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ALLERGIC REACTIONS WITH SKIN PRICK TEST AND INTRADERMAL TEST FROM THE ANTI COVID 19 VACCINES AT PATIENTS WITH HIGH RISK FOR HYPERSENSITIVITY – OUR EXPERIENCE

Leonora Svarça[1], Sonja Bojadzieva[2] , Premtim Rashiti[3], Albiona Rashiti- Bytyçi[4,5]
[1]Department of Allergology and Clinical Immunology,
University Clinical Center of Kosovo, Prishtina, Kosovo
[2]Department of Gastroenterohepatology, University Pediatric Clinic, Faculty of Medicine,
Ss. Cyril and Methodius University in Skopje, North Macedonia.
[3]Faculty of Medicine, Institute of Anatomy, University of Prishtina, Prishtina, Kosovo
[4]National Institute of Public Health, Prishtina, Kosovo
[5] Alma Mater Europaea Campus College Rezonanca

Abstract

Introduction: Vaccines are recognized as one of the most effective public health interventions. Routine immunization has resulted in large reductions in vaccine-preventable disease and death. Vaccine-related hypersensitivity reactions are not uncommon. The concern about the occurrence of hypersensitivity reactions to the vaccine itself or to any component of the vaccine is one of the key obstacles to vaccination. Although this is an uncommon occurrence, it is necessary to establish a reliable approach in order to identify people who are at risk of such suffering. The rapid development and launch of several new COVID-19 vaccines (mRNA and adenovirus vector) is a new experience of modern science. Patients who are considered to be at high risk for allergy and/or have had a previous allergic reaction to the COVID-19 vaccine are usually referred to an allergist for vaccine allergy testing.

Aim: The aim of this study was to present the allergic reactions with Skin Prick Test and Intradermal Test from the anti Covid 19 vaccines (mRNA and adeno viral vector) at patients with a history of allergy to the first COVID-19 vaccine dose as well as patients with high risk of allergic reaction.

Material and methods**:** The research was a retrospective cross-sectional study that was conducted between December 2020 and February 2023 at the Clinic for Allergology and Clinical Immunology at the University Clinical Center in Kosovo,. The research included all patients aged ≥ 18 years who underwent a test for allergy to the vaccine against COVID-19, namely mRNA (BNT162b2, Pfizer) and/or adeno virus vector (AZD1222, AstraZeneca).

Testing for allergy to the vaccine against COVID-19 was done by trained allergists, by applying IDT (intradermal test) or SPT (skin prick test). The study included all patients with an indication for testing for allergy to the Covid-19 vaccine due to a history of hypersensitivity to the first dose of the COVID-19 vaccine and/or due to a high risk of allergic reaction, including a history of atopic allergy or anaphylaxis.

Results**:** SPT and IDT testing for allergic reactions from the mRNA vaccine (BNT162b2, Pfizer) indicated a positive finding in 4 (2.58%) of the patients. All positive findings were obtained from IDT testing. In 1 (0.64%) of the patients there was an IDT (1/100), and in 3 (3.80%) there were IDT (1/10) erythema and papules positive findings.

Testing with SPT and IDT for allergic reactions from the vaccine AZD1222, Astra Zeneca indicated that there was a positive finding in 3 (3.80%) of the patients. All positive findings were obtained from IDT testing. One (1.26%) of the patients had IDT (1/100), and 2 (2.53%) had both IDT (1/100) and IDT (1/10) erythema and papulle positive findings.

Conclusion: Our data support that cutaneous reactions to COVID-19 vaccination are generally minor and self-limited and should not discourage vaccination. Findings of the effect of SPT and IDT testing in the prediction of allergic reactions from the COVID-19 vaccines, as mRNA (BNT162b2, Pfizer) or adenovirus vector (AZD1222, AstraZeneca), are still very limited and further research are

needed. Health care workers must be aware of these potential vaccine reactions and advise patients accordingly.

***Keywords*:** COVID-19, vaccine, hypersensitivity; SPT, IDT, mRNA, adeno viral vector

Introduction

Vaccines are recognized as one of the most effective public health interventions. Routine immunization has resulted in large reductions in vaccine-preventable disease and death. Vaccine-related hypersensitivity reactions are not uncommon. Fortunately, most reported vaccine-related adverse reactions are not serious, and many are not immune-mediated or even do not recur upon re-exposure. Serious anaphylactic or skin adverse reactions occur but are extremely rare. [1-3]

Evaluation of immunization-related hypersensitivity, potentially immune-mediated, is important to help determine the mechanism or mechanisms of the reaction. If acute hypersensitivity is confirmed, this allows future exposure to the required vaccine through desensitization or in divided doses in order to reduce the risk. [2,4,5]

Research to find an effective vaccine to prevent the COVID-19 pandemic has resulted in the production of vaccines with different modes of action that are mainly categorized into three groups. These include: a) vaccines using the whole disease-causing virion, such as the Sinopharm and Covaxin vaccines; b) adenoviral vector vaccines, such as Astra Zeneca, Johnson & Johnson and Sputnik V COVID-19 vaccines; and c) messenger RNA (mRNA)-based vaccines, such as the Pfizer-BioNTech and Moderna vaccines that use a lipid nanoparticle (LNP) delivery system to prevent rapid enzymatic degradation of mRNA molecules. [3-5]

Since the introduction of active vaccination against SARS-CoV2 and the beginning of vaccination campaigns, there have been indications of the occurrence of anaphylactic reactions after the injection of the first dose of vaccine. Most cases of anaphylactic reactions to COVID-19 vaccines occurred less than 30 minutes after vaccination in people with a history of allergic reactions, including anaphylaxis. However, as is the case with any other drug, it is possible for anaphylactic reactions resulting from vaccination to occur in the absence of a history of allergic disease. [6, 7]

Regarding the epidemiology of these adverse events, reports indicate that the overall incidence of anaphylactic reactions due to vaccination against COVID-19, estimated at about 4.5/1.000.000, is higher than the expected rate of severe allergic reactions of 1/1.000.000. Another reported allergic reaction to COVID-19 mRNA vaccines is dermatological reactions, some of which mimic SARS-CoV2 infection itself, suggesting that skin eruptions may be the result of immune rather than viral activation. The incidence of these reactions is 0.22% in vaccinated individuals and represents 16.54% of all adverse effects of vaccination. [5,7,8]

The spectrum of dematological reactions includes manifestation at the injection site but also more extensive reactions. This includes frequent delayed major local reactions, localized redness and swelling, urticaria, and maculopapular rashes. Multiple studies indicate that delayed major local reactions and urticaria are the most common skin reactions following Moderna and Pfizer-BioNTech vaccination. [9,10,11]

The concern about the occurrence of hypersensitivity reactions to the vaccine itself or to any component of the vaccine is one of the key obstacles to vaccination. Although this is an uncommon occurrence, it is necessary to establish a reliable approach in order to identify people who are at risk of such suffering. [9,12,13] The rapid development and launch of several new COVID-19 vaccines (mRNA and adenovirus vector) is a new experience of modern science. Patients who are considered to be at high risk for allergy and/or have had a previous allergic reaction to the COVID-19 vaccine are usually referred to an allergist for vaccine allergy testing. [8,14-16]

Goal

The goal of this study was to present the allergic reactions with Skin Prick Test and Intradermal Test from the anti Covid 19 vaccines (mRNA and adeno viral vector) at patients with a

history of allergy to the first COVID-19 vaccine dose as well as patients with high risk of allergic reaction.

Material and methods

The research was a retrospective cross-sectional study that was conducted between December 2020 and February 2023 at the Clinic for Allergology and Clinical Immunology at the University Clinical Center in Kosovo. The research included all patients aged ≥ 18 years who, underwent a test for allergy to the vaccine against COVID-19, namely mRNA (BNT162b2, Pfizer) and/or adeno virus vector (AZD1222, AstraZeneca).

The Clinic for Allergology and Clinical Immunology at the University Clinical Center of Kosovo was a reference center for allergy testing of the COVID-19 vaccine. During the period of interest for this research, patients who were indicated for such testing from all over the country were referred to this Clinical Center. Testing for allergy to the vaccine against COVID-19 was done by trained allergists, by applying IDT (intradermal test) or SPT (skin prick test). According to the pre-set inclusion and exclusion criteria, the study included all patients with an indication for testing for allergy to the Covid-19 vaccine due to a history of hypersensitivity to the first dose of the COVID-19 vaccine and/or due to a high risk of allergic reaction, including a history of atopic allergy or anaphylaxis.

Data for each patient included: gender, age, place of residence, information on patient allergies (air, food, drug allergy, vaccines, vaccine ingredients), clinical manifestation data (local, systemic, anaphylaxis) and comorbidities (cardiovascular, diabetes etc.).

Statistical analysis

The data analysis was performed using SPSS software package, version 22.0 for Windows (IBM Corp, Armonk, NY, USA). Data were entered in the database by two persons independently to avoid errors. The categorical variables were analyzed with Pearson's X^2 test or Fisher's exact tests. A two-sided analysis with a significance level of $p<0.05$ was used to determine the statistical significance for all tests.

Results

Study group characteristics

The research included a total of 234 patients who, due to a history of allergy to the COVID-19 vaccine or a high risk for an allergic reaction, were sent for an allergy test for the COVID-19 vaccine namely for mRNA (BNT162b2, Pfizer) and/or adeno virus vector (AZD1222, AstraZeneca). Of the patients in the sample, 71 (30.34%) were male and 163 (69.66%) were female, with a gender ratio of 0.43:1. The proportion of women was significantly higher than men for Difference 39.32% [(30.6-47.1) CI 95%]; p=0.0001).

The patients had an average age of 43.06±15.57 years with 50% of them aged <45 years, ie 25% aged >54 years for Median IQR=45 (32-54). The average age of men was 40.83±17.04 years, and of women 44.02±14.85 years. Age of 50% of men was <38.5 years for Median IQR=38.5 (25-55) and for women <46.0 years for Median IQR=46 (33-54). The age of women was insignificantly higher compared to that of men (Mann-Whitney U Test: Z=-1.553; p=0.1204).

Allergological status

The history of previous allergies of the respondents from the sample indicated that the largest part of them 118 (50.43%) reported allergy to drugs. Allergy to previous vaccines, i.e. vaccine ingredients, was reported by 22 (9.40%) vs. 4 (1.71%) respondents respectively. Allergy of unknown

etiology was reported by a third, ie 72 (30.77%) of the respondents. A significant association of food allergy with female gender (p=0.0385), and a significant association of hymenoptera allergy with male gender (p=0.0008) was determined. Allergy to air (p=0.5953), drugs (p=0.5322), previous vaccine (p=0.0733), vaccine ingredients (p=0.0549) and unknown etiology (p=0.2360) did not associate significantly with the gender of the participates (Table 1) .

Most of the respondents in the study, 185 (79.06%) reported an allergy to only one allergen, and only 9 (3.84%) reported an allergy to three or more allergens. There was no significant association of the gender of the respondents with the number of allergens (p=0.3795) (Table 1).

Previous local allergic manifestations were the most common, with 84 (35.90%), followed by systemic allergic manifestations in 61 (26.07%). A previous anaphylactic allergic manifestation was reported by 27 (11.54%) of the respondents. There was no significant association of the gender of the study respondents with the type of previous allergic manifestation, for local (p=0.1835), systemic (p=0.1457) and anaphylactic (p=0.2114) (Table 1).

Table 1. Profile of patients with indication for allergy test for COVID-19 vaccine

Parameters	N (%)			p
	Male	Female	Total	
Previous allergies				
Air	9 (12,68%)	25 (15,34%)	34 (14,53%)	X^2=0,282; df=1; p=0,5953
Food	2 (2,82%)	18 (11,04%)	20 (8,55%)	[1]p=0,0385*
Medications	38 (53,52%)	89 (49,08%)	118 (50,43%)	X^2=0,390; df=1; p=0,5322
Hymenoptera	14 (19,72%)	9 (5,52%)	23 (9,83%)	X^2=11,247; df=1; p=0,0008*
Previous vaccines	3 (4,23%)	19 (11,66%)	22 (9,40%)	[1]p=0,0733
Ingredients of vaccine	1 (1,41%)	3 (1,84%)	4 (1,71%)	[1]p=0,0549
Undefinedo	18 (25,35%)	54 (33,13%)	72 (30,77%)	X^2=1,404; df=1; p=0,2360
Number of allergens				
One	59 (83,10%)	126 (77,30%)	185 (79,06%)	X^2=1,938; df=2; p=0,3795
Two	11 (15,49%)	29 (17,79%)	40 (17,09%)	
≥ three	1 (1,41%)	8 (4,91%)	9 (3,84%)	
Previous allergic manifestations				
Local	21 (29,58%)	63 (38,65%)	84 (35,90%)	X^2=1,769; df=1; p=0,1835
Systemic	23 (32,39%)	38 (23,315)	61 (26,07%)	X^2=2,116; df=1; p=0,1457
Anaphylaxis	11 (15,495)	16 (9,82%)	27 (11,54%)	X^2=1,561; df=1; p=0,2114
Pearson Chi-square test=X^2	[1]Fisher exact test		*significant for p<0,05	

Allergy test findings

Allergy tests for the COVID-19 vaccine were performed in 155 patients for mRNA (BNT162b2, Pfizer) and in 79 patients for adenovirus vector (AZD1222, Astra Zeneca). In 5 (2.14%) of the patients, allergy tests were performed on both vaccines.

Skin Prick Test (SPT) and Intradermal Test (IDT) testing for allergic reactions from the mRNA vaccine (BNT162b2, Pfizer) indicated a positive finding in 4 (2.58%) of the patients. All positive findings were obtained from IDT testing, that is, none of the tested patients had a positive reaction to SPT. In 1 (0.64%) of the patients there was an IDT (1/100) erythema and papulle positive finding, and in 3 (3.80%) there were IDT (1/10) erythema and papules positive findings. Three of the cases with a positive IDT reaction were in women. The mean age of patients with a positive IDT

finding was 52±11.34 with a min/max age of 46/69 years. Previous allergic manifestations in the patient with IDT (1/100) positive finding from the mRNA vaccine (BNT162b2, Pfizer) was anaphylaxis, and in those with positive IDT (1/10) finding it was consequently systemic, anaphylaxis and local (Table 2).

Table 2. Data on COVID-19 vaccine testing results

Parameters	**Data on COVID-19 vaccine testing**					
	SPT (1/1)		**IDT (1/100)**		**IDT (1/10)**	
	Eriteme	**Papulle**	**Eriteme**	**Papulle**	**Eriteme**	**Papulle**
mRNA (BNT162b2, Pfizer)						
Total cases - N (%)	4 (2,58%)					
Case 1	-	-	1 (0,64%)	1 (0,64%)	-	-
Medical history profile	**Case 1:** female, 46 years, previous allergies on medication, and undefined, and previous allergic manifestation local, and anaphylaxis. ITD (1/100) eriteme and papule positive.					
Cases 2-4	-	-	-	-	3 (1,93%)	3 (1,93%)
Medical history profile	**Case 2:** female, 46 years, previous allergies on food, medication, and undefined, and previous allergic manifestation local and systemic. ITD (1/10) eriteme and papule positive. **Case 3:** female, 47 years, previous allergies on food and medication, and previous allergic manifestation anaphylaxis. ITD (1/10) eriteme and papule positive. **Case 4:** male, 69 years, previous allergies on medication, and undefined, and previous allergic manifestation local. ITD (1/10) eriteme and papule positive.					
AZD1222, Astra Zeneca						
Total cases - N (%)	3 (3,80%)					
Case 1	-	-	-	-	1 (1,26%)	1 (1,26%)
Medical history profile	**Case 1:** female, 47 years, previous allergies on food, medication, and undefined, and previous allergic systemic. ITD (1/10) eriteme and papule positive.					
Cases 2-3	-	-	2 (2,53%)	2 (2,53%)	2 (2,53%)	2 (2,53%)
Medical history profile	**Case 2:** male, 24 years, previous allergies on medication, and previous allergic manifestation anaphylaxis. ITD (1/100) and ITD (1/10) eriteme and papule positive. **Case 3:** male, 45 years, previous allergies on air, and previous allergic manifestation local. ITD (1/100) and ITD (1/10) eriteme and papule positive.					
IDT - intradermal test; SPT - skin prick test						

Testing with Skin Prick Test (SPT) and Intradermal Test (IDT) for allergic reactions from the vaccine AZD1222, Astra Zeneca indicated that there was a positive finding in 3 (3.80%) of the patients. All positive findings were obtained from IDT testing, that is, none of the tested patients had a

positive reaction to SPT. One (1.26%) of the patients had IDT (1/100) erythema and papulle positive findings, and 2 (2.53%) had both IDT (1/100) and IDT (1/10) erythema and papulle positive findings. Two of the cases with a positive IDT reaction were in men.

The mean age of patients with a positive finding was 35.33±11.50 with a min/max age of 24/47 years. Previous allergic manifestations in the patient with only IDT (1/10) positive findings from the vaccine AZD1222 were systemic, and in those with positive findings of both IDT (1/100) and IDT (1/10) were anaphylaxis, i.e. local (Table 2).

Discussion

Multiple authors have assessed the utility of skin tests (skin prick test – SPT and intradermal test – IDT) in the evaluation of the possibility for an allergic reaction to COVID-19 vaccines in high-risk patients, as well as in patients that have had an allergic reaction to a previous COVID-19 vaccine dose. Different approaches have been explored. For instance, tests have been performed with recipients from the vaccines such as polyethylene glycol (PEG) and polysorbate, which have previously been known as allergy and anaphylaxis causing agents. In terms of predicting the outcomes of vaccination or revaccination, findings from literature suggest on the limited utility of PEG and polysorbate skin testing for people with suspected risk factors for COVID-19 vaccine reactions or people who have had a previous immediate reaction to COVID-19 vaccine. [14]

Authors have also evaluated the predictiveness of these tests using the vaccines themselves. Skin tests have been performed both in individuals with high risk for an allergic reaction to the COVID-19 vaccines and in individuals that have had a previous immediate allergic reaction to COVID-19 vaccines, when having received a previous dose.
The prevalence of allergies typically occurs in young and middle-aged adults and is more common in females than males. [15]

Having said that, data regarding the subject of interest has shown that analyzed patients have been generally with a female predominance. (15-18) In the evaluation of mRNA COVID-19 vaccines, positive skin tests have been associated with younger age. [18] The results in our study show that the mean age of patients with a positive IDT finding for the allergic reactions from the mRNA vaccine was 52±11.34 years with a min/max age of 46/69 years and female predominance, and from the AZD1222 vaccine was 35.33±11.50 years with a min/max age of 24/47 years and male predominance.

Studies assessing skin tests with mRNA vaccines (including the BNT162b2 vaccine) have shown results of limited utility for the skin prick test (SPT). Skin prick tests with both the BNT162b and AZD1222 vaccines have been non-reactive. [17]

Skin prick tests using mRNA (Pfizer) vaccine seem to be not very sensitive nor specific in prediction and confirmation of the hypersensitivity to its compounds. [19]

Results from our study were in line with these findings showing that none of the patients tested with SPT using either mRNA (Pfizer) or AZD1222 vaccines had a positive reaction. As a consequence, usability of performing these tests remains under discussion.

However, authors have found that IDR tests with mRNA vaccines have a high sensitivity. IDT, when done with the whole vaccines, is of higher utility for detection of IgE mediated allergies and anaphylaxis, and skin testing with IDT particularly, may improve the ability to estimate sensitization to these vaccines. [17] Such testing could help evaluate and identify IgE-dependent anaphylaxis. [18]

Allergic reactions are 4 times more likely to be reported by people with past allergies. However, it is important to note that a history of allergy and/or anaphylaxis are reliant on patient reporting, which may be biased. Therefore, the role of allergists in detecting the risk of these patients becomes crucial. Patients with a history of anaphylaxis may also experience increased anxiety before receiving any drugs. [15]

Several reports show that a minority of patients who suffered an immediate reaction to the COVID vaccines demonstrated sensitivity to vaccine ingredients. [17]
Still, significantly fewer individuals who have had an immediate allergic reaction following a 1st or

2nd dose of an mRNA COVID-19 vaccine had negative ST to vaccines (SPT and IDT), compared to individuals with prior history of anaphylaxis of an injectable drug and/or a documented allergy to PEG and/or polysorbate.[18]

Analysis of both male and female, young to middle aged adults, half of which had previous allergy history (mostly food such as shrimp, crab, as well as drug allergy-ibuprofen, media contrast, MMR vaccine) may suggest that the positive predictive value of AZD1222 vaccine skin testing is significant and useful in evaluating the risk of allergy to the vaccine prior to subsequent doses of vaccines. A role for skin testing with mRNA vaccines in patients with previous allergic reaction to AZD1222 vaccine may also be noted. [20]

To conclude, in the evaluation of the possibility for an allergic reaction from COVID-19 vaccines, sensitization via IDT, systemic reactions during skin testing regardless of sensitization and potentially the severity of the initial reaction may be of prognostic value.[17-19] History of anaphylaxis has been found to be associated with hypersensitivity reactions after a COVID-19 vaccine provocation test which was also conformed in our study. Some authors found that no association with past drug allergy has been observed, which was not in line with the finding from our study where most of the patients with positive ITD reactions had a history of allergy on medication. [15]

Conclusions

Our data support that cutaneous reactions to COVID-19 vaccination are generally minor and self-limited and generally should not discourage vaccination. Presence of a cutaneous reaction, when it appears after injection of the first dose of BNT162b2, Pfizer or AZD1222, Astra Zeneca, should be always carefully elaborated, even no patients with these findings experienced anaphylaxis or another severe adverse event. Findings of the effect of SPT and IDT testing in the prediction of allergic reactions from the COVID-19 vaccines, as mRNA (BNT162b2, Pfizer) or adenovirus vector (AZD1222, AstraZeneca), are still very limited and further research are needed. Health care workers must be aware of these reality and advise patients accordingly.

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