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Acute urticarial rash after COVID-19 vaccination containing Polysorbate 80

We present the case of a 48-year-old Caucasian woman, who developed an acute urticarial rash after the second dose of coronavirus disease 2019 (COVID-19) vaccination with Oxford-AstraZeneca. Though the most common cutaneous adverse reactions to vaccines are non-allergic, we believe the rash may represent an immediate hypersensitivity type I reaction against the vaccine excipient Polysorbate 80 (Pol80), configuring an acute allergic urticaria. Skin prick test with Pol80, were performed and resulted positive, confirming the role of Pol80 in eliciting immediate hypersensitivity in our patient. Of note, sensitizing excipients contained in COVID-19 vaccines are commonly used in everyday products and preexisting sensitizations may cause allergic reactions to vaccines, highlighting the need to undergo allergy consultation upon vaccine administration.

Keywords: COVID-19, COVID-19 vaccines, Vaccine reaction, Allergic urticaria, Urticaria

Introduction

Vaccines against coronavirus disease 2019 (COVID-19) are administered worldwide to control the pandemics we are currently dealing with, but as the number of people receiving vaccination rises, we are inevitably faced with increasing adverse drug reactions [1]. The most common cutaneous adverse reactions to vaccines are non-allergic, as flu like-symptoms and injection site reactions [2,3], whereas immediate hypersensitivity (Coombs and Gell type I) reactions, probably directed against sensitizing excipients of vaccines, are fortunately rare [1,4].

Case Report

Case presentation

We present the case of a 48-year-old Caucasian woman, who developed an acute urticarial rash after COVID-19 vaccination, possibly due to Polysorbate 80 (Pol80) sensitization.

On May 2021 the woman accessed the emergency room showing small, pruritic, oval urticarial wheals on the trunk, rapidly migrating, with a white center and red erythematous flare [1-4], occurred 3 hours after the second dose of Oxford-AstraZeneca vaccination (AstraZeneca, Cambridge, UK) (Fig. 1).

Anaphylaxis was excluded as circulatory, airway, breathing and gastrointestinal symp-



Fig. 1. Small pruritic wheals with pale center and erythematous rim appearing suddenly on the patient's right arm, shoulder, and chest. Written informed consent for publication of this image was obtained from the patient.

toms were absent. Laboratory tests were performed to analyze the inflammatory, chemical, and physical parameters: values were within normal range, except for a total immunoglobulin E value of 234 KU/L (normal range, 0–100 KU/L). Prednisone 25 mg/die was administered for 3 days, then tapered till complete resolution.

When interviewed about her medical history, the patient reported a previous pruritic, maculopapular, eruption, occurred 96 hours after the first vaccine dose, less generalized and spontaneously resolving. The patient had not given any importance to this limited episode, also overlooking to report it before the second Oxford-AstraZeneca dose. When asked for any allergies, she only referred having been diagnosed 10 years earlier with a pickles sensitization, but when the vaccination was administered, the patient was neither informed about excipients contained in it, nor did she consider the pickles allergy relevant. We decided to perform a skin prick test

with Pol80, which resulted positive, confirming its role in eliciting immediate hypersensitivity in our patient [5].

Statement of ethics

The present research complies with the guidelines for human studies and includes evidence that the research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The patient gave written informed consent to publish the case (including publication of images). Written informed consent was obtained from the participant for publication of the details of their medical case and any accompanying images.

Discussion

We believe the presented urticarial rash may represent an immediate hypersensitivity type I reaction against the vaccine excipient Pol80, configuring an acute allergic urticaria.

Indeed, possibly sensitizing excipients are contained in COVID-19 vaccines: Oxford-AstraZeneca contains Pol80, Pfizer-BioNteCh contains polyethylene glycol-2000 (PEG), Moderna also tromethamine [1,4].

Noteworthy, these potentially immunogenic vaccine components are commonly used in everyday products as pickles, as in our case, and preexisting sensitizations to these excipients have been postulated to lead to first-dose reactions to vaccines [4]. PEG and its derivate Pol80 are indeed widely used in food, cosmetic and medical products, including biologics [6,7].

In general, there are no contraindications in administering COVID-19 vaccines in populations with allergic diseases, except for patients with a previous history of severe allergic reactions to the first dose of COVID-19 vaccine or with a proven hypersensitivity to a vaccine component, such as PEG or Pol80. This case shows the importance of a good allergy consultation upon vaccine administration and the need to inform the population about possible, allergic reactions, which may be mild, as in our case, but may be also life-threatening.

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