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# Impact of Personal Characteristics on the First and Second Doses of Pfizer-BioNTech Vaccine-Related Side Effects among Health Staff in Sulaimani City, Iraq

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## Abstract

**Background*:*** The safety and effectiveness of vaccines that have been used against COVID-19 are important for controlling the SARS-CoV-2 pandemic. Unlike classical vaccines, the Pfizer BioNTech vaccine contains the genetic information required to synthesize the SARS-CoV-2 spike protein, usually found on the viral surface. This vaccine is used in Iraq to prevent the virus spread.

**Aim of the study*:*** This study aims to analyze the association between individual backgrounds and side effects after receiving the first and second doses of the Pfizer-BioNTech vaccine.

**Participants and Methods*:*** A prospective cohort study was conducted between April 25th, 2021, and September 28th, 2021, among 110 health staff in Sulaimani city. The SPSS version
22 was used for data entry and analysis.

## Results:

The incidence of side effects was significantly higher females, in individuals older than 35 years, participants with a previous history of SARS-CoV-2 infection, and administrative personnel. Concerning local side effects after the first dose, itching, and after the second dose, pain, and tightness in the injected limb were significantly higher in individuals in the age group >35 years (P<0.05). Regarding systemic side effects, after the first dose, myalgia

and insomnia were significantly higher in the age group >35 years, and arthralgia was significantly higher in unhealthy participants (P<0.05). After the second dose, diarrhea was significantly higher in females, and arthralgia was significantly higher in the age group >35 years (P<0.05).

## Conclusion:

The Pfizer vaccine causes several temporary side effects, the occurrence of side effects is more frequent in females, people greater than 35 years of age, individuals with a prior history of SARS-CoV-2 infection, and administrative staff.

**Keywords:** COVID-19 vaccine, Pfizer**,** SARS-CoV-2**,** Side effects, Health Staff.

## Introduction

The SARS-CoV-2 virus is to blame for the COVID-19 pandemic, which has infected hundreds of millions and killed millions throughout the world [1]. Though there are practical ways to stop the transmission of COVID-19, such as using masks, washing your hands, and avoiding close contact with others, acquiring antibodies against SARS-CoV-2 by vaccination is a very effective way to prevent infection [2].

Vaccination has remained an integral part of primary care medicine for preventing common and life-threatening diseases for decades [3]. One effective strategy for reducing disease outbreaks, particularly COVID-19, is vaccination. The ideal vaccination should be effective and safe. In actuality, vaccination side effects such as fever, injection site pain, and myalgia are prevalent but often mild. However, unfavorable effects like shock, seizures, anaphylaxis, active infection, and even death might happen sometimes [4].

On December 11th, 2020, the Pfizer-BNT162b2 vaccine obtained its first emergency use authorization from the US Food and Drug Administration for people aged 16 years and older. The Pfizer vaccine belongs to a new group of vaccines known as messenger ribonucleic acid (mRNA) vaccines. mRNA vaccines provide portions of mRNA that encode for a specific protein, which in the case of the COVID-19 mRNA vaccines is the spike protein that is present on the surface of the SARS-CoV-2 virus. Because mRNA is extremely degradable, these mRNA vaccines are designed to deliver the mRNA material within liposomes to provide protection. These liposomes, composed of polyethylene glycol and other excipients, are highly immunogenic and are likely to be responsible for the patients' severe local and systemic adverse effects [5].

This study aims to assess the side effects of the Pfizer-BioNTech vaccine among health staff who work at public health facilities in Sulaimani city after the first and second doses in relation to their demographic characteristics.

## Participants And Methods

A prospective cohort study was carried out between April 25th, 2021, and September 28th, 2021, in Sulaimani city. The study population comprised all health staff who had not received COVID-19 vaccines, they worked in public health facilities in Sulaimani city, and they were eligible to receive the Pfizer-BioNTech vaccine.

## Inclusion criteria

Health staff were qualified and ready to receive two intramuscular injections of 30 μg of the Pfizer-BioNTech vaccine, three weeks apart, during the study period.

## Data collection

In this study, 110 health staff took part. The participants were chosen using a convenience sample method. A face-to-face interview was performed to collect data from the respondents using a questionnaire. The participants were followed-up to determine the side effects of the vaccine. The recipients fill out a questionnaire after the first and second doses to record any vaccine-related local and systemic side effects that may appear within seven days following receiving each shot.

## Statistical analysis

SPSS version 22 was used for data input and analysis. Two approaches were used: descriptive and analytic. The descriptive approach involved calculating the mean and standard deviation (SD), percentages, and frequencies. The analytical method included an independent-sample t-test used to compare the means of two distinct samples, and the ANOVA was used to compare the means of more than two samples. The chi-square test ($\chi$2-test) was used to investigate whether category variables were associated with one another. A level of significance was determined by a P-value of $\leq$0.05. Vaccine side effects scores were calculated from side effects that occurred after each dose of the vaccine within seven days. Each side effect is worth one mark.

## Ethical considerations

The study adhered to the principles outlined in the Helsinki Declaration [6] and was approved by the scientific committee of the College of Health and Medical Technology-Sulaimani Polytechnic University, and the General Directorate of Health in Sulaimani city. The participants were informed about the aims of the study. They took part freely and voluntarily. All study participants signed their written consent forms.

## Results

### Side effects after receiving the first and second doses of the Pfizer vaccine in relation to the participants' demographic characteristics

After the first and second doses, the side effects' mean score was greater in females, age group >35 years, blood group B, respondents who had a history of SARS-CoV-2 infection, individuals with technical diplomas, administrative personnel, participants working in a health center, and medical staff. These differences were not statistically significant except for

the first dose for participants in the age group >35 years, previously infected individuals, and administrative staff (P-value <0.05) (Table 1).

**Table (1). The Mean Scores Of The Side Effects Following The First And Second Doses In Relation To The Participants' Characteristics (N=110)**

| Characteristics | No. (%) | Mean (SD) Of Side Effects After 1st Dose | P-Value | Mean (SD) Of Side Effects After 2nd Dose | P-Value |
|---|---|---|---|---|---|
| **Gender** | | | | | |
| Male | 47 (42.7) | 4.98 (3.13) | 0.402 | 5.87 (3.29) | 0.287 |
| Female | 63 (57.3) | 5.51 (3.36) | | 6.59 (3.60) | |
| **Age Group (Years)** | | | | | |
| >35 | 64 (58.2) | 5.97 (3.49) | 0.009 | 6.83 (3.58) | 0.051 |
| ≤35 | 46 (41.8) | 4.33 (2.67) | | 5.52 (3.19) | |
| **Body Mass Index (BMI) ($Kg/M^2$)** | | | | | |
| ≤24.99 | 50 (45.5) | 5.26 (3.09) | 0.949 | 6.38 (3.28) | 0.788 |
| >24.99 | 60 (54.5) | 5.30 (3.42) | | 6.20 (3.64) | |
| **Blood Group** | | | | | |
| A | 34 (30.9) | 5.44 (3.07) | 0.371 | 6.59 (3.53) | 0.740 |
| Ab | 13 (11.8) | 4.23 (2.74) | | 5.62 (3.89) | |
| B | 19 (17.3) | 6.21 (3.16) | | 6.74 (3.28) | |
| O | 44 (40.0) | 5.07 (3.56) | | 6.05 (3.45) | |
| **Health Status** | | | | | |
| Healthy | 78 (71.0) | 5.18 (3.37) | 0.249 | 6.32 (3.39) | 0.370 |
| Unhealthy | 32 (29.0) | 5.53 (3.02) | | 6.19 (3.72) | |
| **Previously Infected With SARS-Cov-2** | | | | | |
| Yes | 57 (51.8) | 5.81 (3.27) | 0.030 | 6.75 (3.97) | 0.072 |
| No | 53 (48.2) | 4.43 (2.71) | | 5.52 (3.49) | |
| **Occupation** | | | | | |
| Physician | 31 (28.2) | 4.16 (2.62) | 0.010 | 6.19 (3.70) | 0.130 |
| Lab And Health Workers | 38 (34.5) | 4.97 (3.07) | | 5.50 (3.15) | |
| Administrative Personnel | 41 (37.3) | 6.41 (3.59) | | 7.07 (3.48) | |

**Comparison of local side effects following the first and second doses of the Pfizer vaccine in relation to participants' characteristics**

Table 2, Table 3, Table 4, and Table 5 show local negative effects of the vaccine after the first and second doses in relation to the individual's gender, age, BMI, and health status, respectively. The results showed after both doses there was no significant association between local side effects and participants' characteristics (P>0.05), except for age, after the

first dose, itching; and after the second dose, pain, and tightness in injected limb were significantly higher in individuals in the age group >35 years than those in the age group ≤35 years (P<0.05).

**Table (2). Comparison Of Local Side Effects After First And Second Doses In Relation To Gender**

| Side Effects | First Dose | | ($X^2$-Test) P-Value | Second Dose | | ($X^2$-Test) P-Value |
|---|---|---|---|---|---|---|
| | Gender | | | Gender | | |
| | Male No (%) | Female No (%) | | Male No (%) | Female No (%) | |
| **Pain (At The Injection Site)** | | | | | | |
| Yes | 37 (78.7) | 55 (87.3) | 0.229 | 42 (89.4) | 57 (90.5) | 0.847 |
| No | 10 (21.3) | 8 (12.7) | | 5 (10.6) | 6 (9.5) | |
| **Tightness In The Injected Limb** | | | | | | |
| Yes | 16 (34.0) | 19 (30.2) | 0.665 | 17 (36.2) | 31 (49.2) | 0.173 |
| No | 31 (66.0) | 44 (69.8) | | 30 (63.8) | 32 (50.8) | |
| **Axillary Lymphadenopathy** | | | | | | |
| Yes | 11 (23.4) | 16 (25.4) | 0.810 | 17 (36.2) | 23 (36.5) | 0.971 |
| No | 36 (76.6) | 47 (74.6) | | 30 (63.8) | 40 (63.5) | |
| **Swelling (At The Injection Site)** | | | | | | |
| Yes | 8 (17.0) | 15 (23.8) | 0.386 | 9 (19.1) | 21 (33.3) | 0.098 |
| No | 39 (83.0) | 48 (76.2) | | 38 (80.9) | 42 (66.7) | |
| **Redness (At The Injection Site)** | | | | | | |
| Yes | 8 (17.0) | 10 (15.9) | 0.872 | 10 (21.3) | 9 (14.3) | 0.337 |
| No | 39 (83.0) | 53 (84.1) | | 37 (78.7) | 54 (85.7) | |
| **Itching (At The Injection Site)** | | | | | | |
| Yes | 5 (10.6) | 9 (14.3) | 0.570 | 6 (12.8) | 12 (19.4) | 0.378 |
| No | 42 (89.4) | 54 (85.7) | | 41 (87.2) | 51 (81.0) | |
| Total | 47 | 63 | | 47 | 63 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | (100.0) | (100.0) | | (100.0) | (100.0) | |

**Table( 3). Comparison Of Local Side Effects After First And Second Doses In Relation To Age**

| Side Effects | First Dose | | ($X^2$-Test) P-Value | Second Dose | | ($X^2$-Test) P-Value |
|---|---|---|---|---|---|---|
| | Age | | | Age | | |
| | >35 No (%) | ≤35 No (%) | | >35 No (%) | ≤35 No (%) | |
| **Pain (At The Injection Site)** | | | | | | |
| Yes | 55 (85.9) | 37 (80.4) | 0.442 | 61 (95.3) | 38 (82.6) | 0.028 |
| No | 9 (14.1) | 9 (19.6) | | 3 (4.7) | 8 (17.4) | |
| **Tightness In The Injected Limb** | | | | | | |
| Yes | 22 (34.4) | 13 (28.3) | 0.497 | 33 (51.6) | 15 (32.6) | 0.048 |
| No | 42 (65.6) | 33 (71.7) | | 31 (48.4) | 31 (67.4) | |
| **Axillary Lymphadenopathy** | | | | | | |
| Yes | 17 (26.6) | 10 (21.7) | 0.562 | 25 (39.1) | 15 (32.6) | 0.488 |
| No | 47 (73.4) | 36 (78.3) | | 39 (60.9) | 31 (67.4) | |
| **Swelling (At The Injection Site)** | | | | | | |
| Yes | 16 (25.0) | 7 (15.2) | 0.213 | 17 (26.6) | 13 (28.3) | 0.844 |
| No | 48 (75.0) | 39 (84.8) | | 47 (73.4) | 33 (71.7) | |
| **Redness (At The Injection Site)** | | | | | | |
| Yes | 13 (20.3) | 5 (10.9) | 0.187 | 11 (17.2) | 8 (17.4) | 0.978 |
| No | 51(79.7%) | 41(89.1) | | 53 (82.8) | 38 (82.6) | |
| **Itching (At The Injection Site)** | | | | | | |
| Yes | 12 (18.8) | 2 (4.3) | 0.025 | 8 (12.5) | 10 (21.7) | 0.196 |
| No | 52 (81.3) | 44 (95.7) | | 56 (87.5) | 36 (78.3) | |
| Total | 64 (100.0) | 46 (100.0) | | 64 (100.0) | 46 (100.0) | |

| Table (4). Comparison Of Local Side Effects After First And Second Doses In Relation To BMI | | | | | | |
|---|---|---|---|---|---|---|
| Side Effects | First Dose | | ($X^2$-Test) P-Value | Second Dose | | ($X^2$-Test) P-Value |
| | BMI ($Kg/M^2$) | | | BMI ($Kg/M^2$) | | |
| | ≤24.99 No (%) | >24.99 No (%) | | ≤24.99 No (%) | >24.99 No (%) | |
| Pain (At The Injection Site) | | | | | | |
| Yes | 42 (84.0) | 50 (83.3) | 0.925 | 45 (90.0) | 54 (90.0) | 1.000 |
| No | 8 (16.0) | 10 (16.7) | | 5 (10.0) | 6 (10.0) | |
| Tightness In The Injected Limb | | | | | | |
| Yes | 15 (30.0) | 20 (33.3) | 0.709 | 18 (36.0) | 30 (50.0) | 0.140 |
| No | 35 (70.0) | 40 (66.7) | | 32 (64.0) | 30 (50.0) | |
| Axillary Lymphadenopathy | | | | | | |
| Yes | 14 (28.0) | 13 (21.7) | 0.442 | 17 (34.0) | 23 (38.3) | 0.638 |
| No | 36 (72.0) | 47 (78.3) | | 33 (66.0) | 37 (61.7) | |
| Swelling (At The Injection Site) | | | | | | |
| Yes | 8 (16.0) | 15 (25.0) | 0.248 | 15 (30.0) | 15 (25.0) | 0.558 |
| No | 42 (84.0) | 45 (75.0) | | 35 (70.0) | 45 (75.0) | |
| Redness (At The Injection Site) | | | | | | |
| Yes | 7 (14.0) | 11 (18.3) | 0.541 | 10 (20.0) | 9 (15.0) | 0.490 |
| No | 43 (86.0) | 49 (81.7) | | 40 (80.00 | 51 (85.0) | |
| Itching (At The Injection Site) | | | | | | |
| Yes | 8 (16.0) | 6 (10.0) | 0.347 | 9 (18.0) | 9 (15.0) | 0.672 |
| No | 42 (84.0) | 54 (90.0) | | 41 (82.0) | 51 (85.0) | |
| Total | 50 (100.0) | 60 (100.0) | | 50 (100.0) | 60 (100.0) | |

**Table( 5). Comparison Of Local Side Effects After First And Second Doses In Relation To Health Status**

| Side Effects | First Dose | | ($X^2$-Test) P-Value | Second Dose | | ($X^2$-Test) P-Value |
|---|---|---|---|---|---|---|
| | Health Status | | | Health Status | | |
| | Healthy No (%) | Unhealthy No (%) | | Healthy No (%) | Unhealthy No (%) | |
| **Pain (At The Injection Site)** | | | | | | |
| Yes | 66 (84.6) | 26 (81.3) | 0.665 | 70 (89.7) | 29 (90.6) | 0.889 |
| No | 12 (15.4) | 6 (18.8) | | 8 (10.3) | 3 (9.4) | |
| **Tightness In The Injected Limb** | | | | | | |
| Yes | 22 (28.2) | 13 (40.6) | 0.204 | 34 (43.6) | 14 (43.8) | 0.988 |
| No | 56 (71.8) | 19 (59.4) | | 44 (56.4) | 18 (56.3) | |
| **Axillary Lymphadenopathy** | | | | | | |
| Yes | 19 (24.4) | 8 (25.0) | 0.943 | 31 (39.7) | 9 (28.1) | 0.250 |
| No | 59 (75.6) | 24 (75.0) | | 47 (60.3) | 23 (71.9) | |
| **Swelling (At The Injection Site)** | | | | | | |
| Yes | 13 (16.7) | 10 (31.3) | 0.088 | 22 (28.2) | 8 (25.0) | 0.732 |
| No | 65 (83.3) | 22 (68.8) | | 56 (71.8) | 24 (75.0) | |
| **Redness (At The Injection Site)** | | | | | | |
| Yes | 13 (16.7) | 5 (15.6) | 0.893 | 14 (17.9) | 5 (15.6) | 0.770 |
| No | 65 (83.3) | 27 (84.4) | | 64 (82.1) | 27 (84.4) | |
| **Itching (At The Injection Site)** | | | | | | |
| Yes | 13 (16.7) | 1 (3.1) | 0.053 | 13 (16.7) | 5 (15.6) | 0.893 |
| No | 65 (83.3) | 31 (96.9) | | 65 (83.3) | 27 (84.4) | |
| Total | 78 (100.0) | 32 (100.0) | | 78 (100.0) | 32 (100.0) | |

**Comparison of systemic side effects after the first and second doses of the Pfizer vaccine in relation to participants' characteristics**

Table 6, Table 7, Table 8, and Table 9 show systemic side effects of the vaccine following both doses in relation to the individual's gender, age, BMI, and health status, respectively. Concerning systemic side effects, after the first dose, myalgia and insomnia were significantly higher in the age group >35 years, and arthralgia was significantly higher in unhealthy participants (P<0.05). After the second dose, diarrhea was significantly higher in females, and arthralgia was significantly higher in the age group >35 years (P<0.05).

**Table( 6). Comparison Of Systemic Side Effects After The First And Second Doses**

| In Relation To Gender | | | | | | |
|---|---|---|---|---|---|---|
| Side Effects | First Dose | | ($X^2$-Test) P- Value | Second Dose | | ($X^2$-Test) P-Value |
| | Gender | | | Gender | | |
| | Male No (%) | Female No (%) | | Male No (%) | Female No (%) | |
| Tiredness | | | | | | |
| Yes | 28 (59.6) | 46 (73.0) | 0.137 | 33 (70.2) | 52 (82.5) | 0.127 |
| No | 19 (40.4) | 17 (27.0) | | 14 (29.8) | 11 (17.5) | |
| Myalgia | | | | | | |
| Yes | 24 (51.1) | 39 (61.9) | 0.256 | 30 (63.8) | 41 (65.1) | 0.892 |
| No | 23 (48.9) | 24 (38.1) | | 17 (36.2) | 22 (34.9) | |
| Fever | | | | | | |
| Yes | 25 (53.2) | 27 (42.9) | 0.283 | 25 (53.2) | 41 (65.1) | 0.208 |
| No | 22 (46.8) | 36 (57.1) | | 22 (46.8) | 22 (34.9) | |
| Arthralgia | | | | | | |
| Yes | 18 (38.3) | 27 (42.9) | 0.630 | 17 (36.2) | 21 (33.3) | 0.757 |
| No | 29 (61.7) | 36 (57.1) | | 30 (63.8) | 42 (66.7) | |
| Headache | | | | | | |
| Yes | 13 (27.7) | 24 (38.1) | 0.252 | 19 (40.4) | 27 (42.9) | 0.798 |
| No | 34 (72.3) | 39 (61.9) | | 28 (59.6) | 36 (57.1) | |
| Insomnia | | | | | | |
| Yes | 13 (27.7) | 16 (25.4) | 0.790 | 19 (40.4) | 27 (42.9) | 0.798 |
| No | 34 (72.3) | 47 (74.6) | | 28 (59.6) | 36 (57.1) | |
| Chills | | | | | | |
| Yes | 8 (17.0) | 9 (14.3) | 0.695 | 13 (27.7) | 11 (17.5) | 0.200 |
| No | 39 (83.0) | 54 (85.7) | | 34 (72.3) | 52 (82.5) | |
| Nausea | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Yes** | **5 (10.6)** | **10 (15.9)** | **0.429** | **8 (17.0)** | **14 (22.2)** | **0.500** |
| **No** | **42 (89.4)** | **53 (84.1)** | | **39 (83.0)** | **49 (77.8)** | |
| **Diarrhea** | | | | | | |
| **Yes** | **6 (12.8)** | **9 (14.3)** | **0.818** | **2 (4.3)** | **12 (19.0)** | **0.021** |
| **No** | **41 (87.2)** | **54 (85.7)** | | **45 (95.7)** | **51 (81.0)** | |
| **Shortness Of Breath** | | | | | | |
| **Yes** | **6 (12.8)** | **6 (9.5)** | **0.589** | **6 (12.8)** | **6 (9.5)** | **0.589** |
| **No** | **41 (87.2)** | **57 (90.5)** | | **41 (87.2)** | **57 (90.5)** | |
| **Chest Pain** | | | | | | |
| **Yes** | **2 (4.3)** | **7 (11.1)** | **0.194** | **2 (4.3)** | **7 (11.1)** | **0.194** |
| **No** | **45 (95.7)** | **56 (88.9)** | | **45 (95.7)** | **56 (88.9)** | |
| **Vomiting** | | | | | | |
| **Yes** | **2 (4.3)** | **2 (3.2)** | **0.765** | **2 (4.3)** | **4 (6.3)** | **0.632** |
| **No** | **45 (95.7)** | **61 (96.8)** | | **45 (95.7)** | **59 (93.7)** | |
| **Allergic Reaction** | | | | | | |
| **Yes** | **0 (0.0)** | **2 (3.2** | **0.218** | **0 (0.0)** | **0 (0.0)** | |
| **No** | **47 (100.0)** | **61 (96.8)** | | **47 (100.0)** | **63 (100.0)** | |
| **Total** | **47 (100.0)** | **63 (100.0)** | | **47 (100.0)** | **63 (100.0)** | |

| Table (7). Comparison Of Systemic Side Effects After The First And Second Doses In Relation To Age | | | | | | |
|---|---|---|---|---|---|---|
| Side Effects | First Dose | | ($X^2$-Test) P-Value | Second Dose | | ($X^2$-Test) P-Value |
| | Age | | | Age | | |
| | >35 No (%) | ≤35 No (%) | | >35 No (%) | ≤35 No (%) | |
| Tiredness | | | | | | |
| Yes | 46 (71.9) | 28 (60.9) | 0.225 | 50 (78.1) | 35 (76.1) | 0.801 |
| No | 18 (28.1) | 18 (39.1) | | 14 (21.9) | 11 (23.9) | |
| Myalgia | | | | | | |
| Yes | 42 (65.6) | 21 (45.7) | 0.037 | 46 (71.9) | 25 (54.3) | 0.058 |
| No | 22 (34.4) | 25 (54.3) | | 18 (28.1) | 21 (45.7) | |
| Fever | | | | | | |
| Yes | 31 (48.4) | 21 (45.7) | 0.773 | 39 (60.9) | 27 (58.7) | 0.813 |
| No | 33 (51.6) | 25 (54.3) | | 25 (39.1) | 19 (41.3) | |
| Arthralgia | | | | | | |
| Yes | 31 (48.4) | 14 (30.4) | 0.058 | 28 (43.8) | 10 (21.7) | 0.017 |
| No | 33 (51.6%) | 32 (69.6) | | 36 (56.3) | 36 (78.3) | |
| Headache | | | | | | |
| Yes | 24 (37.5) | 13 (28.3) | 0.312 | 31 (48.4) | 15 (32.6) | 0.097 |
| No | 40 (62.5) | 33 (71.7) | | 33 (51.6) | 31 (67.4) | |
| Insomnia | | | | | | |
| Yes | 23 (35.9) | 6 (13.0) | 0.007 | 31 (48.4) | 15 (32.6) | 0.097 |
| No | 41 (64.1) | 40 (87.0) | | 33 (51.6) | 31 (67.4) | |
| Chills | | | | | | |
| Yes | 11 (17.2) | 6 (13.0) | 0.553 | 16 (25.0) | 8 (17.4) | 0.341 |
| No | 53 (82.8) | 40 (87.0) | | 48 (90.6) | 38 (82.6) | |
| Nausea | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Yes** | **12 (18.8)** | **3 (6.5)** | **0.065** | **14 (21.9)** | **8 (17.4)** | **0.562** |
| **No** | **52 (81.3)** | **43 (93.5)** | | **50 (78.1)** | **38 (82.6)** | |
| **Diarrhea** | | | | | | |
| **Yes** | **10 (15.6)** | **5 (10.9)** | **0.473** | **9 (14.1)** | **5 (10.9)** | **0.620** |
| **No** | **54 (84.4)** | **41 (89.1)** | | **55 (85.9)** | **41 (89.1)** | |
| **Shortness Of Breath** | | | | | | |
| **Yes** | **8 (12.5)** | **4 (8.7)** | **0.528** | **8 (12.5)** | **4 (8.7)** | **0.528** |
| **No** | **56 (87.5)** | **42 (91.3)** | | **56 (87.5)** | **42 (91.3)** | |
| **Chest Pain** | | | | | | |
| **Yes** | **6 (9.4)** | **3 (6.5)** | **0.590** | **6 (9.4)** | **3 (6.5)** | **0.590** |
| **No** | **58 (90.6)** | **43 (93.5)** | | **58 (90.6)** | **43 (93.5)** | |
| **Vomiting** | | | | | | |
| **Yes** | **3 (4.7)** | **1 (2.2)** | **0.487** | **5 (7.8)** | **1 (2.2)** | **0.199** |
| **No** | **61 (95.3)** | **45 (97.8)** | | **59 (92.2)** | **45 (97.8)** | |
| **Allergic Reaction** | | | | | | |
| **Yes** | **1 (1.6)** | **1 (2.2)** | **0.813** | **0 (0.0)** | **0 (0.0)** | |
| **No** | **63 (98.4)** | **45 (97.8)** | | **64 (100.0)** | **46 (100.0)** | |
| **Total** | **64 (100.0)** | **46 (100.0)** | | **64 (100.0)** | **46 (100.0)** | |

**Table (8). Comparison Of Systemic Side Effects After The First And Second Doses In Relation To BMI**

| **Side Effects** | **First Dose** | | **($X^2$-Test) P-Value** | **Second Dose** | | **($X^2$-Test) P-Value** |
|---|---|---|---|---|---|---|
| | **BMI ($Kg/M^2$)** | | | **BMI ($Kg/M^2$)** | | |
| | **≤24.99 No (%)** | **≤24.99 No (%)** | | **≤24.99 No (%)** | **≤24.99 No (%)** | |
| **Tiredness** | | | | | | |
| **Yes** | **33 (66.0)** | **41 (68.3)** | **0.795** | **41 (82.0)** | **44 (73.3)** | **0.280** |
| **No** | **17 (34.0)** | **19 (31.7)** | | **9 (18.0)** | **16 (26.7)** | |
| **Myalgia** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Yes** | **30 (60.0)** | **33 (55.0)** | **0.598** | **33 (66.0)** | **38 (63.3)** | **0.771** |
| **No** | **20 (40.0)** | **27 (45.0)** | | **17 (34.0)** | **22 (36.7)** | |
| **Fever** | | | | | | |
| **Yes** | **21 (42.0)** | **31 (51.7)** | **0.312** | **32 (64.0)** | **34 (56.7)** | **0.434** |
| **No** | **29 (58.0)** | **29 (48.3)** | | **18 (36.0)** | **26 (43.3)** | |
| **Arthralgia** | | | | | | |
| **Yes** | **24 (48.0)** | **21 (35.0)** | **0.167** | **19 (38.0)** | **19 (31.7)** | **0.487** |
| **No** | **26 (52.0)** | **39 (65.0)** | | **31 (62.0)** | **41 (68.3)** | |
| **Headache** | | | | | | |
| **Yes** | **17 (34.0)** | **20 (33.3)** | **0.941** | **22 (44.0)** | **24 (40.0)** | **0.672** |
| **No** | **33 (66.0)** | **40 (66.7)** | | **28 (56.0)** | **36 (60.0)** | |
| **Insomnia** | | | | | | |
| **Yes** | **11 (22.0)** | **18 (30.0)** | **0.343** | **19 (38.0)** | **27 (45.0)** | **0.459** |
| **No** | **39 (78.0)** | **42 (70.0)** | | **31 (62.0)** | **33 (55.0)** | |
| **Chills** | | | | | | |
| **Yes** | **9 (18.0)** | **8 (13.3)** | **0.500** | **12 (24.0)** | **12 (20.0)** | **0.613** |
| **No** | **41 (82.0)** | **52 (86.7)** | | **38 (76.0)** | **48 (80.0)** | |
| **Nausea** | | | | | | |
| **Yes** | **7 (14.0)** | **8 (13.30** | **0.919** | **10 (20.0)** | **12 (20.0)** | **1.000** |
| **No** | **43 (86.0)** | **52 (86.7)** | | **40 (80.0)** | **48 (80.0)** | |
| **Diarrhea** | | | | | | |
| **Yes** | **5 (10.0)** | **10 (16.7)** | **0.310** | **4 (8.0)** | **10 (16.7)** | **0.174** |
| **No** | **45 (90.0)** | **50 (83.3)** | | **46 (92.0)** | **50 (83.3)** | |
| **Shortness Of Breath** | | | | | | |
| **Yes** | **5 (10.0)** | **7 (11.7)** | **0.780** | **4 (8.0)** | **8 (13.3)** | **0.372** |
| **No** | **45 (90.0)** | **53** | | **46 (92.0)** | **52 (86.7)** | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | (88.3) | | | | |
| **Chest Pain** | | | | | | |
| Yes | 5 (10.0) | 4 (6.7) | 0.525 | 6 (12.0) | 3 (5.0) | 0.182 |
| No | 45 (90.0) | 56 (93.3) | | 44 (88.0) | 57 (95.0) | |
| **Vomiting** | | | | | | |
| Yes | 2 (4.0) | 2 (3.3) | 0.853 | 4 (8.0) | 2 (3.3) | 0.283 |
| No | 48 (96.0) | 58 (96.7) | | 46 (92.0) | 58 (96.7) | |
| **Allergic Reaction** | | | | | | |
| Yes | 1 (2.0) | 1 (1.7) | 0.896 | 0 (0.0) | 0 (0.0) | |
| No | 49 (98.0) | 59 (98.3) | | 50 (100.0) | 60 (100.0) | |
| Total | 50 (100.0) | 60 (100.0) | | 50 (100.0) | 60 (100.0) | |

**Table (9). Comparison Of Systemic Side Effects After The First And Second Doses In Relation To Health Status**

| Side Effects | First Dose | | ($X^2$-Test) P- Value | Second Dose | | ($X^2$-Test) P-Value |
|---|---|---|---|---|---|---|
| | Health Status | | | Health Status | | |
| | Healthy No (%) | Unhealthy No (%) | | Healthy No (%) | Unhealthy No (%) | |
| **Tiredness** | | | | | | |
| Yes | 50 (64.1) | 24 (75.0) | 0.269 | 61 (78.2) | 24 (75.0) | 0.716 |
| No | 28 (35.9) | 8 (25.0) | | 17 (21.8) | 8 (25.0) | |
| **Myalgia** | | | | | | |
| Yes | 42 (53.8) | 21 (65.6) | 0.257 | 48 (61.5) | 23 (71.9) | 0.303 |
| No | 36 (46.2) | 11 (34.4) | | 30 (38.5) | 9 (28.1) | |
| **Fever** | | | | | | |
| Yes | 38 (48.7) | 14 (43.8) | 0.635 | 48 (61.5) | 18 (56.3) | 0.607 |
| No | 40 (51.3) | 18 (56.3) | | 30 (38.5) | 14 (43.8) | |
| **Arthralgia** | | | | | | |
| Yes | 27 (34.6) | 18 (56.3) | 0.036 | 24 (30.8) | 14 (43.8) | 0.193 |
| No | 51 (65.4) | 14 (43.8) | | 54 (69.2) | 18 (56.3) | |
| **Headache** | | | | | | |
| Yes | 25 (32.1) | 12 (37.50 | 0.583 | 34 (43.6) | 12 (37.5) | 0.556 |
| No | 53 (67.9) | 20 (62.5) | | 44 (56.4) | 20 (62.5) | |
| **Insomnia** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Yes** | **21 (26.9)** | **8 (25.0)** | **0.835** | **31 (39.7)** | **15 (46.9)** | **0.491** |
| **No** | **57 (73.1)** | **24 (75.0)** | | **47 (60.3)** | **17 (53.1)** | |
| **Chills** | | | | | | |
| **Yes** | **12 (15.4)** | **5 (15.6)** | **0.975** | **19 (24.4)** | **5 (15.6)** | **0.314** |
| **No** | **66 (84.6)** | **27 (84.4)** | | **59 (75.6)** | **27 (84.4)** | |
| **Nausea** | | | | | | |
| **Yes** | **11 (14.1)** | **4 (12.5)** | **0.824** | **17 (21.8)** | **5 (15.6)** | **0.462** |
| **No** | **67 (85.9)** | **28 (87.5)** | | **61 (78.2)** | **27 (84.4)** | |
| **Diarrhea** | | | | | | |
| **Yes** | **11 (14.1)** | **4 (12.5)** | **0.824** | **8 (10.3)** | **6 (18.8)** | **0.225** |
| **No** | **67 (85.9)** | **28 (87.5)** | | **70 (89.7)** | **26 (81.3)** | |
| **Shortness Of Breath** | | | | | | |
| **Yes** | **9 (11.5)** | **3 (9.4)** | **0.741** | **10 (12.8)** | **2 (6.3)** | **0.315** |
| **No** | **69 (88.5)** | **29 (90.60** | | **68 (87.2)** | **30 (93.8)** | |
| **Chest Pain** | | | | | | |
| **Yes** | **7 (9.0)** | **2 (6.3)** | **0.636** | **5 (6.4)** | **4 (12.5)** | **0.290** |
| **No** | **71 (91.0)** | **30 (93.8)** | | **73 (93.6)** | **28 (87.5)** | |
| **Vomiting** | | | | | | |
| **Yes** | **4 (5.1)** | **0 (0.0)** | **0.192** | **5 (6.4)** | **1 (3.1)** | **0.491** |
| **No** | **74 (94.9)** | **32 (100.0)** | | **73 (93.6)** | **31 (96.9)** | |
| **Allergic Reaction** | | | | | | |
| **Yes** | **2 (2.6)** | **0 (0.0)** | **0.361** | **0 (0.0)** | **0 (0.0)** | |
| **No** | **76 (97.4)** | **32 (100.0)** | | **78 (100.0)** | **32 (100.0)** | |
| **Total** | **78 (100.0)** | **32 (100.0)** | | **78 (100.0)** | **32 (100.0)** | |

## Discussion

## Side effects after the first and second doses in relation to the participant characteristics

### Gender

The results of the current study demonstrated that females had greater mean scores for side effects than males; studies reported that the frequency of COVID-19 vaccines' side effects was significantly higher among females than males[7-9]. Similarly, results of a Japanese study indicated that the occurrence of local and systemic side effects after both doses was significantly higher in females than males [10]. Moreover, a survey was carried out among healthcare workers reported that the COVID-19 vaccines produced limited side effects, and the majority of side effects occurred in females rather than males [11]. A study stated that the

significant predictor of a higher number of adverse effects after the first and second doses was the female gender [12].

After both doses, the prevalence of local side effects such as pain, swelling, itching, and lymphadenopathy was higher in females than males; a result of a study demonstrated that females had significantly higher local side effects than males after the first and second doses [13]. A review reported that vaccines adverse reactions were higher in females than males for several types of vaccines such as measles, mumps, rubella (MMR) vaccine, yellow fever vaccine, and seasonal trivalent influenza vaccine. It also explained that females have a high immune response against the vaccines [14]. This might be due to the hormonal and psychological differences between men and women, which cause women to experience the vaccine's adverse effects more frequently than men [15].

Human and animal sex differences extend beyond anatomical physical features to physiological and metabolic variables that impact essential immune system activities, predisposing males and females to respond differently to infectious illnesses, particularly viral infections. For example, in females, estrogens tend to stimulate higher inflammatory, humoral, and cellular immune responses than in males. Strong immune responses to infections can benefit the host, but hyperactive inflammatory responses can harm host tissues. These variations predispose females more than males to immunological malfunction and diseases, comorbidities, autoimmune illnesses, and bad vaccination responses, among other negative consequences [16]. On the other hand, in males, testosterone suppresses both the innate and adaptive immune responses [17, 18].

## Age

In this study, the occurrence of side effects after both doses was higher in older people than in younger people. A study reported a significant association between the Pfizer vaccine side effects and people aged ≥35 years [19] Likewise, another study exhibited that older people showed a significantly higher possibility of side effects following vaccination with COVID-19 vaccines [20]. In the current study, after the first dose, the occurrence of insomnia was significantly higher in older participants; a case report study indicated that a senior female after receiving the COVID-19 vaccine suffered from insomnia [21].

## BMI

In the present study, there was no significant difference in the mean scores of side effects after both doses in relation to BMI. Similarly, the result of a study displayed no significant association between the occurrence of COVID-19 vaccines' adverse events and individuals' BMI [22]. Moreover, a cross-sectional study was performed among adults in Spine, indicating the association between the COVID-19 vaccine's side effects and BMI was insignificant [23]. Furthermore, a study reported that adiposity parameters such as higher BMI, body fat, waist-to-hip ratio, or waist circumference were not associated with the incidence of more adverse events [24].

## Blood group

After both doses, the differences between the means of the side effects in relation to the blood groups were not statistically significant. Three surveys were conducted among people immunized with COVID-19 vaccines, which displayed no significant association between the seriousness of side effects and blood groups [25-27]. However, the severity of COVID-19 symptoms was higher among individuals with blood group A [28].

## Health status

The current study showed no significant differences between the mean scores of the side effects of the healthy and unhealthy respondents regarding side effects; this finding was in agreement with the result of a study was carried out among medical staff [22]. Mexican research was conducted among health workers who received the Pfizer vaccine revealed no significant association between the incidence of the vaccines' side effects and comorbidities [29].

## Previous history with SARS-CoV-2 infection

Mean levels of the side effects after the first and second were greater in previously infected staff; this finding was in agreement with the result of an observational study was conducted among residents in the United Arab Emirates [19]. A study was carried out among healthcare workers in England who received two doses of the Pfizer vaccine; it reported that the frequency of side effects was higher among previously infected individuals. As well, the adverse event was more severe after the first dose [30]. Similarly, a study showed that people with a prior history of SARS-CoV-2 had high reactogenicity to the Pfizer vaccine [31]. This might be due to the fact that the immune system recognized the viral spike protein from the prior infection, resulting in a robust immunological reaction to the vaccine.

## Occupation

The occurrence of side effects was higher among administrative personnel than among medical staff. Likewise, a study reported that the incidence of side effects was higher in non-medical staff than in medical staff [7]. This may be due to the fact that non-medical individuals have less scientific information about the COVID-19 vaccines than medical individuals [32], which might make them worried about the safety of the vaccine. Psychological factors play an important role in the safety and effectiveness of vaccination, and the immune system's response to vaccines can be impaired by poor psychological status [33]. A cohort study carried out among immunized people in Germany found that pre-existing anxiety and depression considerably increased the probability of reported side effects of the COVID-19 vaccine [34].

## Conclusions

The Pfizer-BioNTech COVID-19 vaccine causes several temporary local and systemic side effects; the incidence of side effects is higher in females, people aged greater than 35 years, individuals with previous SARS-CoV-2 infection, and administrative staff.

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