Correspondence on "Safety of vaccination against SARS-CoV-2 in people with rheumatic and musculoskeletal diseases: results from the EULAR Coronavirus Vaccine (COVAX) physician-reported registry" by Machado *et al*

We read with great interest the article by Machado *et al* who describe safety of vaccination against SARS-CoV-2 in people with rheumatic and musculoskeletal disease. The authors observed that vaccine against SARS-CoV-2 is well tolerated with rare report of I-RMD flare and very rare reports of serious adverse events.

We observed that the authors included only 27 patients with autoinflammatory diseases. We thus propose to complete their observation with the result of our study about 190 patients with autoinflammatory disease (AID).

A web survey assessing adverse effects after COVID-19 vaccination was sent on 7–30 June 2021 to patients with AID followed in the French national adult AID reference centre, and already included in the Juvenile Inflammatory Rheumatism (JIR) cohort. The patients were asked whether they had received a COVID-19 vaccination, the type of vaccine and number of injections. Severe adverse events were defined by the need for hospitalisation. Local reaction, fever, headache, arthralgia, myalgia, allergic reaction, fatigue, nausea, adenopathy, heart disorder, venous thromboembolism and stroke were monitored after the first and the second injection.

The survey was sent by email to 445 patients with AID: 225 (50%) patients answered it, 168 aged between 18 and 55 years old and 57 aged above 55 years old. Among the 190 patients who received two doses of COVID-19 vaccines (online supplemental table), most patients had familial Mediterranean fever (FMF) (n=128, 67.4%); other AID were undefined systemic AID (n=20), TNF-α receptor-associated periodic syndrome (n=13), cryopyrin-associated periodic syndrome (n=9), adult-onset still disease (n=9), mevalonate kinase deficiency (n=7) and A20 haploinsufficiency (n=4). Eleven patients declared also having AA amyloidosis (5.7%). Colchicine was the most used treatment (n=138, 72.6%); 37 (19.5%) patients were on biotherapy, mostly interleukin-1 inhibitors (n=33) and 15 patients were not taking any treatment. Forty-six patients had already contracted SARS-CoV-2.

Out of the 190 (84.4%) vaccinated patients with AID, BNT162b2 (Pfizer/BioNTech) (n=157, 82.6%) and ChAdOx1 nCoV-19 (Astra-Zeneca) (n=22, 11.5%) were the most common vaccines; few patients received CX-024414 (Moderna) (n=11, 5.8%). Eighty-eight patients (46%) developed mild adverse events after the first injection and 70 patients (54%) after the second injection. Among the 153 patients who received BNT162b2, tenderness at the injection site was the most reported event (n=39, 25.5%); others were myalgia (n=28, 18.3%), fever (n=20, 13%) and headache (n=16, 10.5%). Concerning ChAdOx1 nCoV-19, reported events were fever (n=13, 59%), myalgia (n=11, 50%) and intense fatigue (n=2, 9%). Concerning CX-024414, four patients reported fever and myalgia (36%). No severe adverse event requiring hospitalisation has been reported. Twelve patients with FMF (9.3%) reported a mild flare after the first injection, which did not require hospitalisation. No vaccinated patient had developed COVID-19 after the second vaccine injection.

Altogether, this study shows that adverse event of COVID-19 vaccination in patients with AID are similar to the expected adverse effects reported in the general population.² Especially among patients with FMF on colchicine treatment, the vaccine is very safe and should be highly recommended to patients with risk factors of severe COVID-19, since we previously reported death among such patients with FMF.³ It also suggests that COVID-19 vaccination does not usually trigger an AID flare; these data were also reported in patients with autoimmune diseases and AID.⁵ To our knowledge, this is the largest study describing the effects of COVID-19 vaccination among patients with AID: the vaccine is well tolerated; these data combined with the results from Machado *et al* could reassure patients displaying immune systemic disorders including AID patients who are still hesitant about COVID-19 vaccination, especially in the actual context of the resurgence of the epidemy.

Rim Bourguiba ^{1,2,3} Marion Delplanque, ^{1,2,3} Léa Savey, ^{1,2,3} Veronique Hentgen, Gilles Grateau, ^{1,2,3} Sophie Georgin-lavialle ^{1,2,3,5} French national reference Center for autoinflammatory diseases and AA amyloidosis (CEREMAIA)

¹Internal Medecine, Hopital Tenon, Paris, Île-de-France, France

²Service de médecine interne, Hopital Tenon, Paris, France

³UMR_S 933, Sorbonne Universités, UPMC Univ Paris 06, Paris, Île-de-France, France ⁴CeReMAI-Departement of pediatrics, Hôpital Mignot, Le Chesnay, France

⁵Tenon Hospital, Internal Medicine, AP-HP, Paris, France

Correspondence to Dr Rim Bourguiba, Internal Medecine, Hopital Tenon, Paris, France; rim.bourguiba@outlook.com

Handling editor Josef S Smolen

Twitter Rim Bourguiba @Rimbourguiba1 and Sophie Georgin-lavialle @ SophieGeorgin

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ORCID iDs

Rim Bourguiba http://orcid.org/0000-0002-7352-9074 Sophie Georgin-lavialle http://orcid.org/0000-0001-6668-8854

REFERENCES

- 1 Machado PM, Lawson-Tovey S, Strangfeld A, et al. Safety of vaccination against SARS-Cov-2 in people with rheumatic and musculoskeletal diseases: results from the EULAR Coronavirus vaccine (COVAX) physician-reported Registry. Ann Rheum Dis 2022:81:695–709.
- 2 Menni C, Klaser K, May A, et al. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study APP in the UK: a prospective observational study. Lancet Infect Dis 2021;21:939–49.
- 3 Bourguiba R, Delplanque M, Vinit C, et al. Clinical course of COVID-19 in a cohort of 342 familial Mediterranean fever patients with a long-term treatment by colchicine in a French endemic area. Ann Rheum Dis 2021:80:539–40.
- 4 Boekel L, Kummer LY, van Dam KPJ, et al. Adverse events after first COVID-19 vaccination in patients with autoimmune diseases. Lancet Rheumatol 2021;3:e542–5.
- 5 Peet CJ, Papadopoulou C, Sombrito BRM, et al. COVID-19 and autoinflammatory diseases: prevalence and outcomes of infection and early experience of vaccination in patients on biologics. Rheumatol Adv Pract 2021;5:rkab043.

