

COVID-19 Vaccine Allergy (Drug Allergy and Idiosyncratic Reactions)

Associated Drugs

COVID-19 Vaccine (Adenovirus Vector); COVID-19 Vaccine (mRNA)

Range of Reaction

Allergic reactions, including immediate reactions with features of anaphylaxis, have been reported after administration of COVID-19 vaccines (CDC 2021a; CDC 2021b; Greenhawt 2021). Most reported reactions have occurred with the mRNA vaccines; the incidence is rare, but reported reactions are higher than with the viral vector Janssen COVID-19 Vaccine (Shimabukuro 2021). Proposed mechanisms of anaphylaxis include an IgE-mediated mechanism, a complement activation-related pseudoallergy (CARPA) (Klimek 2021), and a non-IgE-mediated immune responses to polyethylene glycol (PEG) (Warren 2021).

COVID-19 Vaccine (Adenovirus Vector):

Severe allergic reactions, including anaphylaxis, have been reported in clinical trials after administration of the Janssen COVID-19 Vaccine. A widespread cutaneous reaction presenting with diffuse, erythematous, and pruritic plaques, along with fever, is reported in one patient after vaccine administration (Sowell 2021). The differential diagnosis in a separate case of cutaneous hypersensitivity included acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), and AGEP-DRESS overlap (Lospinoso 2021). Angioedema of the lips and urticaria was also reported in one patient (FDA 2021).

The Janssen COVID-19 Vaccine contains polysorbate, which has rarely been implicated as an allergen in anaphylactic reactions to polysorbate-containing agents (FDA 2021). The product labeling contraindicates use in patients with known allergy to any component of the formulation (eg, polysorbate).

Local reactions at the injection site, including pain, erythema, and swelling, may occur. Local reactions are generally mild to moderate and resolve in 1 to 2 days (FDA 2021). Delayed reactions at the vaccine site, termed “COVID arm”, have also occurred. Symptoms include a warm, pruritic, swollen area at the injection site that occurs ~1 week after vaccination (Lindgren 2021).

Thrombosis with new onset thrombocytopenia syndrome (also referred to as vaccine-induced thrombotic thrombocytopenia [VITT]), which may be immune-mediated, has also been reported rarely with the adenoviral vector-based vaccines (Greinacher 2021). Thrombosis has been the primary feature in most initial cases (Greinacher 2021; Schultz 2021; Scully 2021). Patients must meet all five of the following criteria to have a definitive diagnosis of VITT: COVID vaccine 4 to 42 days prior to onset of symptoms, any venous or arterial thrombosis, platelet count $<150 \times 10^9/L$, positive PF4 heparin-induced thrombocytopenia ELISA, and d-dimer elevated >4 times ULN (ASH 2021). In a case series of 220 individuals with features of vaccine-induced immune VITT, thrombosis was present in most cases. Common sites of thrombosis included the cerebral veins, deep leg veins, pulmonary arteries, and splanchnic vessels, with most patients presenting with thrombosis at multiple sites (Pavord 2021).

Incidence of VITT is not known but seems to be extremely rare based on reports of a small number of cases among tens of millions of vaccinations (Greinacher 2021; Scully 2021).

COVID-19 Vaccine (mRNA):

Severe reactions, including rare cases of anaphylaxis, have been reported with both the Pfizer-BioNTech (Comirnaty) and Moderna COVID-19 Vaccines (mRNA). Many cases initially thought to be anaphylaxis to the mRNA Vaccine were misdiagnosed and patients were able to successfully receive a second dose of the vaccine (Gold 2020; Krantz 2021). In a review of cases reported, the clinical course was similar with both mRNA vaccines. Symptoms included urticaria, diffuse rash, angioedema, respiratory symptoms, airway obstruction symptoms, and nausea. Of the cases of anaphylaxis reviewed, 32% of the patients had a prior episode of anaphylaxis to a different agent (Shimabukuro 2021). A case of biphasic anaphylaxis after the first dose of the Pfizer-BioNTech Vaccine was also reported (Pitlick 2021).

PEG, an ingredient in both mRNA COVID-19 Vaccines, has been a rare cause of immediate hypersensitivity to other agents; however, these agents contained greater amounts of PEG than the COVID-19 vaccines. In two studies of individuals with a history of allergy to PEG-asparaginase, all were able to tolerate the vaccine without event (Koo 2022; Mark 2021). The product labeling contraindicates use in patients with known allergy to any component of the formulation (eg, PEG).

Local reactions at the injection site, including pain, erythema, and swelling, may also occur. In a study of the Pfizer-BioNTech Vaccine, pain at the injection site was the most frequently reported local reaction. Most local reactions were mild to moderate and resolved within 1 to 2 days (Polack 2020). In patients with dermal fillers, temporary swelling at or near the site of filler injection has been infrequently reported after COVID-19 (mRNA) vaccination. Persons who develop swelling at or near the site of dermal filler should contact their health care provider for evaluation and possible medical treatment (Banerji 2021; CDC 2021c).

Delayed localized hypersensitivity reactions have also been reported with the mRNA vaccines. In a retrospective case-series study of patients with delayed injection-site reactions after receiving the Moderna COVID-19 Vaccine, pain, tenderness, induration, and erythema developed at the injection site (Johnston 2021). In a review of 12 patients with reactions to the Moderna COVID-19 Vaccine, reactions had a varied appearance with characteristics, including annular plaques, edematous plaques, induration, localized rash, papules on the palm and fingers, and elbow plaques (Blumenthal 2021). A delayed reaction in response to a third dose of the Moderna COVID-19 Vaccine is described (Guénin 2021). A delayed urticarial eruption (>4 hours after vaccination) has also been described (Pitlick 2022).

Other reported reactions to the Pfizer-BioNTech COVID-19 Vaccine include vaccine-induced pneumonitis (Matsuzaki 2022), Sweet syndrome (Darrigade 2021), generalized cutaneous hypersensitivity with liver dysfunction (Wong 2021), Stevens-Johnson syndrome (Elboraey 2021), and morbilliform rash (Jedlowski 2021). AGEP has been reported following Moderna COVID-19 Vaccine (Mitri 2021).

Timing

In patients with possible anaphylaxis, symptoms developed in the first 30 minutes (Banerji 2021; CDC 2021b).

COVID-19 Vaccine (Adenovirus Vector):

In a patient with hypersensitivity to the Janssen COVID-19 Vaccine, urticaria developed on day 2 and angioedema developed on day 4 (FDA 2021). In two other separate cases, a cutaneous reaction developed 3 days after vaccine administration (Lospinoso 2021; Sowell 2021).

In a case series of 220 patients, vaccine-induced thrombotic thrombocytopenia occurred 5 to 48 days following vaccination, with a median of 14 days (Pavord 2021).

COVID-19 Vaccine (mRNA):

In a review of reports of anaphylaxis after receipt of mRNA COVID-19 Vaccines, the median onset of reactions was 10 minutes (Shimabukuro 2021). In a review of patients with delayed-onset injection site reactions with the Moderna COVID-19 Vaccine (mRNA), onset was 4 to 11 days following the first dose (Blumenthal 2021). In a separate review, symptoms developed 2 to 12 days following the first dose, lasting a median of 5 days (Johnston 2021).

A patient with a fixed drug eruption to the Pfizer-BioNTech COVID-19 Vaccine developed symptoms 15 days after the vaccine (Mintoff 2021). A patient with vaccine-induced pneumonitis following the Pfizer-BioNTech COVID-19 Vaccine developed symptoms of cough and shortness of breath 3 days after the first dose of the vaccine (Matsuzaki 2022). Sweet syndrome developed 5 days after receiving the Pfizer-BioNTech COVID-19 Vaccine (Darrigade 2021). A macular morbilliform eruption developed in a patient 48 hours following the first and second dose of the Pfizer-BioNTech COVID-19 Vaccine (Jedlowski 2021).

Cross-Reactivity

Evidence of cross-reactivity to this agent and other compounds with similar structures is lacking. Lack of documentation should not be interpreted as a lack of cross-reactivity. If an agent with similar structure is prescribed in a patient with a documented allergy to this drug, the possibility of cross-reactivity should be considered.

Cross-reactivity between mRNA COVID-19 Vaccines and the Janssen COVID-19 Vaccine may occur due to ingredients in the vaccines. The mRNA vaccines contain polyethylene glycol (PEG) and the Janssen COVID-19 Vaccine contains polysorbate. Polysorbate and PEG are structurally related; therefore, cross-sensitivity may occur (CDC 2021c). However, lack of cross-sensitivity was observed in 10 patients with confirmed PEG allergy who received the Janssen COVID-19 Vaccine (Bruusgaard-Mouritsen 2022).

Assessment

In patients reporting an allergy to this medication, a detailed history should be obtained to evaluate the nature of the allergic reaction. In some cases, patient reports of "allergy" represent intolerance, rather than an immunologic reaction. Severe allergic reactions or anaphylaxis to a prior dose of the COVID-19 vaccine are a contraindication to vaccination. Patients with severe reactions should be evaluated by an allergist before administration of additional doses.

In patients with a moderate to severe reaction, skin testing may be performed with residual vaccine if available. Nonirritating concentrations for many other vaccines include prick testing with the undiluted vaccine solution and intradermal testing with the vaccine solution diluted 1:100 (Wood 2007). An undiluted solution of the Pfizer-BioNTech COVID-19 Vaccine was reported as a nonirritant concentration for prick and intradermal skin testing (Marcelino 2021). Polyethylene glycol skin testing has demonstrated limited value (Wolfson 2021)

A skin biopsy from a patient with a delayed large local reaction supported a diagnosis of delayed-type or T-cell-mediated hypersensitivity (Blumenthal 2021). Intradermal testing showed a delayed positive reaction in a patient with vaccine-induced pneumonitis to the Pfizer-BioNTech COVID-19 Vaccine (Matsuzaki 2022).

Laboratory testing for patients with suspected vaccine-induced immune thrombotic thrombocytopenia includes complete blood count with platelet count, prothrombin time, activated partial thromboplastin time, fibrinogen, D-dimer, and imaging to diagnose thrombosis. Additional testing may be necessary (Furie 2021; Nazy 2021).

Reported Allergy: Patient Management Considerations

In general, when a previous severe reaction has occurred, repeated exposure to this agent and related compounds should be avoided. An individualized risk:benefit assessment must be performed in situations in which mild reactions were noted or when no suitable alternative therapy exists. A history of allergy to other allergens may increase the risk of an allergic reaction (Desai 2021). A history of severe reactions to other substances is not a contraindication to vaccination; however, patients should be observed for 30 minutes after receiving the injection (CDC 2021a; CDC 2021b; Shimabukuro 2021). Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during all vaccine administrations (Kroger 2021; Shimabukuro 2021).

Most patients with a mild reaction (eg, mild urticaria, flushing, minimal and spontaneously resolving throat or chest symptoms) to the first-dose mRNA COVID-19 vaccine can safely receive a second dose. Pretreatment with antihistamines, such as fexofenadine and cetirizine, may be given 1 to 2 hours before the next vaccination in patients with mild symptoms. Monitor patients for 30 minutes following vaccine administration (Banerji 2021; Wolfson 2021).

Patients with moderate to severe reactions (eg, tongue or laryngeal swelling, wheezing, hypotension, vomiting, diffuse urticaria) should be evaluated by an allergist. A second dose of an mRNA COVID-19 vaccine should not be administered. Substituting a non-mRNA COVID-19 vaccine for the second dose should be considered (CDC 2021c; Turner 2021). In one case report, a second dose of the Moderna COVID-19 Vaccine was safely administered via a graded dosing protocol in a patient with an immediate hypersensitivity reaction to the first dose (Mustafa 2021). A two-step graded protocol was tolerated in patients with a low suspicion of anaphylaxis to the first dose of the Pfizer-BioNTech Vaccine (Patel 2021). A case report of 15 patients shows the safety of a graded dosing of the second dose of the Moderna or Pfizer-BioNTech Vaccine in patients with immediate hypersensitivity reactions to the first dose (Tuong 2021).

Patients with a local delayed-onset reaction at the injection site may receive the same vaccine product for subsequent doses (CDC 2021c). Delayed-onset local reactions that occur with the first dose are not a contraindication or precaution to the second dose; the same vaccine may be administered but preferably in the opposite arm (Blumenthal 2021).

Management for patients with vaccine-induced immune thrombotic thrombocytopenia includes anticoagulation with a non-heparin anticoagulant, intravenous immune globulin, and plasma exchange (Furie 2021; MacNeil 2021; Warkentin 2021).

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