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# Letter to the Editor (Case report)

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## Cutaneous vasculitis after severe acute respiratory syndrome coronavirus 2 vaccine

**Key message**

- We describe, for the first time, a cutaneous vasculitis after Comirnaty (mRNA BNT162b2 severe acute respiratory syndrome coronavirus 2 vaccine).

Dear Editor, We present the case of a young woman who developed cutaneous vasculitis after the second inoculation with Comirnaty [mRNA BNT162b2 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine]. Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged ≥16 years. It contains mRNA with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID, the so-called spike protein. This is a surface protein of the SARS-CoV-2 virus, which the virus needs to enter the cells of the body.If, later on, people come into contact with SARS-CoV-2 virus, their immune system will recognize it and be ready to defend the body against it. The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination. Comirnaty is given as two injections, usually into the muscle of the upper arm, 3 weeks apart.

The most common side effects of Comirnaty described in trials were usually mild or moderate and got better within a few days after vaccination. These included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills and fever. They affected >1 in 10 people.

Redness at the injection site and nausea occurred in <1 in 10 people. Itching at the injection site, pain in the limb, enlarged lymph nodes, difficulty sleeping and feeling unwell were uncommon side effects (affecting <1 in 100 people). Weakness in muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely, in <1 in 1000 people.

Allergic reactions have occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis), which have occurred when Comirnaty has been used in vaccination campaigns. As for all vaccines, Comirnaty should be given under close supervision, with appropriate medical treatment available.

The Sars-Cov 2 vaccination campaign began a few months ago and, therefore, we expect more evidence in the literature of its adverse effects in a few months, but the described case is the first case of purpuric cutaneous lesions that developed after this vaccine. Few data have been reported in the literature describing cutaneous adverse events after Comirnaty, such as a morbilliform rash, Sweet syndrome and two cases of unspecific rash [1–3]. Purpuric lesions have not been reported previously as an adverse effect in the literature or in the Pfizer-BioNTech briefing document.

A previously healthy, 22-year-old, non-atopic woman taking no regular drugs received her first dose of mRNA BNT162b2 vaccine (0.3 ml into the muscle of her left upper arm), with secondary itching at the injection site, pain in the limb and fatigue that appeared after 12 h and regressed completely after 48 h. Three weeks later, she received the second dose of mRNA BNT162b2, initially with the same side effects as after the first dose.

After 7 days, she developed small, red, raised, itchy lesions on her legs. She described no abdominal pain, arthralgia and microscopic haematuria. On examination, she had purpuric lesions extending over both lower limbs, from the distal third of the thigh to the ankle (Fig. 1A). She underwent a dermatological examination that confirmed purpuric lesions. Before starting the recommended CS therapy, she underwent serum and urinary examinations. Investigations showed no alterations (CRP <5 mg/l and ESR 25 mm/h). Full autoantibody screen was negative; complement (C3 and C4) and serum immunoglobulins were normal. At first, she received only antihistamine therapy, with improvement of the itching, but not of the cutaneous manifestations. The cutaneous vasculitis improved only with oral prednisone. The CS therapy was initiated 8 days after the appearance of lesions at a dosage of 25 mg/day, with amelioration of the skin manifestation after 2 days (Fig. 1B), healing after 3 weeks and no recurrence after 3 months. Ten days after the second dose, she underwent serological tests for the detection of IgG antibodies against SARS-CoV-2 virus: 21.513 a.u./ml (negative is <1.4), in particular against spike protein, 600 a.u./ml (negative <1).

Correlations between vaccination and subsequent appearance of several types of vasculitis have been described in the literature [4, 5]. In temporal association with the administration of various vaccines different forms of vasculitis have been observed and reported, in particular after BCG and vaccines against HPV, influenza and hepatitis [6–9]. We describe, for the first time, a cutaneous vasculitis after Comirnaty.

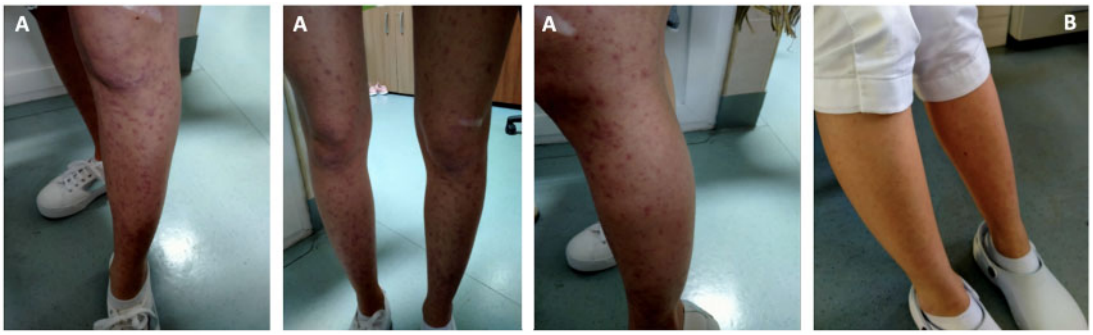
The link between vasculitis and vaccination was possible, and the probable pathogenetic mechanism might involve immune complex deposition in the blood vessel walls. Such a link was suspected based on the timing of the vasculitis and the absence of evidence of other underlying risk factors, with a time to onset within 10 days from vaccination.

An important criterion guiding the assessment of causality of each single event is the temporal relationship between immunization and the side event, which for drug- and vaccine-induced vasculitis is considered to be in the range of 1–6 weeks. COVID-19 is a recent



LETTER

**Fig. 1 Cutaneous vasculitis after severe acute respiratory syndrome** coronavirus 2 **vaccine**




(**A**) Cutaneous lesions 7 days after the second vaccine dose. (**B**) Skin manifestations after 2 days of CS therapy.

pandemic problem, and its vaccine has recently come into use; therefore, the whole population of the world has not yet been vaccinated [9]. Further information is expected over time.

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*Ethical approval:* All procedures performed in studies involving human participants were in accordance with the ethical standards of Institutional and/or National research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent was obtained for publication of this case report.

## Data availability statement

Data are available upon reasonable request by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). All data relevant to the study are included in the article.

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