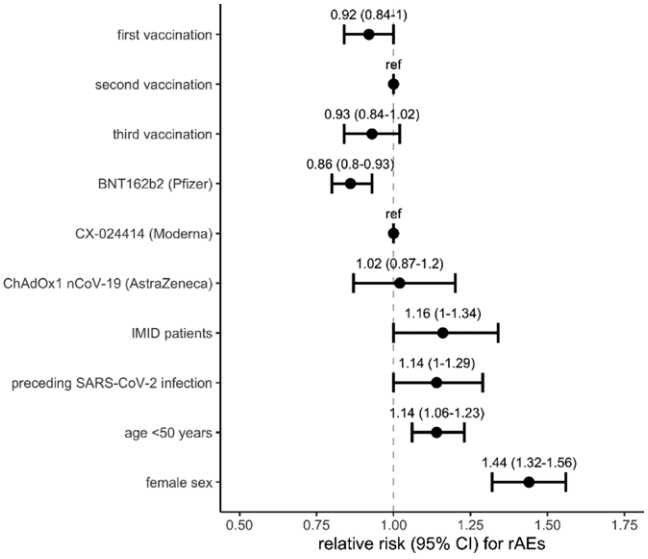


Figure 1. Risk factors for adverse events after SARS-CoV-2 vaccination in patients with immune-mediated inflammatory disease

Conclusion: A third SARS-CoV-2 vaccination was not associated with an increased risk on short-term clinically relevant adverse events when compared to a second vaccination. Although patients with IMIDs may be slightly more at risk to develop adverse events after SARS-CoV-2 vaccination, most adverse events were transient and disappeared within seven days. This message should reassure IMID patients who are hesitant on booster vaccination. Data on potential IMID flare-ups after vaccination will follow.

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