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ORIGINAL RESEARCH

Short-term Side Effects of mRNA-based COVID-19 Vaccine Among Jordanian Population; a Cross-sectional Study

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Abstract: **Introduction:** One type of the developed COVID-19 vaccines that received emergency permission and was approved by the food and drug administration (FDA) is the mRNA-based vaccine. The aim of this study is to gather information on the Jordanian population's experience with the vaccine's side effects. **Methods:** The study objectives were addressed through a cross-sectional study, which collected information regarding the short-term side effects experienced by the vaccinated individuals within one month following the injection of an mRNA-based COVID-19 vaccine. Data collection was carried out in August 2021. Participants were invited to take part in a self-administered web-based survey created using Google Forms. **Results:** Among the study's participants (n= 533), about 56% experienced side effects after the first dose of the mRNA-based COVID-19 vaccine. The most commonly reported side effects after the first dose were sore arm at the injection site (91.6%), and fatigue (83.06%). The female gender was significantly associated with experiencing fatigue, discomfort, chills, and hair loss. Being over 30 years old was significantly associated with experiencing cough. Being a smoker was significantly associated with experiencing shortness of breath and gastrointestinal symptoms. **Conclusion:** The mRNA-based COVID-19 vaccine side effects were common, yet, mild, local, and self-limited. The local pain at the injection site was the most commonly reported side effect. Hopefully, the study's findings will aid in lowering resistance to vaccination.

Keywords: Coronavirus; COVID-19; adverse effects; vaccines; mRNA vaccine; COVID-19 vaccines; Jordan

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1. Introduction

In December 2019, the novel coronavirus (SARS-CoV-2) was first recognized in Wuhan, China. It causes a highly infectious disease referred to as COVID-19 (1). The COVID-19 has spread globally to turn into a worldwide pandemic (2). Healthcare providers, policymakers, governments, and researchers were eagerly working around the clock to provide sufficient prevention and treatment modalities to fight the pandemic (3). Worldwide, several preventive measures were imposed by the governments in order to reduce the spread of the virus and the burden on the healthcare sector; for example, quarantine and social distancing were imposed, also wearing a face mask was made mandatory in public places (4, 5).

The public health emergency needed urgent efforts to develop and test the vaccines to combat the COVID-19 pandemic (3). Thus, several vaccines were developed and granted emergency approval (6). One type of the developed vaccines is the mRNA-based COVID-19 vaccine, which was approved by the United States Food and Drug Administration in December 2020 (7). To get fully vaccinated with the mRNA-based vaccine, two doses are required; the second dose must be administered at least three weeks after the first dose. The vaccine can provide efficient protection one week after the second dose (8).

In January 2021, Jordan was one of the first countries to launch vaccination campaigns, giving emphasis to healthcare professionals and the elderly (9). Despite the government's continuous attempts to guarantee that most of the population is vaccinated; myths, fear, safety concerns, and negative beliefs have adversely shaped the perception of the public, which in turn affected the percentage of infected individuals.

Variation in public awareness and perception toward vaccines is generally documented (10-12). Furthermore, hesitancy is another major factor that influenced the decision of the individual whether to receive the vaccine or not (11, 12). Hesitancy associated with getting vaccinated is com-

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mon, partly due to the fact that the COVID-19 vaccines were rapidly developed (13). Concerns and fears of individuals who are hesitant to vaccinate should be addressed. This calls for urgent public transparency and engagement (12).

Thus, it is crucial to collect data regarding COVID-19 vaccines' side effects in order to educate and clarify to the public what to anticipate post-vaccination. This information may contribute to increasing confidence in COVID-19 vaccines, as well as, decreasing hesitancy.

Hence, the aim of this study is to gather information on the Jordanian population's experience with the COVID-19 vaccine's immediate side effects.

2. Methods

2.1. Study design and settings

The study objectives were addressed through a cross-sectional study, which was performed to collect information regarding the short-term side effects experienced by the vaccinated individuals within one month following the injection of an mRNA-based COVID-19 vaccine. Data collection was carried out in August 2021. Participants were invited to take part in a self-administered web-based survey created using Google Forms. The survey was adjusted in a way that allows the participant to send one response only.

Ethical approval for this study was obtained from the Institutional Review Board Committee at the Faculty of Pharmacy, Applied Science Private University (Ethics code: 2021-PHA-31). Participation in the study was voluntary. Informed consent to participate in the study was provided by participants.

2.2. Participants

Eligibility criteria included residing in Jordan, and having received at least one dose of the mRNA-based COVID-19 vaccine. Individuals living in any geographic area were allowed to participate in the study. Participants should have the ability to provide their information by completing the online survey.

2.3. Data gathering

The survey items were selected based on the existing information regarding the side effects of the mRNA-based COVID-19 vaccine (Pfizer-BioNTech®). Following an extensive review of the literature on PubMed, Google Scholar, and other databases, the first draft of the survey was developed (8, 14, 15). The survey questions were reviewed to merge concepts and eliminate unrelated items.

Three experts in the field reviewed the first draft to ensure its face and content validity, then the survey was updated based on their feedback. Assessment criteria were sent to them (appropriateness of the words used, clarity of items, suitability of content, consistency of survey style and its layout). They informed the research team that the survey is clear, comprehensive, the items are relevant to the study objectives and suitable for the study's aim. Moreover, they confirmed that the study survey is free from difficult terminology and medical jargon.

To assess the clarity of words and item comprehension, a pilot study was conducted. The pilot study participants were excluded from the analysis of the current study, and additional amendments were conducted based on their suggestions. To finalize, the questions were re-evaluated to make them concise and suitable for online administration (format, sequencing, general clarity, and graphic layout).

The final developed survey was organized into two major sections addressing the domains of interest. The first section included items to collect participants' demographic data, such as gender, age, marital status, educational level, employment, living place, and nationality. Additionally, the following information was also collected; whether they were smokers, had any chronic disease(s), whether they were using any medication(s), and if they were previously infected with COVID-19. The second section included items that aimed to collect information regarding the side effects experienced following the injection of mRNA-based COVID-19 vaccine; the following data were collected: the date of vaccination (month), the number of doses that were taken (one or two doses), and the side effects that were experienced after receiving each dose. Additionally, in this section, participants were asked if they needed hospitalization within a month of receiving the vaccine, and they were requested to select the dose that caused the most severe side effects.

2.4. Survey implementation

Study participants were recruited through social media (mainly Facebook and WhatsApp). As the first step in participants' selection, they were asked if they had received the first dose of the mRNA-based COVID-19 vaccine. This question should be answered with 'Yes' in order to be able to open the survey. Eligible participants who indicated a willingness to participate in this study were also able to open a link to see the study's ethics committee approval letter, and afterward, they were able to complete the survey.

Communication between the researcher and the participants was established via e-mail when needed. The survey was designed to take less than five minutes to be completed.

2.5. Statistical analyses

The sample size was determined based on population and the number of vaccinated individuals in Jordan. It was calculated to be a minimum of 384 participants, using a margin of error of 5%, a confidence level of 95%, and a response distribution of 50% (16).

The survey responses were coded and entered into a cus-

Table 1: Demographic characteristics of the studied participants (n= 533)

Parameter	Number (%)
Gender	
Male	119 (22.3)
Female	414 (77.7)
Age (year)	
< 18	8 (1.5)
18-29	219 (41.1)
30-39	195 (36.6)
40-49	75 (14.1)
50-59	27 (5.1)
≥ 60	9 (1.7)
Marital Status	
Married	294 (55.0)
Single	217 (40.7)
Divorced	20 (3.8)
Widowed	2 (0.4)
Living place	
Amman (the Capital)	403 (75.6)
Other cities	130 (24.4)
Nationality	
Jordanian	491 (92.1)
Non-Jordanian	42 (7.9)
Educational level	
Primary school	6 (1.1)
Some high school	27 (5.1)
High school diploma	35 (6.6)
Bachelor's degree	367 (68.9)
Postgraduate degree (Master's or PhD)	98 (18.4)
Employment	
Employed	282 (52.9)
Not employed	236 (44.3)
Retired	15 (2.8)
Smoker	
Yes	154 (28.9)
No	365 (68.5)
Previous smoker	14 (2.6)

tomized database using the Statistical Package for the Social Sciences (SPSS), Version 24.0 (IBM Corp., Armonk, New York, USA). Qualitative variables were presented as percentages. Fisher's exact test was used to assess the association between each side effect after the first dose of the mRNA-based COVID-19 vaccine and participants' gender, age, and smoking status. The p-value cutoff for significance was established at 0.05.

3. Results

3.1. Baseline characteristics of studied cases

The survey was distributed to 545 participants; however, 12 individuals refused to participate in the current study leaving a response rate of 97.8%. The detailed demographic characteristics of the participants are listed in Table 1. The majority of the study's participants were female (77.7%), about 43% of the participants were less than 30 years old, more than half of the participants (55.0%) were married, 92.1% had a Jordanian nationality, and 87.3% had a bachelor's or postgraduate degree. More than half of the participants were employed (52.9%), and about one-third of the participant were smokers (28.9%).

The most common comorbidity among the participants was allergy (19.5%). The percentages of other comorbidities were low, ranging from 0.4% (chronic obstructive pulmonary disease) to 6.6% (thyroid diseases). More than half of the participants (52.7%) were not infected prior to receiving the mRNA-based COVID-19 vaccine, whereas, 37.9% had been affected with COVID-19 prior to vaccination, and the remaining (9.4%) were unsure. In May 2021, 26.1% of the study's participants had received the first dose of the mRNA-based COVID-19 vaccine, while the lowest percentage was reported in January 2021 (2.1%).

3.2. Side effects

Regarding the side effects after the first dose of the mRNA-based COVID-19 vaccine, 300 (56.3%) cases reported experiencing various side effects. The most common side effect that was reported by the participants was sore arm at the site of injection (91.6%). Fatigue and tiredness (83.6%), discomfort (69.6%), muscle/joint pain (60.3%), drowsiness (59.0%), and headache (57.6%) were reported by more than half of the participants (Figure 1).

Association between side effects after the first dose of the mRNA-based COVID-19 vaccine and participants' gender, age, and smoking status were investigated. As shown in Figure 2, there is a significant association between the female gender and experiencing fatigue (p = 0.033), discomfort (p = 0.013), chills (p = 0.003), and hair loss (p-value= 0.017). A significant association was found between being older than 30 and experiencing cough (p = 0.046). Furthermore, a significant association was found between being a smoker and experiencing shortness of breath (p = 0.042), and gastrointestinal symptoms (p = 0.049).

Out of the 533 participants, 402 (75.4%) had received the second dose of the mRNA-based COVID-19 vaccine. Among those participants (n= 402), about 66.0% (n= 267) experienced side effects after the second dose of the mRNA-based COVID-19 vaccine.

The most common side effect that was reported by the participants after the second dose was a sore arm at the site of injection (88.8%). Fatigue, discomfort, muscle/joint pain, headache, and drowsiness were also reported by more than half of the participants (Figure 1).

More than half (58.8%) of the study participants who had side effects after both doses stated that the second dose was accompanied by more severe side effects; in contrast, 24.7%

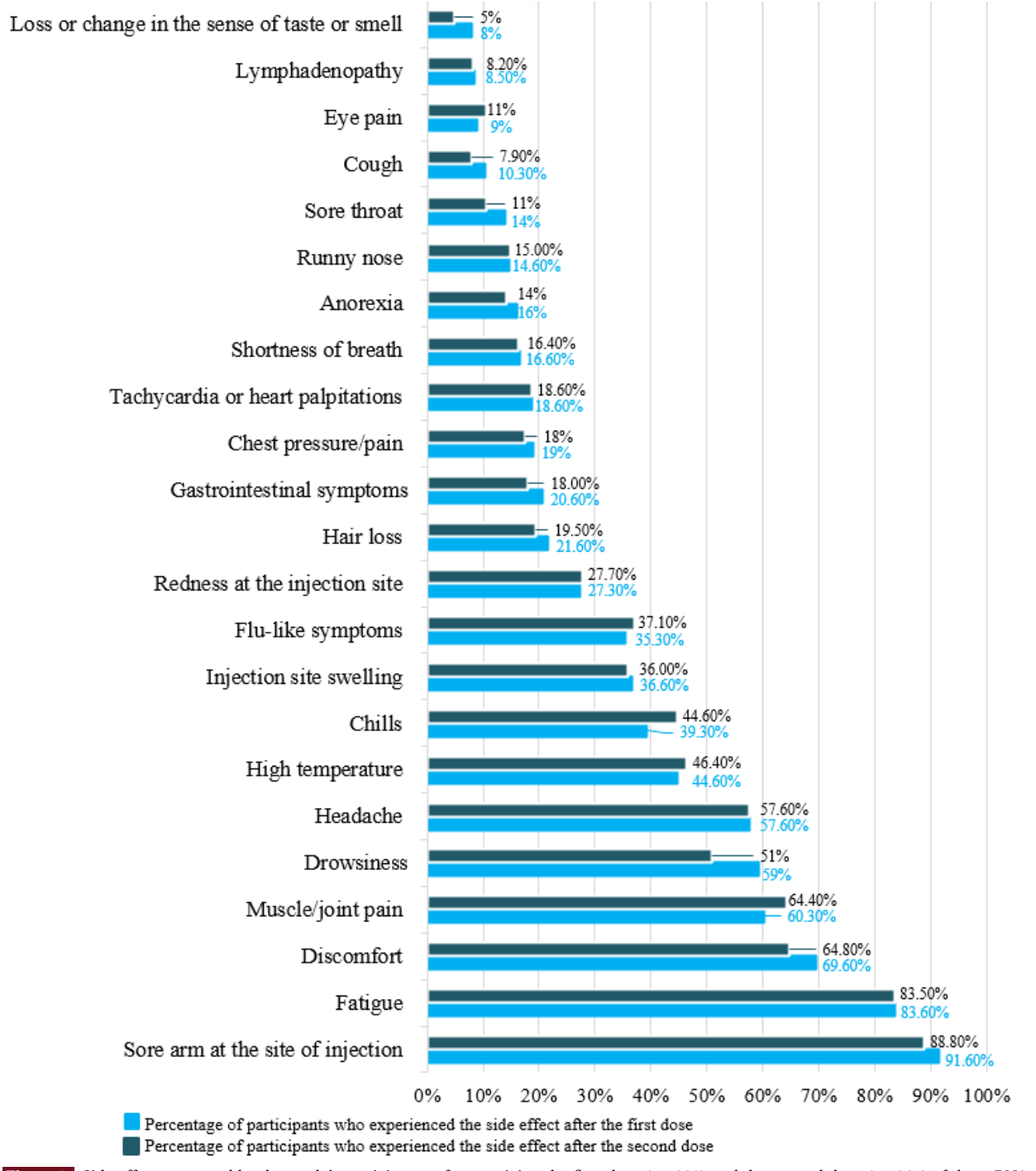

Figure 1: Side effects reported by the study's participants after receiving the first dose (n= 300) and the second dose (n= 267) of the mRNA-based COVID-19 vaccine (the difference was only significant for drowsiness ($p = 0.033$)).

chose the first dose, and 16.5% said there was no difference between the two doses.

A statistically significant increase ($p < 0.000$) was found in the proportion of the participants who experienced side effects after the second dose (66.4%) compared to the first dose. Moreover, as shown in figure 1, drowsiness was the only side effect that showed a significant difference in the proportion of participants who experienced it following the first and

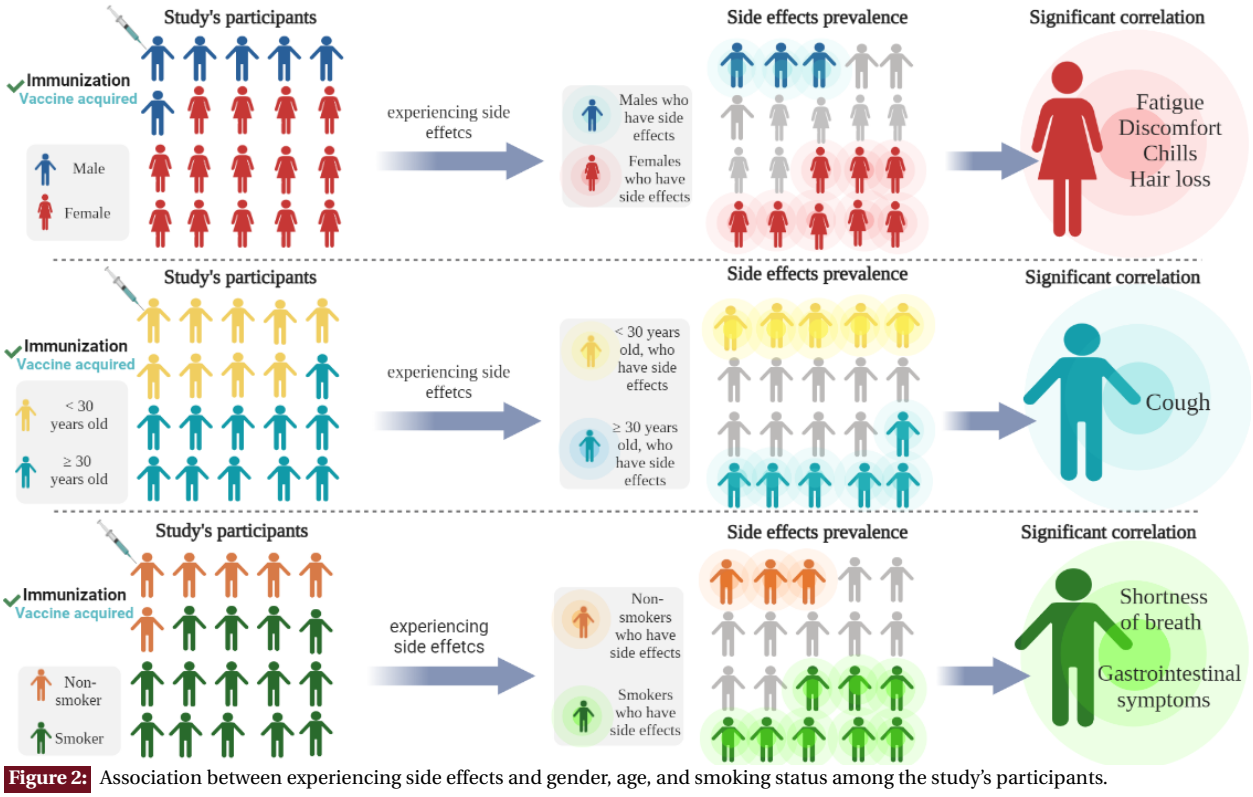

Figure 2: Association between experiencing side effects and gender, age, and smoking status among the study's participants.

the second dose of the mRNA-based COVID-19 vaccine (p = 0.033).

4. Discussion

This is the first cross-sectional study conducted on the Jordanian population to specifically assess the side effects of mRNA-based COVID-19 vaccine. Receiving the COVID-19 vaccine is a major intervention toward containing the pandemic. However, it has been faced with hesitancy (17-19). Limited data about the COVID-19 vaccines development account for the high level of uncertainty and hesitancy toward COVID-19 vaccine acceptance (17). Hesitancy toward receiving the COVID-19 vaccine should be addressed. Thus, similar to the current study, several studies were conducted to reveal side effects associated with COVID-19 vaccines in order to provide the general public with data regarding COVID-19 vaccines, which in turn would decrease hesitancy and explain to the public what to expect after the vaccination (8, 13, 15, 20-26).

Global vaccination campaigns have been launched to stop the COVID-19 pandemic. Real-world observing of COVID-19 vaccine safety is still crucial even though clinical trial studies revealed that the majority of COVID-19 vaccines have excellent safety and efficacy profiles. In the current study, sore arm at the injection site, fatigue, discomfort, muscle/joint pain, drowsiness, and headache were reported by more than half of the participants who experienced side effects (300 out of 533 participants for the first dose, and 267 out of 402 participants for the second dose) after both doses. These findings are in line with several published studies, and are consistent with the side effects listed by the United States Centers for Disease Control and Prevention (CDC) (27). For example, in Saudi Arabia, a survey-based study was conducted to assess the side effects of mRNA-based COVID-19 vaccine, 386 participants completed the survey. The most commonly reported side effects were local pain, fatigue, and muscle pain (79.3%, 42.0%, 39.1%, respectively) (28). Another cross-sectional study conducted in Saudi Arabia documented that the most common side effects reported by the participants were injection site pain, and headache (8). Moreover, a cross-sectional study was conducted among healthcare workers in Czech Republic (15). Injection site pain (89.8%), fatigue (62.2%), headache (45.6%), muscle pain (37.1%), and chills (33.9%) were the most frequently reported side effects experienced by the study participants (n= 877). Moreover, the side effects were more common among older participants (≤/≥43-year-old group) (15). Another cross-sectional study was conducted among healthcare workers (n= 803 received the mRNA-based COVID-19 vaccine), and the most common side effects reported by more than half of the participants

were localized, generalized, and musculoskeletal symptoms (89.5%, 76.0%, 53.3%, respectively) (29). The reported rates of side effects have varied between conducted studies due to differences in race, age, and underlying conditions.

A recent systemic review was undertaken to assess the mRNA-based COVID-19 vaccine side effects. The most frequently reported side effects among the total number of the participants (n= 10,632) in all articles (107 were screened, and 14 were included) were injection site pain, fatigue, muscle pain, local swelling, and headache (77.3%, 43.0%, 39.7%, 33.6%, 33.3%, respectively) (30). The review findings were in line with the current study findings, as the most commonly reported side effect among the current study's population was sore arm at the injection site.

It is obvious that injection site pain was the most commonly reported side effect among most of the studies conducted on different populations (31-33). Moreover, local pain continues to be the most frequent side effect observed in multiple vaccine trials conducted in the past (34). The reason behind this finding may be explained by the fact that several factors contribute to the pain at the injection site such as the technique used for injection, injection velocity, and vaccine temperature. These factors are challenging to standardize and will have a significant impact on a person's experience (35). It is advised to lower the arm that will be receiving the injection in order to reduce the pain, as an injection into a relaxed muscle causes less pain. Furthermore, it is recommended that the medical staff participating in the vaccination process acquire proper training on the best injection technique to lessen differences in the way individuals experience pain after vaccination (36).

Males and females react to vaccination differently. As documented in a systemic review, the rate of experienced side effects is usually higher in females compared to males (69.8%, 30.2%, respectively) (30). Being female, was a statistically significant factor for experiencing higher number of side effects in two cross-sectional studies conducted in Saudi Arabia (8, 28). Various other published studies observed a gender difference, with females experiencing significantly more side effects compared to males (37, 38). This is consistent with the current study's findings. Moreover, the current study revealed that the female gender is significantly associated with experiencing fatigue, discomfort, chills, and hair loss. This is probably due to a combination of biological factors, such as hormones and genes. Additionally, sex variation in pharmacodynamics and pharmacokinetics have been examined, with females being more susceptible to side effects (39). A medical officer at the CDC's Immunization Safety Office stated that women have more reactions to a range of vaccines. This covers both adult influenza and some childhood vaccinations, such as the hepatitis B, and measles, mumps, and rubella (MMR) vaccines (40). On the other hand, these findings should not be deemed bad news for women, as firstly, the side effects were mild, and self-limited, and secondly, interestingly, these physical responses indicate that the vaccine is effective and working.

According to the results of the current study, experiencing cough was significantly associated with being older than 30. Several studies assessed the relationship between age and side effects. Baden et al. found that younger participants (18-64 years old) experienced side effects more frequently than participants over the age of 65 (41). Another survey-based study conducted among German healthcare workers revealed that younger participants were more affected by the systemic side effects compared to the older age participants following receiving the mRNA-based COVID-19 vaccine (67.4% vs. 54.5%) (26). The authors' decision to use a different age cutoff in each study may account for the variance in the studies' findings.

More than half of the current study's participants stated that the second dose was accompanied by more severe side effects. Two cross-sectional studies conducted in Saudi Arabia documented similar results, the first one recorded that after the second dose, higher numbers of side effects were reported by the participants compared to the first dose (28), and the second one indicated a significant increase in the proportion of respondents who experienced side effects after receiving the second dose compared to the first dose (8). According to the data collected by the CDC from mRNA-based COVID-19 vaccine recipients in the United States, more side effects were recorded after the second dose. Furthermore, equivalent findings were generated by the FDA (42), and several other studies (37).

5. Limitations

This study comes with some limitations. The study was based on an online survey, and this might be a source of selection bias.

However, web-based recruitment of participants was found to be cost-effective, facilitating the reach of people who are otherwise difficult to reach, and representative (43, 44). In Jordan, around 90% of the population have internet access, which makes them easy to reach using online-based questionnaires. Another limitation of this study is that it was conducted while the vaccination campaign was still ongoing in Jordan; therefore, the delayed side effects may not have been reported.

6. Conclusions

The current study reveals the side effects associated with the mRNA-based COVID-19 vaccine, which were common, yet, mild, local, and self-limited. The local pain at the injection site was the most commonly reported side effect.

7. Declarations

7.1. Acknowledgments

None.

7.2. Conflict of interest

The author declares no relevant conflicts of interest or financial relationships.

7.3. Fundings and supports

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7.4. Authors' contribution

R.N: Conceptualization, Methodology, Validation, Formal Analysis, Investigation, Data Curation, Writing - Original Draft Preparation, Writing- Review and Editing.

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