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Common side effects of Johnson and Johnson COVID-19 vaccine in Ruffaa city, Gezira, Sudan January (2022)

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Abstract

Background: The Johnson & Johnson (J&J)/Janssen vaccine was listed for emergency use by WHO on 12 March 2021. The vaccine has been authorized for use in Europe, the United States and other countries.

Objectives: This study was conducted to study common side effects of Johnson & Johnson vaccine and the factors associated with adverse effect.

Methods: A cross-sectional community based study conducted at Ruffaa city on January (2022), the sample consisted of 361 participants. Data were collected by using questionnaire designed for this study. Data analysis was performed using statistical package for Social Sciences.

Results: the study revealed that most of participants (83%) was suffered from local side effects more than halve of them complain from pain in site of injection, Pain & Swelling < 5cm (8%), Pain, and Swelling & Redness More than 3 days (7%). And 76% of participants complain from General side effects 19% of them complain from Fever, (10%) complain from Fever, headache, muscle aches and fatigue. there is statistical relation between pre-existing chronic disease, sex and common side effects of vaccine.

The study also revealed that side effects start directly after injection in (63%) of participants. And continue in (87%) from 1-3 days. Study also shows (3%) of participant infected with Covid -19 after vaccination and all of them were hospitalized.

Conclusion: The Johnson & Johnson's Janssen COVID-19 Vaccine did not appear to cause any dangerous complications.

Keywords: Side effects; Johnson & Johnson's Janssen; COVID-19; Vaccine

1. Introduction

Vaccination stays a critical device to assist and prevent further infection and dying and to control the pandemic. [1] The Johnson & Johnson (J&J)/Janssen has developed a vaccine that works in another way than the others vaccines and is

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exceptionally powerful for preventing slight to severe COVID-19 [2], Johnson & Johnson vaccine become listed for emergency use by using WHO on 12 March 2021. The vaccine has been legal to be used in Europe, America and different international locations, with the widest experience thus far in the U.S.A. [1], In randomized medical trials of COVID-19 vaccines reported side effects include injection site events (pain, redness, swelling) and systemic side effects (eg, fatigue, headache, muscular joint ache), with uncommon severe side effects. [3]

The researches stated associations between types of vaccine and several side effects most had been slight effects [4] in the research of this vaccine, nobody developed a severe allergic reaction, and side effects of the vaccine have been much like those of different vaccines, consisting of fever skilled via nine% of volunteers. The vaccine did not appear to cause any critical complications. [2] Very uncommon thromboembolic events, in aggregate with thrombocytopenia, have been reported following vaccination with the J&J vaccine. [1]

The objectives of this study were to identify common side effects that people have identified after receiving single dose of Johnson & Johnson vaccine, and the factors associated with side effects.

2. Methodology

2.1 Study design

A cross-sectional community based study conducted to study common side effects of Johnson & Johnson vaccine and the factors associated with side effects. The study was conducted in Ruffaa city the capital of East of Gezira locality, which is located at north east of Gezira state on January 2022.

2.2 Study subjects and sampling

Simple random sampling consisted of 361 participants received Johnson vaccine lives in Ruffaa city.

2.3 Data

Was collected using questionnaire designed by the researchers, dependent variables: all side effects related to Johnson vaccine, Independent variables :(age, gender, weight, chronic diseases)? Data was analyzed using statistical package for social science (SPSS).

2.4 Ethical consent

The proposal was approved by the scientific committee of researches, faculty of applied medical Sciences, University of Al-Butana, and then permission was taken from manger of health affair, east of Gezira locality and the head of immunization department. The purpose of the study was explained verbally clearly to participants before giving of the questionnaire and they all agreed to participate.

Table 1 Distribution of participants according to their sex and age

Sex	Frequency	Percent
Female	156	43%
Male	205	57%
Age		
18-30	187	52%
31-40	62	17%
41-50	55	15%
51-60	36	10%
61-70	13	4%
>70	8	2%
Total	361	100%

Table 1 Shows that 57% of study sample were male 43% were female and more than halve 52% of them their age ranged between 18-30.

Table 2 Distribution of study sample according to their weight

Weight/ kilo	Frequency	Percent
40-60	180	50%
61-80	141	39%
81-100	35	10%
>100	5	1%
Total	361	100%

Table 2 Shows that 50% of study sample their weight range between 40-60and kilos

Table 3 Previous information about side effects of vaccine and the source of information

previous information	Frequency	Percent
No	144	40%
Yes	217	60%
Total	361	100%
source of information		
TV	46	13%
Radio	6	2%
Social media	81	22%
Vaccine administration	65	18%
Others	19	5%
No previous information	144	40%
Total	361	100%

Table 3 Shows that 60% of participants know the vaccine side effects and most of them 22% their source of information were social media.

Table 4 Distribution of study participants according to pre-existing chronic diseases

Item	Frequency	Percent
Hypertension	18	5%
Cardiac diseases	6	2%
DM	28	8%
Asthma	17	5%
Allergy	23	6%
No pre-existing chronic	269	74%
Total	361	100%

Table 4. Shows that the common pre-existing chronic diseases in the study sample were DM 8% follow by allergy 6%, and 74% of them not complain from chronic diseases

Tale 5 Study Participants suffered from side effects

	Frequency	Percent
No	62	17%
Yes	299	83%
Total	361	100

Table 5 shows most of participant 83% complain from side effects of vaccine

Table 6 Local and general Side effects

Local Side effects:	Frequency	Percent
Pain	208	58%
Swelling > 5cm	8	2%
Redness	14	4%
Pain, Swelling & Redness (More than 3 days)	26	7%
Pain & Swelling < 5cm	29	8%
Pain & Swelling > 5cm	10	3%
Skin rash	4	1%
No local side effects	62	17%
Total	361	100%
General side effects		
Fever	71	19%
Headache	13	4%
Vomiting	3	1%
Muscles ache	6	2%
Fatigue	20	6%
Chest pain	4	1%
Diarrhea	4	1%
Fever, headache & fatigue	31	8%
Fever, headache, muscle aches and fatigue	36	10%
Thrombosis	0	-
No side effects	87	24%
Total	361	100%

Table 6 shows most of participants 83% complain from Local side effects pain in site of injection. And 76% complain from General side effects 19% of them complain from Fever

Table 7 Beginning and period of side effects

Beginning of side effects:	Frequency	Percent
Directly after injection	54	18%
First day	189	63%
2nd day	42	14%
3rd day	6	2%
After 3 rd day	3	1%
2 nd week	5	2%
Total	299	100%
Period of side effects		
1-3 days	260	87%
4-7 days	26	8%
Less than 7days	5	2%
2 Week or more	8	3%
Total	299	100%

Table 7 shows in 63% of study sample the side effects start directly after injection. The period of continuity in 87% of participant was 1-3 days.

Table 8 Infection with COVID-19 after vaccination, Confirmation by laboratory investigation and admission to hospital

Item	Frequency	Percent
Infection with COVID-19 after vaccination		
No	351	97%
Yes	10	3%
Total	361	100%
Confirmation by laboratory investigation		
NO	359	99%
Yes	3	1%
Total	361	100%
Admission to hospital		
NO	351	97%
Yes	10	3%
Total	361	100%

Table 8 Shows 3% of participant infected with Covid -19 after vaccination just 1% of them confirmed by laboratory investigation and all of them 3% was hospitalized.

Table 9 Association between age and side effects

Suffering from side effects		Age						Total	P. value
		18-30	31-40	41-50	51-60	61-70	>70		
No	Count	23	15	13	6	3	2	62	0.189
	%	37.1%	24.2%	21.0%	9.7%	4.8%	3.2%	100%	
Yes	Count	164	47	42	30	10	6	299	
	%	54.8%	15.7%	14.0%	10.0%	3.3%	2.0%	100%	
Total	Count	187	62	55	36	13	8	361	
	%	52%	17%	15%	10%	4%	2%	100%	

Table 9 Shows there is no association between age and side effects

Table 10 Association between sex and side effects

Suffering from side effects		Sex		Total	P. value
		Female	Male		
No	Count	19	43	62	0.026
	% within sex	12.2%	21.0%	17.2%	
	% of Total	5.3%	11.9%	17.2%	
Yes	Count	137	162	299	
	%	45.8%	54.2%	100.0%	
	% of Total	38.0%	44.9%	82.8%	
Total	Count	156	205	361	
	%	43.2%	56.8%	100.0%	

Table 10 Shows there is relation between sex and side effects of vaccine

Table 11 Association between sex and side effects and pre-existing chronic diseases

Suffering from side effects		Pre-existing chronic disease					Total	P. value
		Hypertension	Cardiac	diabetic	Asthma	Allergy		
No	Count	0	0	6	0	1	7	0.038
	%	0.0%	0.0%	21%	0.0%	4.3%	25.3%	
	% of Total	0.0%	0.0%	0.6%	0.0%	0.1%	0.7%	
Yes	Count	18	6	25	17	22	88	
	%	100%	100%	89%	100%	95.6%	96.9%	
	% of Total	19.5%	6.5%	27.1%	18.4 %	23.9%	95.4%	

Table 11 Shows there is relation between chronic disease and side effects of vaccine.

3. Discussion

This study aimed to identify side effects that people have identified after receiving Johnson & Johnson vaccine, and factors associated with those side effects. The study was conducted in Eastern Gezira locality- Sudan consisted of 361 participants 205 male and 156 female, the highest number of people who participated were in the (18-30) years of age category. Halve of the participants their weight range from (40-60) kilo. (22%) of participants received information about vaccine from social media and (40%) of them were haven't prior information about the vaccine. The most common pre-existing chronic diseases among the participants were diabetes (8%) but (74%) of them free from pre-existing chronic diseases. The results shows most of participants (83%) suffer from side effects this result compatible with Hatmal, et al their results showed significant associations between types of vaccine and several side effects [4].

This Study showed that most of participants was suffered from Local side effects halve of them complain from pain in injection site, Pain & Swelling < 5cm (8%), Pain, Swelling & Redness More than 3 days(7%), Redness (4%), This is in line with fact sheet for recipients and caregivers which stated that (side effects that have been reported with the janssen covid-19 vaccine include: injection site reactions: pain, redness of the skin and swelling [5]. Only (1%)of participants complain from Skin rash This is in line with European Medicines Agency which stated that Rare side effects that occurred in less than 1 in 1,000 people are itchy rash[6].

General side effects the study showed that 19% of participants complain from Fever>38, (4%) and (6%) complain from Headache and Fatigue respectively, in this study (10%) of participants complain from Fever>38, Headache, muscle aches and fatigue, (1%) of them complain from vomiting, chest pain and diarrhea. This result is on line with the [7].The FDA's vaccine fact sheet also stated that possible side effects include: headache, fever, fatigue, and nausea [5].

This study showed the beginning of side effects in (63%)of participants were started on First day just (14%) in 2nd day, and Period of side effects take 1-3 days in (87%)of participants, this result not compatible with U.S. Centers for Disease Control and Prevention (CDC)which stated that most common side effects of the vaccine in the trials were usually mild or moderate, occurred within two days after vaccination, and compatible with Period of side effects the participants got better within 1 or 2 days[8].

This study showed that (3%) of participants Infected with COVID-19 after vaccination this results in line with after clinical trial Janssen announced that the vaccine was 66% effective in a one-dose regimen in preventing symptomatic COVID-19, with an 85% efficacy in preventing severe COVID-19 [9]. The Janssen COVID-19 Vaccine may not protect all vaccinated individuals [5]. The study also shows there is statistical relation between chronic disease and side effects of vaccine. And between sex and side effects of vaccine.

4. Conclusion

In conclusion this study concluded that the more common local side effects of Johnson & Johnson's Janssen COVID-19 Vaccine are pain and swelling and common general side effects are Fever, Headache, muscle aches and Fatigue. This study shows association between chronic disease and side effects of vaccine. And between sex and side effects of vaccine.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

Statement of ethical approval

The present research work does not contain any studies performed on animals/humans subjects by any of the authors.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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