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CASE REPORT

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Anaphylaxis to the Pfizer/BioNTech COVID-19 Vaccine with Positive Polyethylene Glycol Skin-Prick Test in Brazil

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ABSTRACT

A 56-year-old male patient attended at the Medicine Allergy Section with a current history of itchy red spots on the body reported that a few hours after receiving the the Pfizer/BioNTech messenger RNA (mRNA) COVID-19 vaccine, started with red and pruritic lesions. On physical examination, the patient did not show any considerable alteration. Under dermatological examination diffuse red urticarial lesions were present in the thoracic region. A biopsy of the urticarial lesion for histological analysis and epicutaneous-prick test (SPT) with polyethylene glycol (PEG) 335, 600, 3350 and 6000 with reading after 15 minutes were performed. Urticaria biopsy showed eosinophilic and lymphocytic infiltrate and SPT was positive for PEG 6000 (wheal size 5mm). The patient was treated with an antihistamine and corticosteroid 30mg per day for 5 days. Upon returning, the lesions had disappeared. PEG allergy is not so common and it seems to occur to higher molecular weight PEGs or higher concentrations. However, since the use of this molecule as an excipient in mRNA vaccines have no precedent before COVID-19, not much information was available and anaphylaxis reactions to mRNA vaccine from Pfizer/BioNTech COVID-19 induced or supposedly induced by PEG have been reported.

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KEYWORDS

Anaphylaxis; COVID-19; mRNA vaccine; polyethylene glycol.

Introduction

Cases of anaphylaxis after vaccination with the Pfizer/BioNTech mRNA vaccine against COVID-19 have been reported since the beginning of its use [1] and, as the cause of this allergy has not yet been fully clarified, the excipients used were considered as potential allergens causing those reactions. Although excipients are inert ingredients, most of the time without pharmacological activity, the PEG molecule, as it was one of the excipients used initially in mRNA vaccines, was considered as a candidate allergen [2] and even confirmed as the cause of these reactions in some cases [3].

We report here the case of a patient who developed anaphylaxis after receiving the mRNA vaccine from Pfizer/BioNTech, in which a reaction to PEG 6000 was detected in the epicutaneous-prick test.

Case Report

A 56-year-old male patient attended at the Service of Clinical and Experimental Immunology and Allergy - Santa Casa da Misericórdia do Rio de Janeiro-Brazil-General Hospital with a current history of itchy red spots spread over the body reported that a few hours after receiving the Pfizer/BioNTech mRNA vaccine against COVID-19, started with red and pruritic lesions.

Although being a long-term hypertensive patient under use of amlodipine and losartan he did not have any reports of drug allergies in his medical history. On physical examination, the patient was without fever, with stained mucous membranes, acyanotic, and anicteric, with head and neck unchanged. Nasal mucosa was normal, as well as the oral cavity. Heart rate was normal with 70 beats per minute, and blood pressure of 120x80 mmHg, abdomen with painless flaccidity, bilateral and symmetrical pulses.

Upon dermatological examination diffuse red urticarial lesions that disappeared with the pressure of a glass slide were present in the forearms, thorax and back (Figure 1). Biopsy of a lesion with punch 4 for histological analysis and epicutaneous-prick test with PEG 335, 600, 3350 and 6000 with reading after 15 minutes were performed. As a result the following readings were obtained for PEG 335: (1mm, negative), PEG 600: (1mm, negative), PEG 3350 (3mm), considered negative and PEG 6000: (wheal size 5mm) positive. The negative control: phenolic saline solution was (negative) and the positive control: histamine 1mg/mL was positive, (9mm) (Figure 2). Histopathological examination of the skin biopsy showed reticular dermis with separation of collagen bundles and scant perivascular and interstitial inflammatory infiltration consisting of lymphocytes, neutrophils and eosinophils characterizing urticaria.

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The patient was treated with an antihistamine and corticosteroid 30mg per day for 5 days. Upon returning, the lesions had disappeared.

Once the allergic reaction to PEG was confirmed through the epicutaneous-prick test, despite the patient never having reported any allergy to drugs or any products containing PEG, as a prophylactic measure, the patient was provided with a report suggesting the use of another vaccine (not mRNA) for the second dose and care when using products containing PEG or its polysorbate structural analogue.

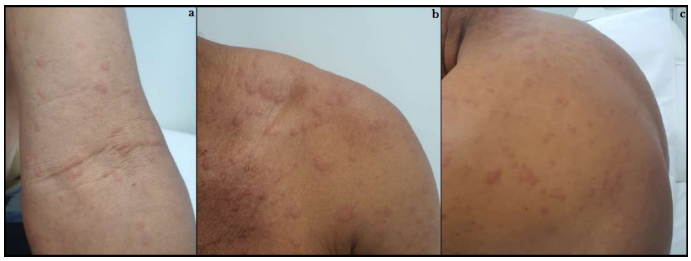

Figure 1: Urticarial lesions spread across the: (a) forearm; (b) chest, (c) back.

Figure 2: Skin Prick Test to PEG showing a positive reaction (5mm wheal size) to PEG 6000.

Discussion

The increasing reports of anaphylaxis after vaccination with mRNA vaccines against COVID-19 have been the subject of investigation with divergent opinions about the appropriate management of the second dose. Although the consensus for such cases is that those who have had a severe reaction to the first dose of COVID-19 vaccine should not get the second dose from the same manufacturer, reports based on meta-analyses involving more than 1,000 subjects state that these patients may receive the second dose under the supervision of an allergist [4]. As allergic reactions to vaccines can be caused by some component of the vaccine itself or by excipients contained in it, we understand that investigation of the cause the reaction must be conducted mainly directed to those excipients [5]. Considering that the allergenic potential of PEG (macrogol) has been increasingly reported for several compounds and that it is one of the main excipients of the Pfizer/BioNTech mRNA vaccine, it become the main molecule related to immediate anaphylaxis to the vaccine, and determination of such allergy is fundamental to the determination of the risk of undergoing a second dose of the same vaccine, although opinions and behaviors are still divergent.

In the case reported here, the importance of SPT for PEG was evidenced and should be indicated when a patient vaccinated with the mRNA vaccine has an immediate allergy reaction. If the test result is positive, the patient should be instructed to consider this information in their medical history in order to guide possible future drug interventions, as well as to avoid any cosmetic, industrial or food products [6] containing PEG or even, vaccination containing PEG or Polysorbate. It is important however that the performance of SPT for PEG should always be assisted by an allergist or trained medical professionals to promptly diagnose and treat any immediate substance-induced reaction during the test.

This is a typical case of IgE-mediated immediate hypersensitivity, which has been proven to be triggered by the PEG present in the Pfizer/BioNTech anti-COVID-19 vaccine.

To our knowledge, this is the first case report of allergy to (PEG), with a positive PEG skin test in Brazil, causing anaphylaxis to the Pfizer/BioNTech COVID-19 vaccine.

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