

SARS-CoV-2 infection and side effects reported following COVID-19 vaccines: an observational study using surveillance data

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Abstract

Introduction

Coronavirus disease 2019 (COVID-19) is continuing to spread around the worldwide. This prospective study was aimed to find out the occurrence of SARS-CoV-2 infection among the vaccinated HCWs and investigate the short-term Adverse Events Following Immunization (AEFIs) reported by this group.

Material & Methods:

The data was tabulated and examined for a variety of factors, including gender, age, role, work environment, previous COVID-19 diagnosis, date of vaccine administration, kind of vaccine, AEFIs, and clinical severity of the condition...The SPSS program version 25 was used to conduct the analyses.

Results:

After the immunization, 48 people (2.14 %) reported symptomatic infection, thus they were included in the final study. AstraZeneca-Oxford was given to 41 individuals, while Sinopharm was given to 7.

The median age of the participants was 35 years old. 56.1 percent of the 41 viral vector-based vaccine recipients were females, and 60.1 percent were under the age of 35. 100.0 percent of the 6 inactivated vaccination recipients were females, and 85.7 percent were under 45 years old.

The time to infection following two doses of covid 19 vaccine ranged from 20 to 200 days (average: 152.4), and the time to infection after one dose of vaccination ranged from 2 to 26 days (average: 11.2 days). Only two (4.2%) of the vaccinated HCWs required hospitalization. The majority of the AEFIs reported were mild to moderate in severity.

Conclusion

Our findings imply that the HCWs immunizations lowered the number of COVID-19 cases in our institution, resulting in less severe disease.

Keywords: SARS-CoV-2 infection; COVID-19 vaccines; Side effects; Healthcare workers;

List of abbreviations:

- COVID-19: Coronavirus disease 2019
- HCWs: The healthcare workers
- PVI: The post-vaccination infection
- AEFIs: Adverse Events Following Immunization
- FV: Fully vaccinated
- PV: Partially vaccinated
- SAE: Systemic Adverse Event
- LAE: Local Adverse Event
- CDC: The Centers for Disease Control and Prevention
- BTI: Breakthrough infection
- VOC: Variants of concern
- VOC: Variant of high consequence
- VOI: Variant of interest
- EMA: European Medicines Agency

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I. Introduction

Coronavirus disease 2019 (COVID-19) is continuing to spread around the worldwide to more than 280 million confirmed cases and 5.4 million deaths as of December 20, 2021 [1]. In Morocco, there have been over 951,000 documented COVID-19 cases, with a cumulative incidence rate of 2.7 percent and over 14,802 deaths [1]. COVID-19 is a viral infection produced by the SARS-CoV-2 virus [2]. The prevention of this disease is focused on following COVID-appropriate behavior and immunization [3]. The COVID-19 pandemic has sparked the largest worldwide vaccine development initiative in history, with a number of vaccines receiving emergency use authorization [4].

This epidemic has had serious consequences in various disciplines and areas, including the economy, social services, and health care. It is obvious that the only way to terminate this pandemic is through vaccination campaigns [5].

One of the greatest tactics for pandemic control is mass vaccination along with physical separation, excellent hygiene practices, travel restrictions, mask use, and early diagnosis of COVID-19 infection. Several vaccinations have been approved for use internationally by the World Health Organization [6, 7]. Despite mass vaccination programs, the emergence and spread of COVID-19 Variants of Concern (Delta, Omicron...) in a number of countries, vaccine hesitancy, and vaccine supply issues imperil pandemic control efforts [8,9].

The immunization program in Morocco has supplied free vaccines to all Moroccan inhabitants. Starting with the elderly and healthcare professionals (HCWs). HCWs are at a significant risk of getting COVID-19 since they are the frontline employees in care of the patients [10]. Despite the fact that COVID-19 immunizations are regarded efficacious and safe, concerns about the vaccine's efficacy and side effects have been raised [11]. As a result, the goal of this prospective study was to determine the prevalence of SARS-CoV-2 infection among vaccinated HCWs at a university hospital in Morocco, as well as to look at the short-term adverse effects observed by this group after receiving COVID-19 vaccines.

II. Material & Methods

This study was carried at the academic hospital Hassan II, Fez, Morocco. The data of all COVID-19 positive vaccinated HCWs was obtained from the hospital's occupational health department, compiled, and analyzed. The research took place after the vaccine campaign, from March 15 to November 15, 2021. (08 months).

Because HCWs were vaccinated on different dates, not all of them were monitored for the full eight months. The study's HCWs who developed the post-vaccination infection (PVI) during the study period were noted. Doctors, paramedics, nurses, and administrative staff were among the HCWs involved. Sex, age, role, work environment, source of infection, previous diagnosis of COVID-19, date of vaccine administration, type of vaccine (ChAdOx1 nCoV-19 or Sinopharm), Adverse Events Following Immunization (AEFIs), time to infection after their last vaccination dose, clinical severity of the disease, and need for hospitalization were all analyzed.

During the study period, 2246 HCWs were vaccinated with Astrazeneca COVID-19 vaccine (ChAdOx1 nCoV-19 (recombinant)) (91,1%) and Sinopharm COVID-19 vaccine (BBIBP-CorV) (8,9%), with 215 partially vaccinated (PV) (single dose) and 2031 fully vaccinated (FV) (two doses). Because the vaccine

impact was not inspected by antibody testing in this trial due to logistical constraints, only symptomatic HCWs (48 persons) who reported and were found COVID-19 positive were evaluated.

To investigate for AEFIs, symptoms were recorded using a report form templates. The reported AEs were classified as systemic events (SAE) (fever, fatigue, chill, headache, nausea, vomiting, diarrhea, myalgia, arthralgia, urticaria, and others) and local events (LAE) (Injection Site Pain, Tenderness, Swelling at the injection site).

Data analysis was performed using the SPSS Statistics, version 25.

III. Results

Demographic Characteristics

After covid-19 vaccination, 48 people (2.14 %) reported symptomatic illness, thus they were included in the final analysis. AstraZeneca-Oxford (viral vector-based vaccination; n = 41) and Sinopharm (inactivated vaccine; n = 7) were given to a total of 41 individuals. The first dose was given to the participants between February 1 and June 2, 2021.

The average age of the population was 35 years old. 56.1 percent of the 41 viral vector-based vaccine users were women, 60.1 percent were under 35, 48.8 percent were nurses, and 36.6 percent had 5–10 years of work experience (Table 1). 100.0 percent of the 6 inactivated vaccination users were women, 85.7 percent were under 45, 42.9 percent were nurses, and 42.8 percent had 5–10 years of experience.

Medical Anamneses

Overall, 42.8 percent of inactivated vaccine receivers and 41.5 percent of viral vector-based vaccination users reported at least one non-communicable condition. Allergy was the most frequent chronic condition (8.3 %), followed by Diabetes Mellitus and asthma (6.2 %). (Table 2)

COVID-19-Related Anamneses

Only one person in the viral vector-based vaccine group (2.4%) received only one dose, whereas the vast majority of inactivated vaccine users (71.4%) received two. Only one inactivated vaccination recipient and eight viral vector-based vaccine recipients had previously been affected. In all, 29 individuals (60.4%) said they had recently been exposed to COVID-19 patients (Table 3).

After one dose of vaccination, the time to infection ranged from 2 to 26 days (average: 11.2 days), while after two doses of immunization, the time to infection ranged from 20 to 200 days (average: 152.4). Maximum infections occurred in August 2021, during the second wave of COVID-19 in Morocco. There were moderate symptoms such as fatigue, fever, cough, sore throat and loss of taste and smell. Of all the vaccinated HCWs, only two (4.2%) required hospital admissions. There was no significant AEFIs and no mortality.

Local and Systemic Side Effects:

The inactivated vaccine group had greater LAE related to the injection site than the viral vector-based vaccine group. At least one LAE was reported by 42.8 percent of inactivated vaccine receivers and 29.3 percent of viral vector-based vaccination recipients, respectively. Overall, the most common LAE was injection site pain (25.0%), followed by tenderness (14.6%) and injection site swelling (2.6%).

SAE were also more common in the inactivated vaccination group than in the viral vector-based vaccine group. At least one SAE was reported by 71.4 percent of inactivated vaccine users and 51.2% of viral vector-based vaccination recipients, respectively. Myalgia was the most prevalent SAE (29.2%), followed by fever (20.8%), headache (18.7%), arthralgia (14.6%), chills (12.5%), and fatigue (12.5%). (Table 4).

In comparison to the older age group (>35 years), the younger age group (35 years) was more affected by SAE after receiving Viral Vector and Inactivated vaccinations. (Figure 1 and 2). In contrast, 48.1 percent of females reported adverse effects after the first dose of vaccination, compared to 31.4 percent of males, and 63.3 percent of females versus 45.2 percent of males after the second dosage.

The great majority of reported negative effects lasted two days or less.

IV. Discussion

SARS-CoV-2 infection after vaccination is well-known after one or two the doses of vaccine [11, 12]. The Centers for Disease Control and Prevention (CDC) has defined SARS-CoV-2 infection following immunization with an approved vaccine as a breakthrough infection (BTI) [13]. Therefore, in this study, 75.2% of HCWs had BTI. Duggan et al [12] concluded that COVID-19 vaccination is indeed effective in preventing severe symptoms following infection, a severe disease with low hospitalizations and deaths [12].

In our study, we noted that in a population of 2635 HCWs in an academic hospital, the PVI after the first dose was 2.15% and the PVI after the second dose of vaccine was 2.12%, among those observed for less than 08 months. This means that protective immunity develops after vaccination.

Amit S et al, founded precocious symptomatic infections following the first dose of COVID-19 vaccine [14]. The proportions of symptomatic COVID-19 cases were 1.2 and 2.8 per 10,000 person-days on days 15-28 and 1-14 after the first dose, respectively [14].

In a large study of the United Kingdom [15], it was observed that COVID-19 infections fell by 65.00 percent after the first dose of vaccine (Pfizer-BioNTech or Oxford-AstraZeneca), and after the second dose, these declines were the largest increased to 70.00 percent.

It is worth noting that the risk of SARS-CoV-2 infection remains in the early post-vaccination phase, as immunity takes time to expand, whereas in the later post-vaccination period, immunity declines with longer follow-up. The SIREN study showed that the COVID-19 vaccines does not prevent all cases of infection [16]. However, most studies have shown good protection against severe SARS-CoV-2 infection and death from the vaccine used, even with the Delta strain [17], studies have shown progressively diminishing protection against each type of infection [18-20].

As protection against COVID-19 infection wanes after two doses of the COVID-19 vaccine, policymakers have begun to consider whether a third dose or booster shot is needed to protect the most vulnerable communities and minimize disruption to health care and the economy. The Ministry of Health and Social Protection, Government of Morocco has also advised people to get booster shots, continue to wear masks and practice social distancing in public even after being fully vaccinated.

In our study, 2.14 percent of HCWs developed PVI. Of all vaccinated participants, only 4.2 percent required hospitalization. In preclinical studies, the efficacy of AstraZeneca (ChAdOx1 nCoV-19) vaccine was 73 percent [21]. For the inactivated vaccine (BBIBP-CorV), its efficacy was 78.1 percent [22].

In the present study, females had a 1.42 times higher chance of becoming infected. This could be attributed to the greater involvement of females in patient care as nursing personnel, as the likelihood of PVI was highest among nursing staff (28.2%), followed by medical staff (18.1%) in this study. Medical and nursing workers had the highest risk of contracting PVI, compared to paramedical (1.8 %), supporting, and administrative staff (1.5 %).

COVID-19 variants have emerged, posing substantial concerns because these mutant viruses can evade the human immune system. As a result, they have a better chance of breaking through the human barriers generated by vaccination. These new 'variants of concern (VOC)' are more lethal than wild-type SARS-CoV-2 and include spike protein alterations, raising vaccine effectiveness concerns [23-24].

The emergence of PVI in HCWs in our study could be due to a number of factors, including (i) a lack of adherence to safety precautions, (ii) a lower immunogenic response in some individuals, (iii) a progressive loss of protection, (iv) the occurrence of the second COVID-19 wave in Morocco, and (v) the emergence of VOC [24].

Antibody titer testing after COVID-19 immunization is imprecise, and routine post-vaccination testing may cause overconfidence in those with higher levels and anxiety in those with lower levels [25]. Though serum antibody levels have been linked to protection against a variety of infectious illnesses, protective levels for SARS-CoV2 have yet to be determined [3]. Because genomic sequencing can reveal SARS-CoV2's phylogenetic properties, more frequent testing is required to monitor the disease's spread and mutant virus generation [26]. Depending on their virulence and severity, viral variants or mutants have been categorized as variants of interest (VOI) or variants of substantial consequence (VOC) [24].

VOI and VOC have been documented in a variety of countries. The WHO has given them Greek alphabet names to make their names easier to remember and to reduce the stigma associated with these mutations [27]. Delta variant (B.1.617.2) and Omicron variant are the most commonly observed VOCs on the planet (B.1.1.529).

According to our findings, 52.1 percent of HCWs experienced at least one adverse effect after receiving COVID-19 immunizations; 71.4 percent following inactivated vaccine, and 48.8 percent following the viral vector-based vaccine. Our findings showed that inactivated vaccines were associated with more frequent local and systemic side effects as compared to live vaccines (42.8 percent vs. 29.3 percent and 71.4 percent vs. 51.2 percent). The majority of investigations have focused on the Moderna, Pfizer-BioNTech, and AstraZeneca vaccines [28-30], with only a few focusing on the Sinopharm COVID-19 vaccine [31].

Myalgia was the most prevalent AEFI, with 29.2 percent of individuals reporting it, followed by injection site pain (25.0%), fever (20.8%), and migraine/headache (18.7 %). In China, the Sinopharm vaccination resulted in 14.3 percent localized pain and 2.4 percent fever with no fatigue, headache, or muscle aching [32]. The AEFIs may differ due to demographic variation and different settings. Vaccination studies are underway in a number of nations, including the United States, Europe, Australia, and China, and more research should be done in diverse age groups and situations. A clinical trial with BioNTech-Pfizer vaccine was done in the United States, and AEFIs were examined; 83.3 percent of participants reported fatigue, 100 percent reported headache and localized pain, 58.3 percent myalgia, and 66.7 percent fever [33]. In another trial done by AstraZeneca in the United Kingdom, 70 percent of patients reported fatigue, 68 percent headache,

60percentmyalgia, and 51percent fever [34]. These findings suggest that the Sino-pharm vaccine has little side effects. Nonetheless, as compared to the inactivated Sino-pharm vaccine, the viral vector-based AstraZeneca vaccine has a higher safety profile in our study. However, because some studies have a limited sample size, these comparisons should be made with caution.

In a trial of HCWs in Turkey, Riad et al [35] discovered that more than 10percent of the participants reported injection site pain (41%), fatigue (23%), and headache (18%), which was similar to our finding for the inactivated Sinopharm vaccine. In the safety report of the European Medicines Agency (EMA) for the viral vector-based AstraZeneca vaccine, headache (52%), fatigue (53%), malaise (44%), myalgia(43%), fever (41%) and chills (32%) [36]. Various publications on vaccine side effects mention injection site pain [28, 30, 31]. Because an injection into a tense muscle causes greater pain than an injection into a relaxed muscle, doctors advise lowering the patient's arm to be injected to lessen pain[30]. Furthermore, vaccinations in situ should be stored at a low temperature; the Astrazenica and Sino-pharm COVID-19 vaccines should be stored at room temperature. Injections given without adequate warming may result in pain at the injection site [30].

In the present study, the younger adults (under 35 years) were more likely to have AEFIs than older adults (over 35 years). Vaccine reactogenicity has been linked to a transient increase in inflammatory cytokines, implying that vaccine reactogenicity decreases with age [37].

Some COVID-19 vaccine side effect studies[30, 31] have reported results that are similar to ours. Furthermore, the CDC claims that adverse effects are more noticeable after the first shot [38]. We found that the frequency of side effects after the second dosage of vaccine was moderately higher than the first shot, similar to the findings of recently published research [28]. This discovery could be explained by immune system responses. The immune system may create cytokines that cause inflammation in muscles, blood vessels, and other tissues, as well as flu-like symptoms that continue many days following immunization [39].

Women were more frequently afflicted by AEFIs than males in our study. Furthermore, most studies have found that females experience higher adverse effects than males for both COVID-19 vaccination dosages [28, 30, 31]. The differences in side effects documented across genders for inactivated virus vaccinations such as the measles-mumps-rubella combo vaccine, influenza, and attenuated Dengue vaccines show that females have stronger immune responses and more frequent side effects [40].

Limitations of the study

There were some limitations to this investigation. Because it was a single-center trial, the sample size was extremely modest. Because only two vaccine types were utilized, the benefits and hazards of other vaccination types could not be compared.

There was no comparison group because no asymptomatic HCWs were collected. The vaccinated HCWs were only rated after they reported any symptoms, and there was no scheduled follow-up. Due to the lack of repeat RT-PCR testing and routine antibody testing (for logistical reasons), some asymptomatic PVIs may have been missed, resulting in 'over-reporting' of the vaccine's protective effect.

V. Conclusion

The most essential tool for achieving herd immunity and ending the COVID-19 epidemic is vaccination. Our findings imply that the HCWs immunizationslowered the number of COVID-19 cases, resulting in less severe disease. We also found that two doses of the vaccine reduce the risk of our employees contracting COVID-19, and that this risk will likely fall further once HCWs receive booster doses. The majority of the AEFIs reported were mild to moderate in severity and lasted only one or two days. More research is needed in the long run to prove this, taking into account the types of vaccines used and the types of viral variations in circulation in the country.

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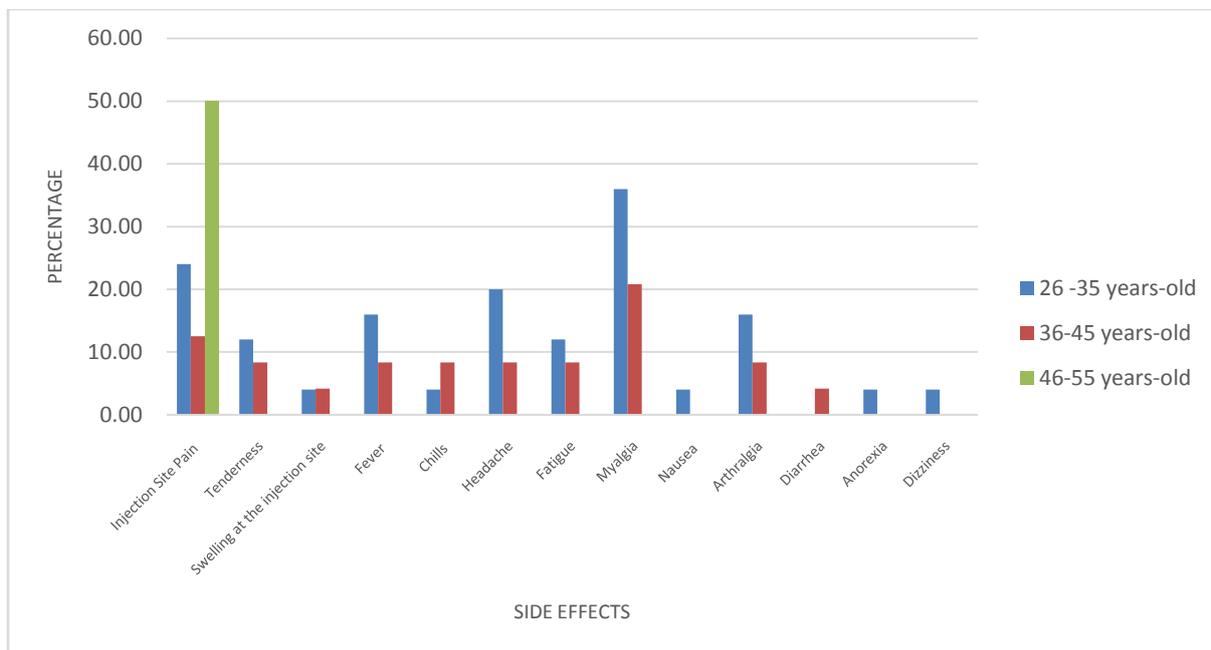


Figure 1. Side Effects of Viral Vector Vaccine of Participating Stratified by Age Group, (n = 41)

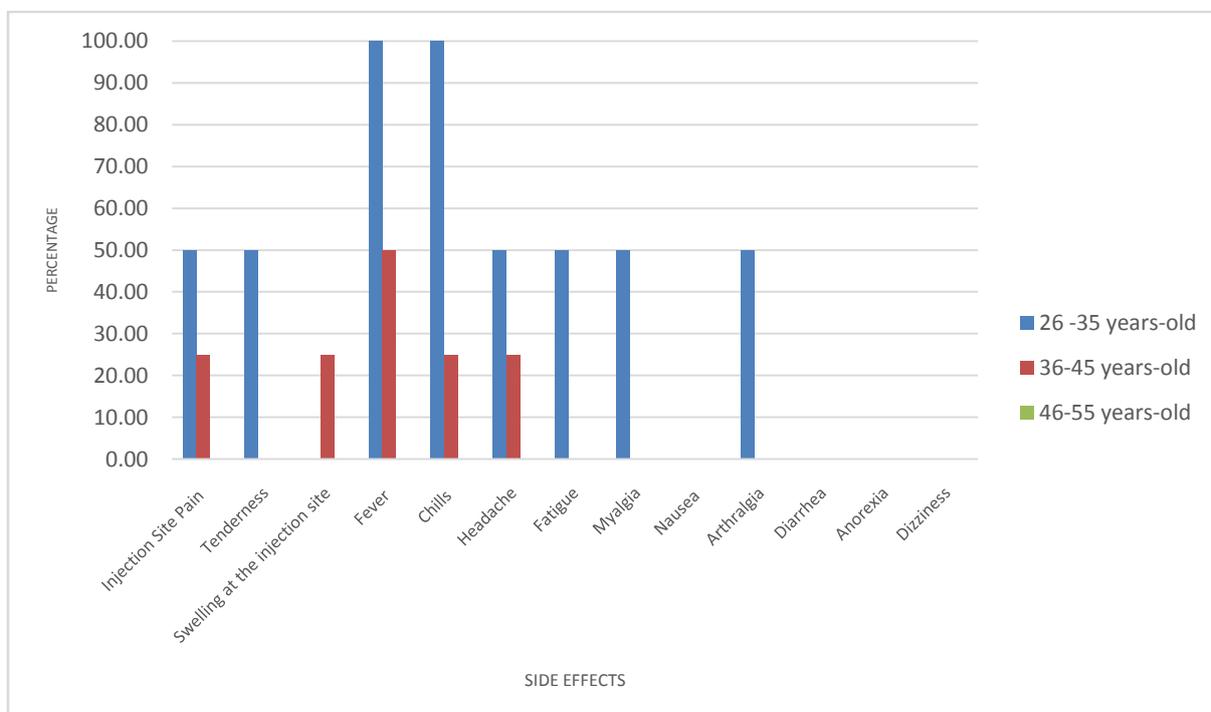


Figure 2. Side Effects of Inactivated vaccine of Participating Stratified by Age Group, (n = 7)

Table 1: Demographic Characteristics of Participating (n = 48).

Variable	Outcome	Viral Vector Vaccine	inactivated vaccine	Total
Gender	Female	23 (56.1%)	7 (100.0%)	30(62.5%)
	Male	18 (43.9%)	0 (0.0%)	18(37.5%)
Age group (yr)	26 -35 years-old	25(60.9%)	2 (28.6%)	27 (56.3%)
	36-45 years-old	14(34.2%)	4(57.1%)	18 (37.5%)
	46-55 years-old	2(4.9%)	1 (14.3%)	3 (6.2%)
	≥56 years-old	0(0.0%)	0(0.0%)	0(0.0%)
staff of Category	Nursing	20 (48.8%)	3(42.9%)	23(47.9%)
	Medical	18 (43.9%)	0 (0.0%)	18 (37.5%)
	Administration	3 (7.3%)	1 (14.2%)	4 (8.3%)
	Paramedic and supporting	0(0.0%)	3 (42.9%)	3 (6.3%)
Work Experience	1–2 years	5 (12.2%)	0 (0.0%)	5 (10.4%)
	2–5 years	11 (26.8%)	0 (0.0%)	11 (22.9%)
	5–10 years	15 (36.6%)	3 (42.8%)	18 (37.6%)
	>10 years	10 (24.4%)	4(57.2%)	14 (29.1%)
Hospital admission	Yes	2 (4.9%)	0 (0.0%)	2(4.2%)
	No	39 (95.1%)	7 (100.0%)	46 (95.8%)
ICU admission		0(0.0%)	0 (0.0%)	0 (0.0%)
Deaths		0(0.0%)	0 (0.0%)	0 (0.0%)

Table 2: Medical Anamneses of Participating (n = 48)

Variable	Outcome	Viral Vector Vaccine	Inactivated vaccine	Total
Noncommunicable Diseases (NCDs)	Allergy	3(7.3%)	1(14.3%)	4(8.3%)
	Asthma	2(4.9%)	1(14.3%)	3(6.2%)
	Blood Disease	2(4.9%)	0(0.0%)	2(4.2%)
	Bowel Disease	1(2.4%)	0(0.0%)	1(2.1%)
	Cancer	1(2.4%)	0(0.0%)	1(2.1%)
	Chronic Hypertension	2(4.9%)	0(0.0%)	2(4.2%)
	Dermatologic Disorder	1(2.4%)	0(0.0%)	1(2.1%)
	Diabetes Mellitus	2(4.9%)	1(14.3%)	3(6.2%)
	Neurologic Disorder	1(2.4%)	0(0.0%)	1(9.7%)
	Rheumatoid Arthritis	1(2.4%)	0(0.0%)	1(9.7%)
	Thyroid Disease	1(2.4%)	0(0.0%)	1(9.7%)
	Total		17(41.5%)	3(42.8%)

Table 3: COVID-19-related Anamneses of Participating (n=48)

Variable	Outcome	Viral Vector Vaccine	Inactivated vaccine	Total
Doses	One	1 (2.4%)	2 (28.6%)	3 (6.3%)
	Two	40(97.6%)	5(71.4%)	45 (93.7%)
Infection	Yes	8 (19.5%)	1 (14.3%)	9 (18.7%)
Exposure	Yes	26 (63.4%)	3 (42.8%)	29(60.4%)

Table 4. COVID-19 Vaccines General Side Effects of Participating (n=48)

Variable	Outcome	Viral Vector Vaccine	Inactivated vaccine	Total
Local SE	Injection Site Pain	10 (24.4%)	2 (28.6%)	12 (25.0%)
	Tenderness	5(12.2%)	1(14.3%)	6 (12.5%)
	Swelling at the injection site	2(4.8%)	1(14.3%)	3 (6.2%)
Systemic SE	Fever	6 (14.6%)	4 (57.1%)	10(20.8%)
	Chills	3 (7.3%)	3(42.9%)	6 (12.5%)
	Headache	7(17.1%)	2 (28.6%)	9 (18.7%)
	Fatigue	5 (12.2%)	1 (14.3%)	6 (12.5%)
	Myalgia	12 (29.3%)	2 (28.6%)	14 (29.2%)
	Nausea	1 (2.4%)	0(0.0%)	1 (2.1%)
	Arthralgia	6 (14.3%)	1 (14.3%)	7 (14.6%)
	Diarrhea	1 (2.4%)	0 (0.0%)	1 (2.1%)
	Anorexia	1 (2.4%)	0 (0.0%)	1 (2.1%)
	Dizziness	1 (2.4%)	0 (0.0%)	1 (2.1%)

BADREDDINE MOUKAFIH, et. al. "SARS-CoV-2 infection and side effects reported following COVID-19 vaccines: an observational study using surveillance data" *IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)*, 17(4), (2022): pp. 01-08.