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ADVERSE EFFECTS OF THE JOHNSON & JOHNSON COVID-19 VACCINE REPORTED BY KABUL UNIVERSITY OF MEDICAL SCIENCES STUDENTS, KABUL, AFGHANISTAN.

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Abstract

Background: Coronaviruses are enveloped RNA viruses, which have caused global pandemic and outbreak. HCoV infects humans and causes respiratory diseases with mild to severe consequences. Varying degrees of Janssen vaccine adverse effects may be experienced by recipients. pain, redness, swelling at injection site, fever, fatigue, headache, muscle pain, chills, joint pain, nausea and vomiting are the common side effects of this vaccine and a rare side effect is thrombosis with thrombocytopenia syndrome (TTS) and Guillain–Barre syndrome (GBS).

The aim of this study is to assess the adverse effects of Janssen COVID-19 vaccine among KUMS students.

Methods & Material: An interview- based, observational retrospective study was conducted to assess adverse effects of Johnson & Johnson (Janssen) COVID-19 vaccine among KUMS students. Students were asked to report all the adverse effects they suffered within the first week of vaccination. Interrelation of the adverse effects was analyzed with the age and sex of all the participants. The population had no history of previous COVID-19 vaccines.

Result: The most common adverse effects of Janssen COVID-19 vaccine was pain at injection site. Most of the participants reported headache, fever and chills after taking single dose of Janssen Vaccine. The rare side effects of this vaccine were Anxiety, dizziness, arm weakness, hypotension and chest pain. Prevalence of the side effects was higher in age group <20 than age group ≥20. Those effects were mild to moderate in severity and there were no hospitalization reports. There was no case of severe adverse effect or Guillain–Barre syndrome (GBS). Adverse effects were more severe in participants with history of other SARS-CoV-2 infection.

Conclusion: Participants reported that the adverse effects of the Janssen COVID-19 vaccine were mild to moderate in severity, with no severe cases and a short duration.

Keywords: Adverse effects, Vaccine, COVID-19, Janssen COVID-19 vaccine

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1. Introduction

Coronaviruses are enveloped RNA-typed viruses. There have been six types of known coronaviruses including (SARS-Cov) and (MERS-CoV), significant zoonotic viruses, which have caused global pandemics and outbreaks. Coronavirus has a specific morphology, the name is being taken from the outer fringe, or coronal of embedded envelope protein. HCoV infection infects humans and causes respiratory diseases with mild to severe consequences. In recent years, we have witnessed the occurrence of two zoonotic, highly pathogenic HCoVs: SARS-CoV and MERS-CoV[1].

The novel coronavirus infection was first discovered in Wuhan, China, in December of 2019 and quickly spread over the world.[2] The World Health Organization (WHO) was informed of the outbreak by China and was able to respond quickly by coordinating diagnostics development; issuing guidance on patient monitoring, specimen collection, and treatment; and providing up-to date information on the outbreak [1].

Every year, 2–3 million fatalities due to global disease are prevented due to immunization.[3] As of April 2022, 512 million confirmed cases of COVID-19, 6.23 million deaths, 11.6 billion of vaccine doses hav been administered globally and 59.5% of the population are fully vaccinated according to data provided by WHO[4].

2. Methodology

An interview- based, observational retrospective study was conducted to assess the adverse effects of Janssen COVID-19 Vaccine amongst Kabul University of Medical Sciences (KUMS) students from 13th to 29th March, 2022. After the administration of a single dose of the mentioned vaccine, a professional interviewer interviewed all the participants. Students were asked to report all the adverse effects they suffered within the first week of vaccination. A total number of 300 students participated in this study. The list and pertinent data of the students who have received vaccinations were obtained from the KUMS immunization department. The participating students had never received any form of Covid-19 vaccines before.

The Research and Ethics committee of KUMS (Protocol no. 45) evaluated and approved the study protocol. Prior to the study, all participants were asked for their informed consent and were given an overview of the study's goals and results. Participation was completely optional, and participants had the chance to withdraw from the study anytime with no negative consequences. When consent for participation was obtained, participants were asked to report any adverse effects they experienced during the week after the initial immunization dose. In order to ensure that no negative reaction was forgotten the participants were first asked to describe any reactions they may have experienced after getting the vaccine and then, they were provided with a list of adverse reactions they may have suffered. The CDC brochure and reports from randomized control trials on the COVID-19 vaccination were used to compile the list [10].

IBM SPSS statistics version 25 was utilized for descriptive statistics and Chi-square analysis. Frequency and percentage tables were used to show participants' answers. Chi- square test was utilized to study any associations between adverse effects of the Janssen COVID-19 vaccine declared by participating students, participating students' ages and sex. A p-value of <0.05 was considered statistically significant.

COVID-19 vaccines can be vector vaccines such as AstraZeneca and Janssen vaccines or messenger RNA (mRNA) vaccines such as the Moderna COVID-19 and Pfizer-BioNTech vaccines or protein subunit vaccines, and inactivated vaccines such as Sinopharm vaccine[6,7].

The COVID-19 vaccine from Janssen uses existing technology that requires a virus called adenovirus, a common cause of respiratory infections. The body develops an immune response to the key part of the SARS-CoV-2 virus particle which is produced by altering the DNA of the adenovirus. The adenovirus that carries the SARS-CoV-2 DNA particle cannot proliferate, so it does not cause infection. The distribution of this vaccine is simple and effortless, as this system is based on stable DNA molecules and it does not require ultracold preservation[8].

Varying degrees of Janssen vaccine adverse effects may be experienced by recipients. pain, redness, swelling at injection site, fever, fatigue, headache, muscle pain, chills, joint pain, nausea and vomiting are the common side effects of this vaccine and a rare side effect is thrombosis with thrombocytopenia syndrome (TTS) and Guillain–Barre syndrome (GBS)[3,9].

To date, no extensive research has been done to assess the risks associated with the Janssen vaccination in Afghanistan. The aim of this study was to assess the side effects of Janssen vaccine among Kabul University of Medical Sciences students.

3. Results

Demographic Characteristics

A total number of 300 students participated in the study. Table 1 shows the demographic data of the participating students. The participants' average age was 20.08±1.91, with more than half of the vaccinated participants 20 or older than 20 years old.

Most of the vaccinated participants were female students (54%), and 46% of the participants were male students.

Characteristics	Frequency (n and %)
Sex	
Male	138 (46%)
Female	162 (54%)
Age (Mean± SD)	20.8±1.91
Age groups	
<20 years	102 (34%)
≥20 years	198 (66%)
History of SARS-Cov-2 infection	178 (59.3%)
Yes	122 (40.7%)
No	

Table. 1 shows the type of the vaccination that participants got and their demographic characteristics. (N=300).

Adverse Effects Frequency

Figure 1 demonstrates adverse effects frequency of Janssen COVID-19 vaccine experienced by participants of this study within first week after receiving Janssen vaccine.

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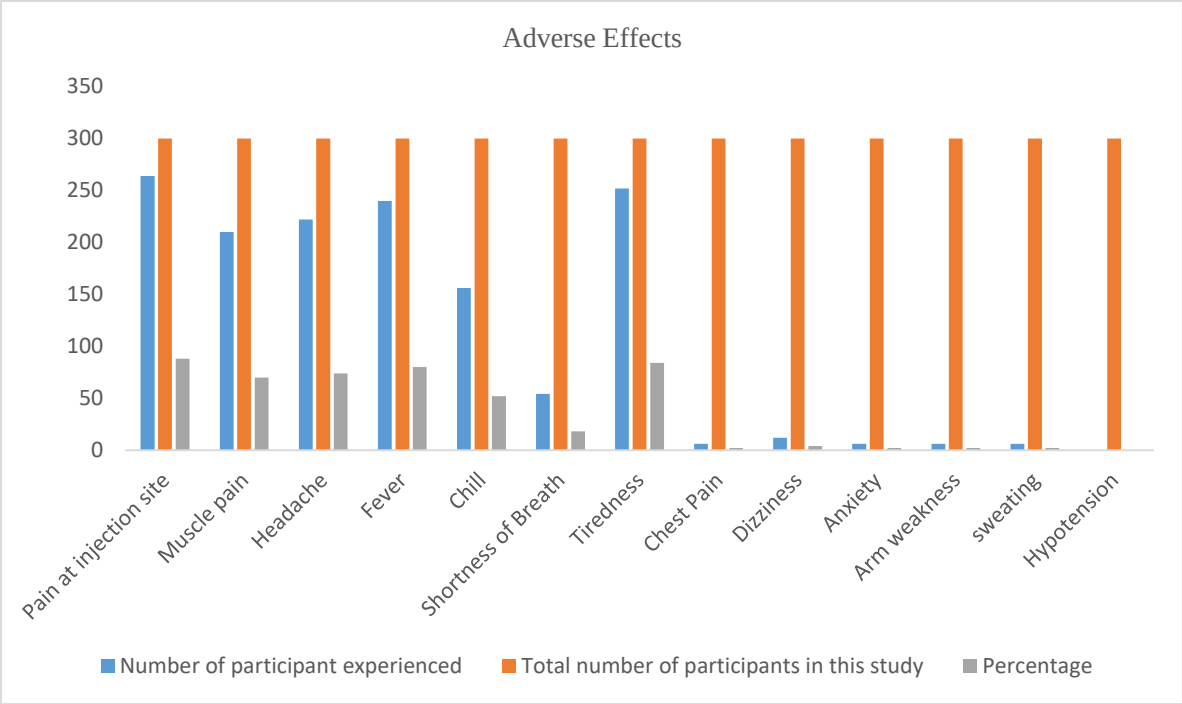

Adverse Reaction	Number of participant experienced	Total number of participants in this study	Percentage
Pain at injection site	264	300	88
Muscle pain	210	300	70
Headache	222	300	74
Fever	240	300	80
Chill	156	300	52
Shortness of Breath	54	300	18
Tiredness	252	300	84
Chest Pain	6	300	2
Dizziness	12	300	4
Anxiety	6	300	2
arm weakness	6	300	2
Sweating	6	300	2
Hypotension		300	0

Figure 1 Adverse Effects of Janssen vaccine experienced by the students participated in this study

The participants reported pain at the site of injection as the most common adverse effect, which was reported by 264 (88%) participants. Tiredness was the second highest reported adverse, which 252 (84%) participants reported this reaction followed by fever 240 (80%), headache 222 (74%) and muscle pain 210 (70%). Half of the participants had reported chills after getting single dose of Janssen Vaccine.

Less common adverse effects of Janssen vaccine reported were shortness of breath (18%), dizziness (4%), and hypotension (4%). Rare adverse effects were chest pain (2%), arm weakness (2%), Anxiety (2%) and sweating 6 (2%).

	Frequency (n and %)				
	Aged ≥20 years		Aged <20 years		Chi-square test
	N=198	%	N=102	%	P value
Pain at injection site	168	84.8%	90	88.2%	0.902
Muscle pain	120	60.6%	84	82. 4%	0.377
Headache	132	66.7%	84	82. 4%	0.535
Fever	150	75.8%	84	82.4%	0.802
Chill	84	42.4%	66	64.7%	0.291
Shortness of Breath	30	15.2%	24	23.5%	0.508
Tiredness	150	75.8%	96	94.1%	0.497
Chest pain	6	3.03%	0	0%	0.472
Dizziness	12	6.06%	0	0%	0.310
Anxiety	6	0.33%	0	0%	0.472
Arm weakness	6	0.33%	0	0%	0.472
Sweating	6	0.33%	0	0%	0.472
Hypotension	12	6.06%	0	0%	0.310

Table 3 summarizes the declared adverse effects by the participating students and their association with positive history of SARS-CoV-2 Infection.

	Frequency (n and %)		
	Previous Infection with SARS-CoV-2		
	Yes	No	P Value
	n=178	n=122	
Pain at injection site	157 (88.2%)	101 (82.8%)	0.619
Muscle pain	110 (61.8%)	94 (77.1%)	0.115
Headache	134 (75.3%)	82 (67.2%)	0.418
Fever	160 (89.9%)	74 (60.6%)	0.004
Chill	90 (50.6%)	60 (49.2%)	0.867
Shortness of Breath	36 (20.2%)	18 (14.7%)	0.272
Tiredness	157 (88.2%)	89 (72.9%)	0.151
Chest pain	0 (0%)	6 (4.9%)	0.003
Dizziness	10 (5.6%)	2 (1.6%)	0.090
Anxiety	2 (1.12%)	4 (3.3%	0.194

Arm weakness	1 (0.65%)	5 (4.1%)	0.033
Sweating	4 (2.2%)	2 (91.6%)	0.714
Hypotension	8 (4.5%)	4 (3.3%)	0.605

Table 4, shows that the adverse reactions of Janssen vaccine were much higher in those who had previous history of SARS-CoV-2 infections. The most common adverse effects reported by the participants with previous Infection with SARS-CoV-2 were pain (88.2%), headache (75.3%) and fever (89.9%).

The prevalence of adverse effects of Janssen vaccine was higher in age group of less than 20 years old in compared to 20 years old or older, yet, the difference was not statistically significant.

Muscle pain was reported more frequently in students aged <20 years, but was not significantly significant. Moreover, headache and chills were also reported significantly higher in participants aged <20 years than ≥20 years. Chest pain, dizziness, Anxiety, arm weakness, tiredness, sweating and hypotension were only reported in student's ≥20 years.

Compared to those with positive history of SARS-CoV-2 infections, chest pain was most common in participants with negative history of SARS-CoV-2 infections (4.9%) with a P-Value of (0.003). Although there was no severe case of hospitalization.

4. Discussion

Adverse effects of vaccines are a concern of the general public around the world. False information regarding adverse effects of vaccines has led to a decrease in public willingness and a negative attitude toward vaccine uptake in society and causing an increase in COVID- 19 cases. Level of trust and willingness for COVID-19 vaccine can be affected by several factors including cultural and religious faiths, information about the vaccines and socio-economic status. [12] Factors that encourage individuals to get vaccinated are family members, employer/ colleagues/organization, doctor, COVID-19 infected people among family/friends [13].

In a study conducted in Pakistan, malaise, headache, and fever were reported to be the most common side effects of the vaccine, [14] whereas our study's participant reported pain at injection site as the most common adverse effect. This effect was reported by 264 (88%) participants. Tiredness was the second highest reported adverse reaction by the participant, 252 (84%) participants reported this reaction followed by fever 240 (80%), headache 222 (74%) and muscle pain 210 (70%). Half of the participants had reported chills after getting single dose of the Janssen vaccine. The findings of this article were similar to what the fact sheet for recipient and caregivers.

Less commonly adverse effects of the Janssen vaccine were shortness of breath, dizziness, and hypotension. Rare adverse effects were pain at heart site, arm weakness, Anxiety and sweating which were the rare findings of this study.
Guillain Barre Syndrome, immune thrombocytopenia (ITP) and blood clots with low levels of platelets which were reported by previous studies were not reported by this study [1, 3, and 11].

Prevalence of adverse effects were common in the participants with a previous history of SARS-CoV-2 infections, whereas the adverse effects were less common in participants with no previous history of SARS-CoV-2 infections. This finding was also reported by previous studies too[15,16].
As this research was conducted amongst the students of Kabul University of Medical Sciences who have received the single dose of Janssen COVID-19 vaccine as an interview-based study, and the participants were asked about a list of adverse effects of the vaccine, and interviews were done shortly after vaccination and therefore the likelihood of recall bias was small, and this was the strength point of this study.
Due to limited supply of Janssen vaccine in Afghanistan, only a small group of students were vaccinated. Small sample size may make it difficult to generalize the findings; however, the finding of this study can help to decrease the people's fear of vaccine side effects especially rare side effects.

5. Conclusion

This study found that the severity of adverse effects of Janssen vaccine was short term and mild to moderate. No case of severe adverse effects was found and there was no report Guillain–Barre syndrome (GBS). None of the cases needed hospitalization.

The finding of this study will help health promoters in assuring the public about the safety of this vaccine and will encourage them to take the vaccine shots and help in declining the COVID-19 cases and overcome the pandemic in Afghanistan as Janssen vaccine is the most common vaccine used in Afghanistan.

Ethical Approvement and Informed Consent

The Research and Ethics committee of KUMS (protocol no. 45) reviewed and approved the study protocol. The participation in this study was voluntarily and each participant had the option to leave the research. at any time.

Declaration of interest

No conflict of interest is declared by the authors.

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