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Case Report
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Anaphylaxis to COVID-19 mRNA Vaccine in a Japanese Woman: A Positive Case of Skin Prick Testing for Polyethylene Glycol

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Abstract

A 32-year-old woman with atopic dermatitis was applied for the Pfizer-BioNTech COVID-19 vaccine in our hospital. She had a history of severe allergic reactions to cosmetics on her face. Five minutes after intramuscular injection of 0.3 ml vaccine, the patient complained of pharyngeal discomfort and respiratory symptoms (continuous coughing, wheezing, and dyspnea). We diagnosed her with anaphylaxis. She was tested skin prick tests to detect whether the allergic reactions are caused by polyethylene glycol, and showed positive. Our patient had atopic dermatitis, and we speculated that she was to be exposed percutaneously to PEG through cosmetics daily and sensitized.

Keywords: COVID-19; mRNA vaccines; Anaphylaxis; Polyethylene glycol; Skin prick test

Introduction

The vaccines against Coronavirus disease 2019 (COVID-19) including mRNA vaccines, which have a new mechanism of action, are an emerging world health concern [1]. In February 2021, the Pfizer/BioNTech COVID-19 vaccine (COMIRNATY®) was approved for COVID-19 prevention, and the vaccination of healthcare workers with the new coronavirus mRNA vaccine was started in Japan. This vaccine showed a 95% efficacy at preventing symptomatic COVID-19 infection [2]. Nevertheless, mRNA vaccines have been reported to cause allergic reactions including anaphylaxis [3], and the prevalence of anaphylaxis due to the Pfizer-BioNTech vaccine is approximately 1:200,000 in the United States [4]. While the accurate mechanism of allergy to this vaccine has not been identified, novel lipid nanoparticles containing Polyethylene Glycol (PEG) 2,000 have been suggested as the causative agent [3,4]. We herein report a case of anaphylaxis to the COVID-19 mRNA vaccine.

Case Presentation

A 32-year-old woman was applied for the Pfizer-BioNTech COVID-19 vaccine in our hospital in March 2021. She was a nurse with atopic dermatitis and with a history of anaphylaxis due to allergy to crabs and cats and an immediate hypersensitivity reaction to pesticides. She had a history of severe allergic reactions to cosmetics on her face. Five minutes after intramuscular injection of 0.3 ml vaccine, the patient complained of pharyngeal discomfort and respiratory symptoms (continuous coughing, wheezing, and dyspnea). We diagnosed her with anaphylaxis (Brighton level 2) [5]. To detect a causative agent, we administered Skin Prick Tests (SPTs). Referred to the report of Banerji et al. [3], we used PEG 4000 (Movicol®) at three concentrations (2.19, 21.9, and 219 mg/ml) to diagnose allergy to PEG. We used PEG 4000 instead of PEG 3350 (Miralax®) because we could not get PEG 3350 in Japan. We also used the pneumococcus vaccine (Prevnar 13®) in a 10x dilution (0.02 mg/ml) of polysorbate 80, an allergenic substance contained in various vaccines [3]. Subsequently, we performed SPTs for these dilutions. In addition, histamine hydrochloride (10 mg/ml) and normal saline were used as positive and negative controls, respectively [6]. This study was approved by the ethics committee of Kizawa Memorial Hospital (2021-018). The SPT for PEG 4000 showed a 5 mm × 4 mm erythema and a 2 mm × 1 mm wheal for the 2.19 ml/ml solution, a 7 mm × 5 mm erythema and a 3 mm × 3 mm wheal in the 21.9 mg/ml solution, and a 10 mm × 9 mm erythema and a 5 mm × 5 mm wheal for the 219 mg/ml solution, in a dose-dependent manner (Figure 1). Histamine dihydrochloride solution showed a 25 mm × 23 mm erythema and a 7 mm × 6 mm wheal, while normal saline showed a 5 mm × 3 mm erythema and a 1 mm × 1 mm wheal. The

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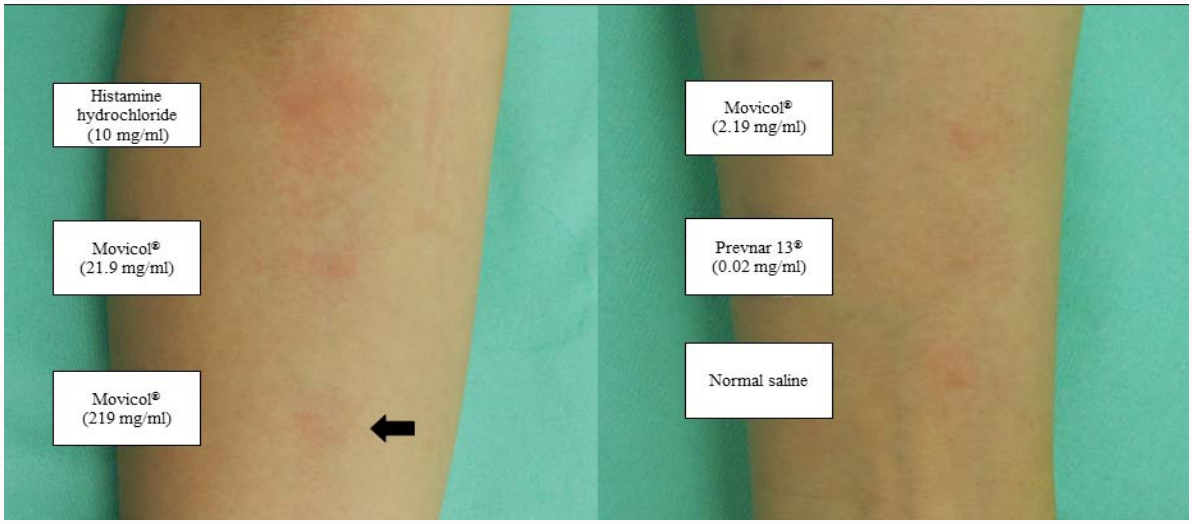

Figure 1: Results of skin prick tests. Positive reaction to Movicol® 219 mg/ml (black arrow).

SPT for response to 219 mg/ml of PEG4000 was positive, revealing the sensitization of the patient to PEG. The SPT for Prevnar 13® was negative, which suggests that there was no allergy to polysorbate. She denied other tests such as challenge tests to administer PEG. Thus, we finally diagnosed anaphylaxis to PEG.

Discussion

In our case, sensitization to PEG was demonstrated in a patient who developed anaphylaxis with an initial vaccination of the Pfizer-BioNTech COVID-19 vaccine, and PEG was considered as the causative substance. In previous reports, 90% of patients who developed anaphylaxis associated with the initial vaccination were also women [6]. Although the mechanism of allergy to the Pfizer-BioNTech COVID-19 vaccine has not been clarified thus far, PEG is a likely causative agent [3,4]. PEG is generally recognized as a safe substance, and it is used in various applications in a wide range of products [7]. However, various case reports of immediate-type allergy to PEGs have been reported recently. Although the mechanisms underlying PEG allergy are not well understood, percutaneous sensitization likely plays a role in some cases [8,9]. In our case, due to the patient's immediate hypersensitivity reaction to cosmetics, history of atopic dermatitis, and fragile skin barrier, percutaneous sensitization to PEG *via* cosmetics was speculated. In addition, cross-sensitization between macrogols with various molecular weights has been reported [10]. Our patient had atopic dermatitis, and we speculated that she was to be exposed percutaneously to PEG through cosmetics daily and sensitized. Further investigations are required to fully elucidate the pathogenesis.

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