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*Case report*

# Eosinophilic Granulomatosis with Polyangiitis after mRNA-1273 SARS-CoV-2 Vaccine

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**Abstract:** During one of the worst global health crises, millions of people were vaccinated against SARS-CoV-2. In rare cases, new onset systemic inflammatory diseases were reported with temporal coincidence to the vaccination. We describe a case of severe Eosinophilic Granulomatosis with Polyangiitis (EGPA) in a young asthmatic woman, occurring after a 2nd dose of mRNA-1273 vaccine. She presented with multisystem EGPA with cardiac and central nervous system involvement, complicated by secondary immune thrombocytopenia (ITP). We review the reported cases of EGPA coinciding with SARS-CoV-2 mRNA vaccination. All potentially vaccine-related EGPA cases reported so far occurred within 14 days from immunization. EGPA is very rare with an incidence of 1:1'000'000 inhabitants and the number of reported post-vaccination EGPA cases lies within the expected incidence rate for the period. While we cannot prove a causal relationship between the vaccine and EGPA onset, the temporal relationship with the vaccine immune stimulation is intriguing, in a disease occurring almost always in adults with asthma and/or chronic rhinosinusitis and driven by an aberrant Th2 lymphocyte activation with hypereosinophilia. Nevertheless, cases of inflammatory diseases emerging in the context of vaccination remain rare and the benefits of preventing severe Covid presentations with SARS-CoV-2 mRNA vaccines remains unquestionable.

**Keywords:** eosinophilic granulomatosis with polyangiitis; SARS-CoV-2; mRNA vaccine; immune thrombocytopenia

## 1. Introduction

During the SARS-CoV-2 global health crisis, hundreds of millions of people were immunized against SARS-CoV-2 with various vaccines. In Switzerland, approximately 6 million people received at least one dose of mRNA SARS-CoV-2 vaccine by November 2022.[1]. From January 2021 to March 2022, the Swiss Agency for Therapeutic Products (Swissmedic) evaluated 13,388 reports of suspected adverse events to the vaccines, with mRNA 1273 vaccine accounting for 68% of cases [2]. About 38% of adverse events were classified as serious. In rare cases there were reports of immune-mediated inflammatory diseases (IMID) flares or even new-onset IMID after SARS-CoV-2 vaccines.[3] We report here a severe case of Eosinophilic Granulomatosis with Polyangiitis (EGPA), occurring in temporal relationship with SARS-CoV-2 vaccination and complicated by immune thrombocytopenia

(ITP). This adds to the few reports of flares and new onset EGPA after mRNA vaccines reviewed below [4–8].

## **2. Materials and Methods**

We describe a severe case of EGPA with multisystem manifestations complicated by ITP after mRNA SARS-CoV-2 vaccination. We also present other similar cases found in the literature, which are resumed in Table 1.

**Table 1.** Reported cases of new-onset eosinophilic granulomatosis with polyangiitis or disease flares after immunization with mRNA vaccines.

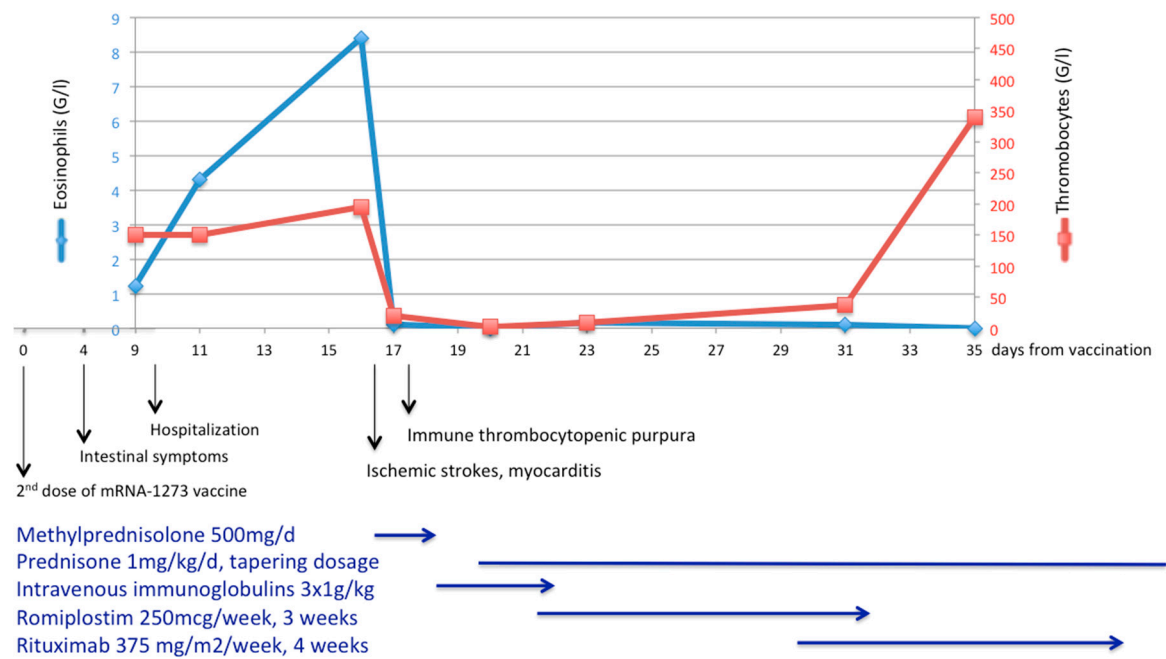
Case	Age, gender	Pre-existing respiratory disease	Pre-existing EGPA (treatment)	mRNA vaccine type	Time between immunization and EGPA symptom onset in days (vaccine dose)	Clinical presentation	Complications	Peak blood eosinophil count (G/l)	ANCA positivity (type)	FFS	Treatment received
[4]	62, F	Asthma	No	BNT161b 2	Few days (2 <sup>nd</sup> dose)	Fever, numbness in feet and palms, walking disability, purpura, peri-orbital oedema	Polyneuropathy, optic nerves inflammation, myocarditis, vasculitis at cutaneous biopsy	13.4	Yes (anti-MPO)	1	MP, RTX
[5]	63, M	Allergic rhino-sinusitis and asthma	No	mRNA-1273	1 (1 <sup>st</sup> dose)	Diplopia, headache, dry cough	3 <sup>rd</sup> cranial nerve palsy, myopericarditis Rhabdomyolysis, acute kidney injury, pauci-immune crescentic glomerulonephritis and interstitial nephritis with prominent eosinophilia	12.4	No	2	MP, P, CYC
[6]	79, F	No	No	BNT162b 2	14 (2 <sup>nd</sup> dose)	Myalgia, Weakness	Progressive paraesthesia of hands and feet, myalgia, walking disability	5.3	Yes (p-ANCA, anti-MPO)	1	MP, P, CYC
[7]	79, F	Asthma	No	mRNA-1273	14 (2 <sup>nd</sup> dose)	Progressive paraesthesia of hands and feet, myalgia, walking disability	DVT, vasculitic neuropathy with eosinophil infiltration	12.4	Yes (p-ANCA, anti-MPO)	0	P, AZA

[20]	N/A, M	Rhino-sinusitis and asthma	Yes (untreated for 7 years)	BNT162b 2	5 (1st dose)	Weakness, neuropathic pain, blurry vision Myalgia, arthralgia, dyspnoea, cough, chest pain, paraesthesia	Polyneuropathy, mild left foot drop	0.94	No	0	P
[21]	71, F	Rhino-sinusitis and asthma	Yes (MEP, ICS)	BNT162b 2	10 (1st dose)		Mononeuritis multiplex	4.3	Yes (p-ANCA)	0	MP, P, BEN
[8]	63, F	Allergic rhinitis and asthma	Yes (AZA)	mRNA-1273	14 (1 <sup>st</sup> dose)	Dyspnoea, chest pain	Myocarditis	0.88	No	1	MP, P, CYC
[8]	64, M	Asthma and rhinosinusitis with nasal polyps	No (but constitutional symptoms for 3 months)	BNT162b 2	2 (1 <sup>st</sup> dose)	Numbness thigh, purpura, chest pain	Endomyocarditis, cutaneous vasculitis, mononeuritis multiplex, possible glomerulonephritis	5.39	No	1	MP, P, CYC
Present case	46, F	Allergic rhino-sinusitis and asthma	No	mRNA-1273	4 (2 <sup>nd</sup> dose)	Enteritis, fever, fatigue, myalgia	Myocarditis, multiple strokes, immune thrombocytopenia	8.4	No	2	MP, P, IVIG, RPL, RTX, BEN

AZA: azathioprine; FFS: Five factor score; MP: methylprednisolone pulses; P: Prednisone; IVIG: intravenous immunoglobulins; RPL: romiplostim; CYC: cyclophosphamide; RTX: rituximab; BEN: benralizumab.

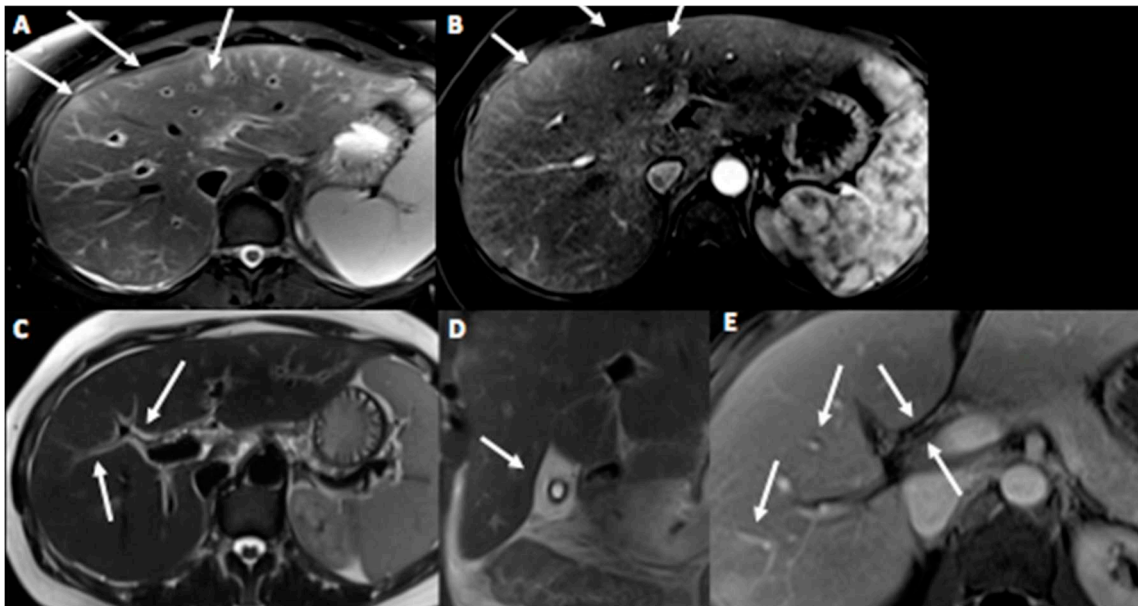
3. Case Presentation

A 46-year-old woman of European descent developed fever, asthenia and myalgia the day after her second dose of mRNA-1273 vaccine. She was known for allergic rhinosinusitis and moderate asthma but had no other health issues. The patient never tested positive for SARS-CoV-2 and the first vaccine, a month earlier, was well tolerated. Four days after the initial symptoms she developed severe watery diarrhoea with vomiting and consulted the emergency room. Upon admission, she was hemodynamically stable. Her temperature was 38°C and her oxygen saturation was normal. The abdomen was tender without guarding. The remaining clinical examination was normal. Blood test showed leucocytosis 17.6 G/l (reference range: 4-10) with neutrophilia 14 G/l (ref. 1.8-7.5), eosinophilia 1.2 G/l (<0.3), and cholestasis. Eosinophilia increased, peaking at 8.4 G/l (Figure 1).



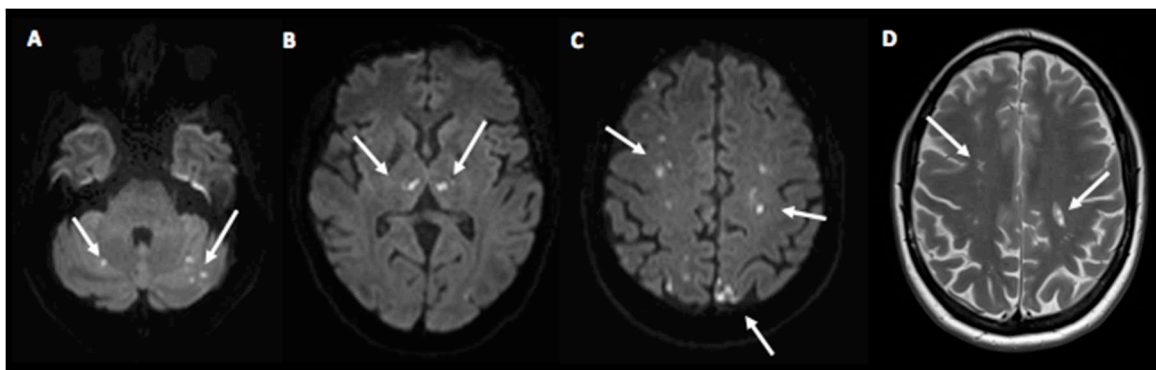
**Figure 1.** Disease course in a 46 year-old patient with new onset eosinophilic granulomatosis with polyangiitis occurring after SARS-CoV-2 mRNA 1273 vaccine. Disease manifestations with evolution of blood eosinophil and thrombocyte count and treatment received. Multiple ischemic strokes occurred at the peak of peripheral blood eosinophilia (8.4 G/l).

Total serum IgE was 1361 kU/l (ref. 5-50 kU/l). IgG 4 levels were in the normal range. Extensive search for parasitic, viral, and bacterial infection was negative, as were anti-neutrophil cytoplasmic antibodies (ANCA). Abdominal MRI showed diffuse inflammatory cholangiopathy (Figure 2).



**Figure 2.** Liver MRI showing cholangiopathy disease. Magnetic Resonance Imaging with WI-weighted images, performed 10 days after symptom onset, showing patchy and ill-defined T2 hypersignal lesions (A, arrow) with discrete arterial phase enhancement (B, arrow). Periportal oedema (C, arrow), diffuse gallbladder wall thickening (D, arrow) and biliary wall enhancement on portal venous phase (E) are seen on T2.

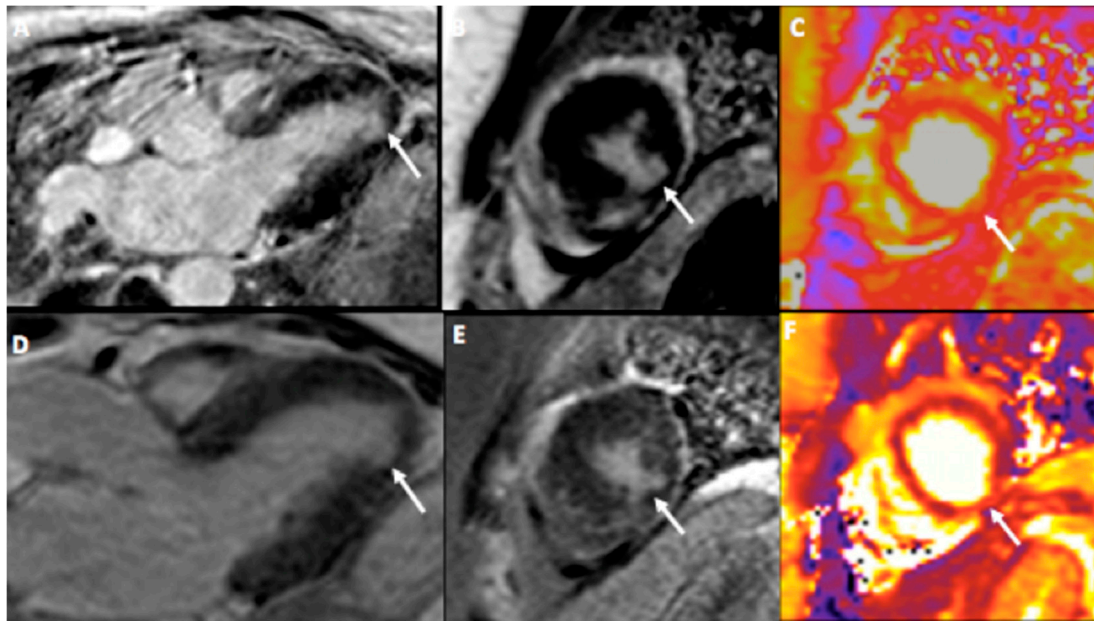
Hematologic work-up including bone-marrow biopsy and oncogenomic and molecular analysis (BCR-ABL and FISH analysis for PDGFA, PDGFB, FGFR1, PCM-JAK2) showed no arguments for a clonal hypereosinophilic syndrome. Whole body 18-FDG PET-CT was inconspicuous. CT-scan showed pulmonary interstitial infiltration and lung function test confirmed an obstructive pattern. Endoscopy revealed ileum and colon eosinophilic infiltrates. During work-up, the patient developed left leg dystonia and right extrapyramidal syndrome. Brain MRI revealed multiple ischemic lesions (Figure 3).



**Figure 3.** Cranial MRI showing multiple ischemic lesions of the brain. Brain MRI performed 15 days after symptom onset (A, B, C). Diffusion weighted images denote multiple focal acute infarcts in the posterior and anterior circulation territories: in both cerebellar hemispheres (A, arrows), in the thalami (B, arrows), and bilateral cortical and subcortical fronto-parieto-occipital regions (C, arrows). (D) Axial T2 weighted MRI performed after 3 months shows residual infarction lesions in corona radiata (arrows).

High-sensitive troponins T were elevated [peak at 916 ng/l (ref. <14)] and cardiac MRI showed changes consistent with myocarditis (Figure 4).





**Figure 4.** Cardiac MRI consistent with myocarditis. Cardiac MRI performed initially (A, B, C) and after 3 months (D, E, F). Three chamber (A) and short axis (B) LGE images demonstrating a focal medio-mural lesion in the inferior and inferolateral apical myocardial segment (arrows), persistent on control MRI 3 months later (D, E, arrows). T2-imaging short axis apical images (C, E) showing a focal T2 hypersignal in the same territory, translating a myocardial inflammatory oedema. LGE: late gadolinium enhancement.

The patient received intra-venous methylprednisolone pulses than switched with oral prednisone and anti-aggregation with acetylsalicylic acid, with normalization of eosinophils count (Figure 1). The day after starting methylprednisolone, she developed severe thrombocytopenia (Figure 1). Platelets decreased from 195 G/l (ref. 150-350) to 20 G/l in 24 hours with a nadir at 2 G/l three days later. The work-up for thrombocytopenia was negative (heparin induced thrombocytopenia, viral serologic panel, disseminated intravascular coagulation, thrombotic microangiopathy and antiphospholipid antibodies). Venous thrombosis was excluded and anti-PF4 antibodies were negative, which spoke against vaccine-induced immune thrombotic thrombocytopenia [9]. The diagnosis of immune thrombocytopenic purpura secondary to EGPA was retained. However, the platelet count did not increase under high-dose glucocorticoids, intravenous immunoglobulin and weekly romiplostim. Eventually, the thrombocytopenia subsided after four weekly rituximab courses of 375 mg/m<sup>2</sup> (Figure 1) and blood count, including eosinophils, remained normal thereafter.

Upon achieving remission, monthly injections with the anti-IL-5 receptor antagonist benralizumab were added and Prednisone progressively reduced to 5mg/day. 6 months after the diagnosis, the patient still had moderate dystonia impairing her daily activities. Two years later, the patient is still receiving benralizumab and is doing fine.

#### 4. Discussion

Our patient fulfils the latest ACR/EULAR criteria for EGPA (obstructive airway disease, blood eosinophil count >1 G/l and predominant extravascular eosinophilic inflammation on biopsy), [10] and had involvement of bowel, biliary tree, heart and central nervous system.

EGPA is an immune-mediated disease developing in patients with asthma and/or chronic rhinosinusitis. ANCA are found in a minority of patients [11]. EGPA may be separated in two clinical entities: a vasculitic and an eosinophilic phenotype. Patients with vasculitis are more often ANCA positive, while the eosinophilic subtype more often affects the myocardium and has worse prognosis [11]. There is considerable overlap between the two entities. In our ANCA-negative patient, the



multiple ischemic cerebral infarctions seen on the MRI are consistent with a small-to medium size vasculitis. It is likely that the high eosinophil count had contributed to myocarditis and cerebral ischemia, due to cytotoxicity to cardiomyocytes and endothelial cells and pro-thrombotic effects [12].

The association of thrombocytopenia and EGPA is uncommon. There are reports of thrombotic microangiopathies complicating EGPA [13] but this was unlikely in our patient, in the absence of haemolysis and schistocytes.

The Five Factor Score, a useful tool to evaluate prognosis and guide the intensity of treatment in systemic vasculitis [14], was worryingly high, indicating the need of immunosuppressants in addition to systemic corticosteroids.

Given the concomitant presence of refractory ITP, the choice of rituximab over cyclophosphamide was made. Rituximab associated to corticoids as second line treatment or as induction therapy in ITP is reported efficacious [15]. Moreover, rituximab has shown efficacy in retrospective studies among patients with EGPA refractory to standard therapy [16]. A controlled trial to evaluate rituximab as induction treatment in EGPA is currently ongoing [17].

EGPA is a rare disease with an estimated prevalence of 10.7 per 14 million adults [11]. In Switzerland, 6 million people have received at least one dose of mRNA vaccine [1] and so far 4 cases of EGPA after mRNA vaccination have been reported from the Swiss Agency for Therapeutic Products. EGPA, a Th2 pathway mediated disease, is anecdotally associated with vaccines and allergen-specific immunization procedures [18]. To the best of our knowledge, there is no study on Th2 response after immunization with SARS-CoV-2 vaccines. A mRNA-1273 vaccine phase I clinical trial has shown a predominant Th1 response after in vitro spike protein stimulation of T cells collected from vaccinated participants [19]. We can hypothesize that in our patient, with her atopic predisposition, asthma and possibly pre-existing immune dysregulation, repeated administration of the mRNA induced an excessive Th2 response, leading to EGPA.

We compiled other reports of new onset EGPA or relapses after prolonged EGPA remission secondary to immunization with mRNA vaccine in (Table 1).

All but one case occurred in patients with pre-existing asthma and or rhinosinusitis. Peak peripheral blood eosinophil values ranged from 0.88–13.4 G/l. Half of cases presented with ANCA. Most needed treatment with immunosuppressants.

In addition to ours, three other cases of EGPA after mRNA vaccine had been reported to Swissmedic by November 2022, all aged 60 or more. We do not have more details concerning these patients. While we ignore how many spontaneous EGPA cases occurred in the same period, the incidence of the four potentially vaccine-related EGPA cases in a population of 8 Mio people corresponds to the reported natural occurrence of the disease.

As with EGPA, other cases of IMID were reported to flare or to newly occur after immunization with mRNA vaccines [3]. As in our case, while the temporal relationship to the immunization is evident, it is impossible to prove a causal relationship between the vaccine and the IMID. Up to the present day, these cases remain fortunately rare and do not preclude to use mRNA vaccines SARS-CoV2, given the established benefits in protecting from severe Covid-19 [2].

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