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The First Hundred Patients with Acute Reactions to the COVID-19 Pfizer-BNT Vaccine in Lebanon

Matar A[1], Raslan A[2], Mucharrafieh U[3], Sakr CJ[4], Mahfoud ZR[5] and **Bizri A[6]***

[1]*Department of Internal Medicine, American University of Beirut Medical Center, Beirut, Lebanon*
[2]*Department of Internal Medicine, division of Infectious Diseases, American University of Beirut Medical Center, Beirut, Lebanon*
[3]*School of Medicine, American university of Beirut, Beirut, Lebanon*
[4]*Department of Family Medicine, American University of Beirut Medical Center, Beirut, Lebanon*
[5]*Employee Health Unit, American University of Beirut, Beirut, Lebanon*
[6]*Department of Population Health Sciences, Weill Cornell Medicine, Qatar*

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***Corresponding author:**
Abdul Rahman Bizri
Department of Internal Medicine
American University of Beirut Medical Center
Aboukhater Building, 1107 2020 Riad El Solh
Lebanon
E-mail: ab00@aub.edu.lb

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Abstract

The COVID-19 Pfizer-BioNTech vaccine has been shown to cause rare side effects occurring in the few days after its administration. This retrospective descriptive study, aiming at looking at the immediate reactions occurring within 30 minutes of taking the vaccine, showed that non-allergic symptoms such as hypertensive peaks, syncope and panic attacks were more common than allergic reactions. This reflects the psychological susceptibility of a frail population, in which careful measures should be taken to increase the rates of vaccination.

Keywords: COVID-19, vaccine, Pfizer-BioNTech, reactions, adverse events.

Introduction

Corona virus 2 (SARS-CoV-2), a recent addition to the human corona viruses family, was the cause of a worldwide pandemic, as labeled by the World Health association (WHO) in March 2020[1]. A 2% fatality rate was reported with the Corona virus disease 2019 (COVID-19), and its long-term sequelae are still unknown, even in those who initially present with mild symptoms. On August 23, 2020, the Food and Drug Administration (FDA) approved the COVID-19 Pfizer-BioNTech (Pfizer-BNT), an mRNA-based vaccine requiring 2 shots administered 21 days apart and conferring 95% protection against COVID-19 in those older than 16 years of age[2].Since December 2019, when immunization with Pfizer-BNT vaccines started worldwide, numerous studies have been published on adverse events that occurred in the first few days after the administration of the first or second dose, ranging from mild to severe[3].To date, no studies have been conducted emphasizing the immediate reactions that occurred within 15 to 30 minutes of taking either dose of the vaccine. We aimed at focusing on the adverse events that occurred immediately after receiving the Pfizer-BNT vaccine at one of the largest immunization centers in Lebanon. The goal of this study was to recognize the most common acute reactions, in order to allow for better preparedness of vaccine administration sites.

Methods

Data

Vaccination campaigns using the Pfizer-BNT vaccine started in Lebanon on February 14, 2021, with around 160 centers accredited by the Lebanese Ministry of Public Health to administer the vaccine. The American University of Beirut Medical Center (AUBMC)

represents one of the largest immunization centers in the country (https://www.moph.gov.lb/maps/covid19.php). Upon receiving the first or second dose of the vaccine, individuals had to wait in an observation area, where they were monitored between 15 and 30 minutes for the emergence of any adverse event, defined as any complaint or reaction the patient had during this time[4]. The names of the first hundred who received the vaccine and had a reaction in the observation area were collected over a period of three months by vaccination taskforce personnel, along with demographic characteristics and details of the reaction. A deidentified list by those same taskforce personnel was created, excluding patients' identifiers, such as name, date of birth or medical record number. The deidentified data included the following variables: age, gender, first or second dose, type of reaction, outcome, and history of allergy and nature of prior allergies.

Statistical analysis

Statistical analysis was performed using IBM SPSS (version 28.0.0.0). Descriptive analysis was done and variables were summarized via frequency distributions or means and standard deviations.

Ethical approval

This study was approved by the Institutional Review Board at the American University of Beirut Medical Center (IRB ID: BIO-2021-0085).

Results

Of the first 100 patients with an immediate reaction following the administration of the Pfizer vaccine, 64% were women, mean age was 56±23 (median=66) years, and 53% were above the age of 60years. Three out of four patients had only one reaction, while 25% had at least 2 reactions. The reactions more commonly followed the first dose (81%). Out of the 100 patients, 35% had a history of allergy; most allergies were drug allergies (20 of 35). The most common previous allergic reaction was rash, while prior anaphylaxis only occurred in 3 of the 35 patients (Table 1). Most patients were discharged home, while 32% were sent to the ED. Out of the patients sent to the ED, 59% were women, with a mean age of 54±24 (median=59) years, and 18 out of 32 were older than 60 years of age. The big majority of adverse reactions followed the first dose (66%) and a minority had more than one reaction. Half the patients sent to the ED had a history of allergies (Table 1). Only two patients were admitted to the hospital, the first for resistant elevated blood pressure and the second for anaphylactic shock. Only the second patient had a history of anaphylaxis to tramadol.

Table 1. Nature of previous allergic reactions in those who had a history of allergy among the total population and those admitted to the ED

	Total population (n=35)	ED (n=15)
Rash	15 (43%)	7 (47%)
Angioedema	8 (23%)	4 (27%)
Anaphylaxis	3 (9%)	2 (13%)
Unknown	9 (26%)	2 (13%)

Out of the 100 patients, the most common events were elevated blood pressure (BP), defined as systolic BP above 160mmHg and diastolic BP above 100 mmHg (20%) and nonspecific dizziness (20%), followed by an itchy rash (18%) and syncope (14%). Most of those admitted to the Emergency Department (ED) had an itchy rash (37.5%), followed by hyperventilation (25%), high BP (21.9%), and palpitations (18.8%), alone or in combination (Table 2).Reactions were divided into true allergic reactions (20%) consisting of either an itchy rash, angioedema or anaphylaxis, and non-allergic reactions (80%), such as pain or tingling at the injection site, headache, syncope, high BP, palpitations, shortness of breath and non-specific dizziness (Table 3). Out of those who had an allergic reaction, 75% were women, 13 had taken the first dose and all 13 were sent to the ED. Half those patients had a history of allergy. Out of the patients who had non-allergic reactions, 61% were women, 70% had taken their first dose, a quarter (%) was admitted to ED and a quarter (%) had a history of allergy.

Table 2. Reactions and their frequency among the total population and those admitted to the ED

	Total population (n=100)	Patients admitted to ED (n=32)
Tingling/pain at injection site	5 (5%)	0 (0%)
Arm or leg tingling	11 (11%)	1 (3%)
Headache	10 (10%)	3 (9%)
Syncope	14 (14%)	4 (13%)
High BP	20 (20%)	7 (22%)
Nonspecific dizziness	20 (20%)	5 (16%)
Throat discomfort	3 (3%)	0 (0%)
Palpitations	11 (11%)	6 (19%)
Hyperventilation	9 (9%)	8 (25%)
Itching and rash	18 (18%)	12 (38%)
Subjective fever or chills	4 (4%)	3 (9%)
Metallic taste sensation	1 (1%)	0 (0%)

Table 3. Differences between allergic and non-allergic reactions

	Allergic reaction (n=20)	Non-allergic reaction (n=80)
Age >60	7 (35%)	46 (58%)
Women	15 (75%)	49 (61%)
First dose	13 (65%)	56 (70%)
History of allergy	10 (50%)	21 (26%)
ED	13 (65%)	19 (24%)

Discussion

Immediate adverse events, especially allergic reactions, were seen more commonly in women, a trend that has been reported in most studies on Pfizer-BNT side effects, with proportions ranging from 64.2% to 90%[5]. In fact, women have a higher predisposition to developing side effects from vaccines, possibly secondary to higher susceptibility to autoimmune disorders[6]. This might be caused by differences in endocrine and sex hormones that contribute to different immune responses between men and women[7].

The mean age of those who had an acute allergic reaction was 47.7yearswith 65% of people being below the age of 60years, similar to numbers reported from Saudi Arabia, Malta, Czech Republic and the United States[5]. Younger

patients tend to have more robust immune systems, inducing cytokine release and leading to inflammatory effects on different tissues, hence leading to more frequent reactions compared to the elderly[5]. Allergic reactions including itchy rash, angioedema and anaphylaxis followed the first dose in 65% of cases and the second dose in only 35% of cases. Although the FDA Fact Sheet for Recipients and Caregivers reported that the most common adverse events encountered in the first 3 days after administration of the vaccine, including pain at the injection site, headaches, muscle and joint pain, chills and elevated body temperature occur more common after the second dose compared to the first[8]. Our study showed that both allergic and non-allergic reactions occurred more commonly after the first dose than the second. This could be because first doses of the vaccine were administered more frequently than second doses, since this was still at the beginning of the vaccination campaign. It could also be explained by the fact that our study only investigated side effects occurring within 30 minutes of vaccine administration, and that adverse events can take place at any point in the few days following vaccine reception. Furthermore, patients who developed an allergic reaction with the first dose were not allowed to receive their second dose, in order to avoid anaphylaxis. This could have contributed to the lower numbers of allergies detected following the second dose, although a recent multicenter retrospective study at Massachusetts General Hospital supported the safety of Pfizer-BNT vaccine second dose administration in patients reporting immediate allergic reactions after the first dose[9]. Half of those who had a true allergic reaction had a previous history of allergy. It is well known that the frequency of allergic reaction to Pfizer-BNT vaccine is higher among patients with a history of allergies, particularly in those with a history of high-risk allergies. Despite that, it has been deemed safe to immunize those patients, especially under supervised medical care[10].

Most patients who required transfer to the emergency department, were mainly those with angioedema and the one patient with anaphylaxis. Most of the patients who had an itchy rash, local or systemic, were treated with an oral antihistamine, monitored for at least an extra hour in the observation area, and discharged upon resolution of their rash.

The vast majority of adverse reactions immediately following the administration of the Pfizer-BNT vaccine were non-allergic in nature and included but were not limited to: stage III hypertension (defined as systolic BP above 160 mmHg and diastolic BP above 100 mmHg), syncope, hyperventilation and palpitations as well as headaches. Most of those adverse events resolved spontaneously, but needed longer monitoring in the observation area, and 24% had to be admitted to the ED.. Those were eventually diagnosed with hypertensive urgency, vasovagal syncope and panic attack. Twenty of those 100 adverse events consisted of stage III hypertension. Since our data was deidentified, history of hypertension was not collected but all those patients had a normal electrocardiogram (ECG). Two patients had headaches that resolved when BP was controlled, and none had chest pain. A recent case series from Lausanne reported 9 patients with stage III hypertension developing within minutes of Pfizer-BNT administration. Eight of the nine patients had history of controlled hypertension, while none of the nine patients had ECG changes. Hypotheses included hypertension to vaccine components such as polyethylenglycol, but more likely a stress response, pain response or white coat effect[11]. Syncope from vasovagal response represented 14% of adverse events, which might have been highly related to fear and phobia of needles or the vaccine itself. The public opinion on vaccination in Lebanon has been very mixed, despite multiple initiatives by public and private institutions to address and mitigate the hesitancy and the resistance of some people towards the vaccine (references: MOPH website; AUB postings on social media and our website). This might have contributed to the immediate pre-vaccination fear instilled in the Lebanese people, where more than a third of the population already suffers from anxiety disorders[12]. Twenty percent of the adverse events consisted of hyperventilation and palpitations, occurring in patients who were ultimately diagnosed with panic attacks, all of whom had a feeling of impending doom, and all of which improved spontaneously, except for two patients who needed a short-acting benzodiazepine. This adds to the theory that a big part of the immediate reactions to the Pfizer-BNT vaccine were indeed attributed to psychological factors in a population that is psychologically fragile at baseline. This is a crucial finding since robust evidence has demonstrated that psychological distress can alter the immune system's response to vaccines and plays a massive role in the prevalence and severity of vaccine-related side effects[13]. Measures were eventually taken in the post-vaccination monitoring area in order to decrease this category of adverse events, including detailed explanations of potential side effects of the vaccine by a healthcare worker in the monitoring area, increasing the number of medical doctors in the observation area in order to answer patients' questions and concerns in a timely manner, as well as treating patients with side effects in a separate room from the monitoring area. Another retrospective study is needed to see whether these interventions succeeded in decreasing adverse events related to psychological stress.

Limitations of this study included the low number of adverse events investigated, and the unavailability of data on all who received the vaccine at our center, which only allowed for a descriptive analysis. In addition, the deidentified data did not permit further review of medical records to assess past medical history of the patients, as well as their long-term outcome after occurrence of those adverse events.

Conclusion

Immediate reactions to the Pfizer-BNT COVID-19 vaccine consisted mostly of non-allergic events, including hypertensive peaks, syncope and panic attacks, some of which required admissions to the emergency department. This shows the psychological susceptibility of a frail population, in which careful measures should be taken to decrease the frequency of those adverse events.

Conflicts of Interest

The authors report no conflicts of interest

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