International Journal of Advances in Medicine
Alharbi AA et al. Int J Adv Med. 2022 Mar;9(3):194-200
http://www.ijmedicine.com
pISSN 2349-3925 | eISSN 2349-3933
DOI: https://dx.doi.org/10.18203/2349-3933.ijam20220381

Original Research Article

Survey data of COVID-19 vaccine side effects among Qassim University members

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Received: 31 January 2022
Revised: 07 February 2022
Accepted: 08 February 2022

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ABSTRACT

Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was initially reported as a culprit for many unexplained cases of pneumonia in Wuhan, China. Since then, COVID-19 vaccine is highly recommended as a protective measure of this pandemic. This study aimed to measure the safety profile of the COVID-19 vaccine among Qassim University members.
Methods: This is a cross-sectional observational study conducted among Qassim University members, Saudi Arabia. A pre-specified questionnaire was distributed among prospective members of the campus using an online survey. Participants who were vaccinated by either one or two doses were the subjects of this study. Consent was sought from the participants or next of kin and the data collection were lasted for over three months.
Results: The 604 respondents were able to recruit (51.7% males versus 48.3% females). 55.6% of respondents were in the younger age group (age ≤25 years). The most commonly received vaccine was Pfizer (67.3%) while the most common side effect was local pain at the site of injection (89.4%) and tiredness (76.7%). Females were significantly more being associated with having COVID-19 vaccine side effects, while complained about fever was significantly higher in the AstraZeneca vaccine ($p<0.001$).
Conclusions: Our findings were consistent with literatures, our study finds local pain at the site of injection, tiredness, muscle pain, headache and fever as the most common side effects of the COVID-19 vaccine. The side effects of the COVID-19 vaccine had a greater impact on female respondents than their male counterparts.

Keywords: COVID-19 vaccine, Side effect, Pfizer, AstraZeneca

INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was initially reported as a culprit for many unexplained cases of pneumonia in Wuhan, China. It was reported in December 2019, hence its name. It was rapidly spreading infectious pathogen resulting in an epidemic, then disseminated globally to other countries throughout the world. In February 2020, the World Health Organization (WHO) named the disease as COVID-19 and in March 2020, characterized as a pandemic. The virus that cause COVID-19 was referred to as 2019-nCoV.

Severe COVID-19 associated sepsis is characterized by acute respiratory distress syndrome (ARDS), secondary bacterial pneumonias, thrombotic complications, myocarditis, and gastrointestinal involvement are more prevalent in those with comorbidities such as

hypertension, diabetes, cardiac disease, cancer and age >70 years.[1]

Current data are limited in many aspects, including the way how it would be prevented. Recently, plenty vaccine candidates against SARS- CoV-2, which causes COVID-19, have entered clinical trials.[2] In December 2020, first COVID-19 vaccine was approved by United States food and drug administration (US FDA) which was manufactured by Pfizer-bioNTech companies. And currently other vaccines are FDA approved, such as Moderna vaccine, the university of Oxford/AstraZeneca vaccine and Johnson and Johnson vaccine. These vaccines had variable safety profile in different populations.[3,4] In these vaccines, the most frequently encountered adverse events were headache, fatigue, myalgia, chills, and injection site pain.[3,4]

Since COVID vaccine is highly recommended as protective measure of this pandemic, we are looking for the safety profile of all Saudi food and drug authority approved vaccine, among Qassim University members.

METHODS

Trial design

Cross-sectional observational study using prespecified questionnaire was used.

Study setting

Online survey distributed among Qassim University members was conducted.

Sample size

We estimated the sample size by Epi-Info app, the estimated size was 586. The study conducted over a period of 4 months from 1st August 2021 till end of November 2021.

Sampling technique

Non-probability sampling technique through online distribution was used in the study among various Qassim University members.

Inclusion criteria

Participant 18 years or more, Qassim university members, and vaccinated participants either one or two doses were included in the study.

Exclusion criteria

Duplicated attempt of the survey (through direct question and by tracing electronic device IPs), and not meeting inclusion criteria were excluded.

Data collection methods

Data will be collected by online survey (questionnaire), which will be distributed among participants. And a copy of questionnaire will be attached. It was validated and revised by two research experts, and we conducted a pilot study with 10 participants to confirm and verify the instrument's validity.

Data analysis plan

Categorical variable in the research was utilized.

Chi square between categorical variable, parametric (T test) if normally distributed from standard deviation after discussion and collaboration with biostatistician.

Pilot study

A pilot study for a sample of study population was conducted to ensure the feasibility of the study, clarity of the questionnaire questions, and to estimate the time needed to fill it. The pilot study sample data will not be included in the main study sample.

Consent

Consent will be sought from participants or next of kin.

Statistical analysis

The data were analyzed using statistical packages for social sciences (SPSS) version 26 (Armonk, NY: IBM Corp., USA). Categorical variables are presented using numbers and percentages. The prevalence of COVID-19 vaccine side effects as compared with the age group, gender, and type of vaccine by using Chi-square test. The level $p<0.05$ was considered as the cut‑off value for significance.

RESULTS

A total of 604 university members had been recruited. Table 1 describes the basic demographic characteristics of participants. The most common age group was 18–25 years old (55.6%) with more than half being males (51.7%). Student in a non-medical field constitutes 54.8%. Higher educational levels constitute most of the respondents (75.5%) and most of the respondents were living in the Qassim area (92.5%). The most common type of vaccine was Pfizer (67.3%).

Figure 1 shows the COVID-19 vaccine side effects. It can be observed that the most common side effect was local pain at the site of injection (89.4%), followed by tiredness (76.7%) and muscle pain (72.7%).

Figure 2 depicted the timing when the COVID-19 vaccine side effects appeared or disappeared. It was revealed that

the side effect mostly appeared (45.4%) or disappeared (54.5%) in a duration of 1–3 days.

Table 1: Basic demographic characteristics of participants (n=604).

Study data	N (%)
Age group (years)	
18–25	336 (55.6)
>25	268 (44.4)
Gender	
Male	312 (51.7)
Female	292 (48.3)
Occupational status	
Employee in the medical field	14 (02.3)
Employee in a non-medical field	57 (09.4)
Student in a medical field	202 (33.4)
Student in a non-medical field	331 (54.8)
Educational level	
General education	148 (24.5)
Higher education	456 (75.5)
Residence area	
Qassim	559 (92.5)
Outside Qassim	45 (07.5)
Type of vaccine *	
Pfizer	263 (67.3)
Oxford AstraZeneca	59 (15.1)
Both	69 (17.6)

*213 were missing cases and have been excluded from the analysis.

When measuring the prevalence of COVID-19 side effects according to age group, it was found that COVID-19 side effects such as itching (p=0.010), breathlessness (p=0.043) and joint pain (p=0.028) were more common among age group >25 years. We also observed that the prevalence of respondents who indicated that the COVID-19 vaccine side effect disappeared between 1–3 days was more common among the younger age group (age ≤25 years) (p=0.001) (Table 2).

When measuring the prevalence of COVID-19 side effects according to gender, it was observed that the prevalence of COVID-19 side effects such as swelling (p<0.001), redness (p=0.002), itching (p=0.037), local pain at the site of injection (p<0.001), numbness (p<0.001), muscle pain (p=0.001), tiredness (p=0.004), diarrhea (p=0.029), nausea and vomiting (p<0.001), breathlessness (p<0.001), joint pain (p<0.001) and fainted (p=0.020) were significantly more common among females.

On the other hand, the prevalence of respondents who stated that the COVID-19 vaccine side effect disappeared between 1–3 days was more common among males (p=0.004) (Table 2).

In Table 4, the prevalence of headaches due to COVID-19 vaccine side effects was more common among AstraZeneca vaccine. Other COVID-19 vaccine side effects did not show a significant relationship with the type of COVID-19 vaccines (p>0.05).

Table 2: Prevalence of COVID-19 vaccine side effect in age group (n=604).

COVID-19 vaccine side effect	≤25 years N (%) (n=336)	>25 years N (%) (n=268)	P value§
Swelling	62 (18.5)	63 (23.5)	0.128
Redness	52 (15.5)	54 (20.1)	0.134
Itching	47 (14.0)	59 (22.0)	0.010 **
Local pain at the site of the injection	295 (87.8)	245 (91.4)	0.151
Numbness	94 (28.0)	88 (32.8)	0.196
Fever	195 (58.0)	164 (61.2)	0.432
Headache	205 (61.0)	184 (68.7)	0.051
Muscle pain	249 (74.1)	190 (70.9)	0.379
Tiredness	254 (75.6)	209 (78.0)	0.490
Coughing	41 (12.2)	23 (08.6)	0.151
Diarrhea	24 (07.1)	25 (09.3)	0.328
Nausea and vomiting	52 (15.5)	54 (20.1)	0.134
Breathlessness	30 (08.9)	38 (14.2)	0.043 **
Joint pain	110 (32.7)	111 (41.4)	0.028 **
Fainted	19 (05.7)	15 (05.6)	0.976
Anaphylactic reaction	21 (06.3)	09 (03.4)	0.104
Swollen lymph node	17 (05.1)	13 (04.9)	0.907
Hospital admission	08 (02.4)	07 (02.6)	0.856
Time when COVID-19 vaccine side effect appeared (days)			
No symptoms	25 (07.4)	24 (09.0)	0.094
<1	145 (43.2)	111 (41.4)	

Continued.

COVID-19 vaccine side effect	≤25 years N (%) (n=336)	>25 years N (%) (n=268)	P value§
1–3	156 (46.4)	118 (44.0)	
4–7	09 (02.7)	07 (02.6)	
>7	01 (0.30)	08 (03.0)	
Time when COVID-19 vaccine side effect disappeared (days)			
No symptoms	44 (13.1)	41 (15.3)	
<1	41 (12.2)	36 (13.4)	
1–3	201 (59.8)	128 (47.8)	0.001 **
4–7	46 (13.7)	45 (16.8)	
>7	04 (01.2)	18 (06.7)	

§P value has been calculated using Chi-square test; **significant at p<0.05 level.

Table 3: Prevalence of COVID-19 vaccine side effect in gender (n=604).

COVID-19 vaccine side effect	Male N (%) (n=312)	Female N (%) (n=292)	P value§
Swelling	43 (13.8)	82 (28.1)	<0.001**
Redness	40 (12.8)	66 (22.6)	0.002**
Itching	45 (14.4)	61 (20.9)	0.037**
Local pain at the site of injection	260 (83.3)	280 (95.9)	<0.001**
Numbness	68 (21.8)	114 (39.0)	<0.001**
Fever	180 (57.7)	113 (38.7)	0.367
Headache	193 (61.9)	196 (67.1)	0.177
Muscle pain	208 (66.7)	231 (79.1)	0.001**
Tiredness	224 (71.8)	239 (81.8)	0.004**
Coughing	30 (09.6)	34 (11.6)	0.418
Diarrhea	18 (05.8)	31 (10.6)	0.029**
Nausea and vomiting	36 (11.5)	70 (24.0)	<0.001**
Breathlessness	18 (05.8)	50 (17.1)	<0.001**
Joint pain	80 (25.6)	141 (48.3)	<0.001**
Fainted	11 (03.5)	23 (07.9)	0.020**
Anaphylactic reaction	13 (04.2)	17 (05.8)	0.349
Swollen lymph node	17 (05.4)	13 (04.5)	0.573
Hospital admission	10 (03.2)	05 (01.7)	0.239
Time when COVID-19 vaccine side effect appeared (days)			
No symptoms	25 (08.0)	24 (08.2)	
<1	137 (43.9)	119 (40.8)	
1–3	136 (43.6)	138 (47.3)	0.421
4–7	11 (03.5)	05 (01.7)	
>7	03 (01.0)	06 (02.1)	
Time when COVID-19 vaccine side effect disappeared (days)			
No symptoms	37 (11.9)	48 (16.4)	
<1	50 (16.0)	27 (09.2)	
1–3	180 (57.7)	149 (51.0)	0.004**
4–7	35 (11.2)	56 (19.2)	
>7	10 (03.2)	12 (04.1)	

§ P value has been calculated using Chi-square test; ** significant at p<0.05 level.

Table 4: Prevalence of COVID-19 vaccine side effect in the type of vaccine (n=604).

COVID-19 vaccine side effect	Pfizer N (%) (n=263)	AstraZeneca N (%) (n=59)	Both N (%) (n=69)	P value§
Local pain at the site of injection	242 (92.0)	54 (91.5)	65 (94.2)	0.806
Tiredness	198 (75.3)	50 (84.7)	58 (84.1)	0.123
Muscle pain	190 (72.2)	45 (76.3)	49 (71.0)	0.777

Continued.

COVID-19 vaccine side effect	Pfizer N (%) (n=263)	AstraZeneca N (%) (n=59)	Both N (%) (n=69)	P value§
Headache	166 (63.1)	43 (72.9)	52 (75.4)	0.088
Fever	139 (52.9)	49 (83.1)	55 (79.7)	<0.001**
Joint pain	103 (39.2)	28 (47.5)	28 (40.6)	0.503
Numbness	100 (38.0)	15 (25.4)	21 (30.4)	0.131
Swelling	58 (22.1)	12 (20.3)	18 (26.1)	0.706
Redness	51 (19.4)	11 (18.6)	12 (17.4)	0.930
Nausea and vomiting	50 (19.0)	14 (23.7)	14 (20.3)	0.713
Itching	43 (16.3)	10 (16.9)	16 (23.2)	0.410
Breathlessness	40 (15.2)	05 (08.5)	08 (11.6)	0.343
Coughing	27 (10.3)	06 (10.2)	08 (11.6)	0.946
Diarrhea	21 (08.0)	04 (06.8)	09 (13.0)	0.353
Fainted	21 (08.0)	01 (01.7)	04 (05.8)	0.205
Swollen lymph node	14 (05.3)	01 (01.7)	01 (01.4)	0.211
Anaphylactic reaction	09 (03.4)	01 (01.7)	02 (02.9)	0.782
Hospital admission	04 (01.5)	02 (03.4)	01 (01.4)	0.603

§P value has been calculated using Chi-square test; **significant at p<0.05 level.

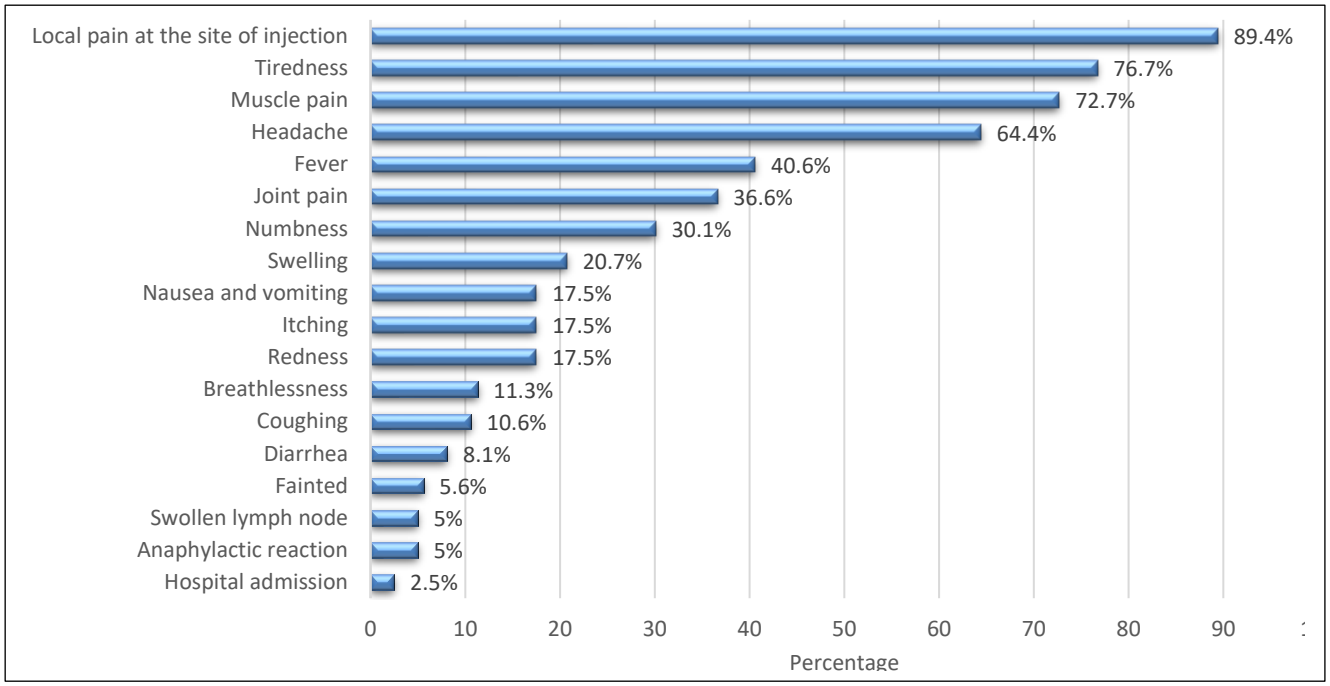

Figure 1: COVID-19 vaccine side effects.

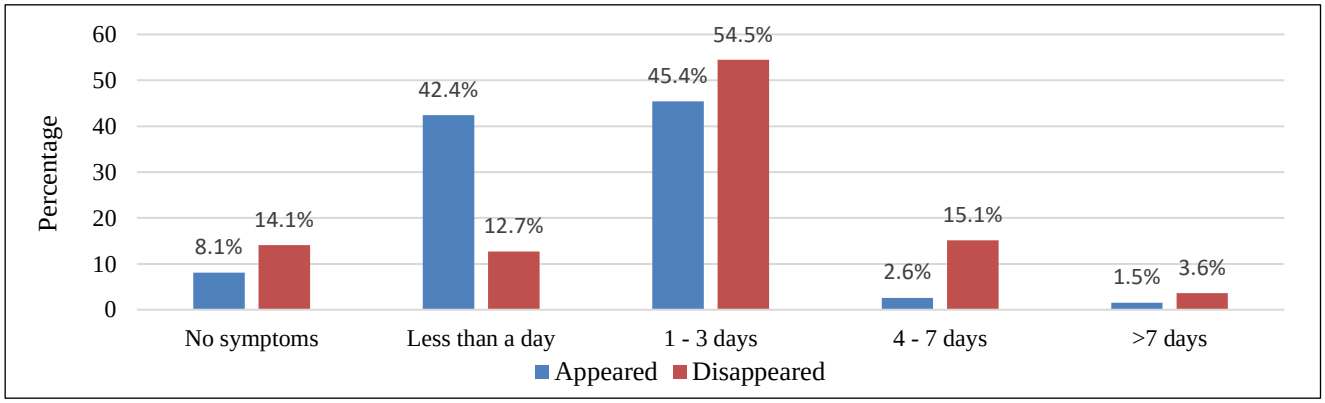

Figure 2: Timing when COVID-19 vaccine side effect appeared or disappeared.

DISCUSSION

Saudi Arabia is one of the countries that demonstrated an excellent rate toward its vaccination campaigns, not only showing its effectiveness against the virus but also exhibiting a wide range of support among its population.[5] Despite a higher rate of acceptance, some minorities are against it. These people are hesitant and are against vaccination. The rapid development of a vaccine against COVID-19 has led this small group of population to become skeptical about its efficacy and safety.[6] This study could shed more light regarding the safety and side effects of the COVID-19 vaccine. Our study revealed that the most common side effect experienced by the subjects was pain at the site of injection (89.4%), followed by tiredness (76.7%), muscle pain (72.7%), headache (64.4%) and fever (40.6%). Various papers reported pain at the site of injection as the most dominant COVID-19 vaccine side effect.[7-10] However, in Jazan Province, Saudi Arabia, most healthcare providers experienced flu-like symptoms such as chills, headache, fever, fatigue, tiredness and myalgia.[6] In Indonesia, a significant proportion of hospital staff suffered muscle pain, headache and tiredness post-vaccination against COVID-19.[12]

Our study suggests that the side effect of the COVID-19 vaccine showed a direct association with age, where the younger the participants are being more affected by the COVID-19 vaccine side effect. Such instances had been documented by Riad et al, according to their reports, the Corona vaccine side effect was associated with younger age, previous infection and compromised health status.[8] However, Saeed and his colleagues, reported that the prevalence of side effects on two doses was more common among those who were 49 years or older.[9] In our study, we stratified the age group based on ≤25 years versus >25 years. Accordingly, we found that the prevalence of COVID-19 side effects was more common among the age group of more than 25 years. Contrary to our reports, Riad et al, noted that mRNA-based COVID-19 vaccines were highly probable safe for young adults.[10]

Consistent with findings of recently published articles, we perceived that female university members were more being affected by the COVID-19 vaccine than their male counterparts.[6,8-11] In our study, both local and systemic side effects were more prevalent among females. These side effects include swelling, redness, itching, local pain at the site of injection, numbness, muscle pain, tiredness, diarrhea, nausea and vomiting, breathlessness, joint pain and fainting.

In our study, the most common type of vaccine was Pfizer, however, the side effect was more common with AstraZeneca vaccine. It has been observed in publications that Pfizer has better efficacy than Oxoford-AstraZeneca. Such observation had been documented by Ahsan et al, accordingly, they reported minor side effects experienced by those who received the Oxford-AstraZeneca vaccine with 16.8% reporting major vaccine-related side effects.[6] On the other hand, participants who took Pfizer did not report any incidence of side effects. This had also been supported by the study of Al Hazmi et al. According to their research, the side effect was significantly more in AstraZeneca than Pfizer where fatigue and fever were more common with Oxford-AstraZeneca.[7]

Recent findings noted that the side effect of the COVID-19 vaccine generally lasted between 1–3 days. This is also true in our study where the side effects of the vaccine mostly disappeared between 1 to 3 days (Table 3). In Jazan, Saudi Arabia, 84% of side effects were felt immediately on the day of receiving the vaccine with fewer than 16% starting to detect such side effects on the second- and third-day post-vaccination.[7] Hence, about three quarters (75%) indicated that the duration of side effects lasted from 1 to 3 days with consistent findings reported in the Czech Republic.[10,11]

The study has few limitations as the sample size was small, and it was a non-randomized and non-controlled study. And the study was retrospective, only short-term survey was done.

CONCLUSION

Consistent with literatures, this study finds local pain at the site of injection, tiredness, muscle pain, headache and fever as the most common side effects of the COVID-19 vaccine. The side effects of the COVID-19 vaccine had a greater impact on female respondents than their male counterparts. Itching, breathlessness and joint pain were detrimental side effects among older respondents. It is interesting to note that a significant proportion of respondents complained about fever due to the side effect of the AstraZeneca vaccine. Further research is needed to determine the side effects of the COVID-19 vaccine among university students and other staff.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Alharbi AA, Alkhdairi AA, Aldubayyan SF, Alrubaish NS, Alshaya AK, Alghofaily FK. Survey data of COVID-19 vaccine side effects among Qassim University members. Int J Adv Med 2022;9:194-200.