ORIGINAL PAPERS

A Cross-sectional Study to Assess the Incidence of Adverse Drug Reactions to the Covishield Vaccine among Healthcare Workers of a Tertiary Care Government Institute in North India

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Abstract

Background: Vaccines are a key strategy to stop the COVID19 pandemic. The present study was conducted to assess the incidence of Adverse Drug Reactions to the Covishield vaccine among healthcare workers. **Materials and Methods:** A cross-sectional, observational, questionnaire-based study was carried out on healthcare workers of R.U.H.S. College of Medical Sciences, Jaipur, Rajasthan. The study tool consisted of a digital questionnaire. **Results:** The present study was carried out among 316 healthcare workers who received the first dose of the Covishield vaccine. 83 (26.26%) participants complained of side effects after receiving the first dose of the Covishield vaccine. Fatigue (64), fever (52), body ache (40), swelling at the vaccination site (35), headache (25), and pain in the limb (18) were the most prevalent symptoms. Most post-vaccination symptoms were found to be mild. 67 participants showed side effects of vaccination within 24 hours while 16 showed side effects after 24 hours. **Conclusion:** This study reflects that one-fourth of participants complained of side effects after receiving the first dose of the Covishield vaccine. These side effects are not severe and should not be an obstacle to the successful control of the Covid-19 pandemic in India.

Keywords: adverse drug reaction, COVID-19, covishield vaccine, side effects, vaccination.

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INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative virus of the coronavirus disease 2019 (COVID-19) pandemic.[1] In this pandemic, most countries have inflicted protective measures such as wearing masks, social distancing, and stay-at-home-strategy, but these measures are not going to persist. Therefore, to manage, reduce, and eradicate COVID-19 infection, therapeutic and preventative solutions were required.[2]In terms of preventative measure, herd immunity is needed to be achieved once the disease has spread to become a pandemic.[3] However, waiting for herd immunity through infection with the virus is not ethical or acceptable. Therefore, extended vaccination campaigns were accepted for developing population immunity.[4, 5]

Various scientific techniques like the use of different viruses or viral parts are being developed Rapid development of a safe and effective COVID-19 vaccine.[6]The overarching goal is for COVID-19 vaccines to provide equitable protection and promotion of human well-being among people globally. The goal of vaccination is to expose the body to an antigen and elicit an immune response that can stop or kill the virus if a person later contracts it without actually causing the disease. In the world's fight against the COVID-19 pandemic, vaccines emerged as the greatest rescuer and many vaccines were developed and entered clinical trials in early 2020. Governments all across the world began vaccination efforts against COVID-19 after many of these vaccines received emergency authorization. General mistrust in vaccines and concerns about future side effects were barriers to achieving population immunity to COVID-19 through vaccination. Surveys have shown that people worry about the potential adverse effects of the COVID-19 vaccine which they believe would be worse than the disease itself.[8]

A survey done on vaccine perception for COVID19 vaccine showed that the safety of the vaccine with no major side effects emerged as the greatest motivating factor to get vaccinated.[9] As vaccine-related fears on safety and side effects play important role in determining the decision regarding vaccination.[10] No vaccine is free from any side effects or complications. Early side effects either local pain, redness, and swelling, or systemic like headache, nausea, tiredness, myalgia, chills, and fever are expected with any vaccines.[11] However, there may be other serious side effects such as anaphylaxis to a vaccine component, which was reported to be secondary to allergic reactions to polyethylene glycol (PEG).[12]In India, The Government introduced the vaccination campaign all over the country on January 16, 2021.[13] As per the official data, as of May 4, 2021, a total of 158932921 doses overall including both the first dose and second dose of the vaccine has been provided in India.[14,15] However, very less studies in the recent past have been conducted to analyze the perception of people of India on the side effects of COVID-19 vaccines. Therefore, in this study, we aimed to identify vaccine side effects reported among the Indian population who have received the Covishield vaccine.

MATERIALS AND METHODS

A cross-sectional, observational, questionnaire-based study was conducted under the department of Pharmacology of R.U.H.S. College of Medical Sciences at Jaipur, Rajasthan. It was approved by an Institutional ethics committee (EC/P-42.1/2021). A convenient sample approach was adopted in this study where Healthcare workers were invited to participate. The study population consists of Healthcare workers of R.U.H.S. College of Medical Sciences, Jaipur. Not willing Healthcare workers will be excluded from the study.

The study tool consisted of a digital questionnaire that was prepared in the English language. The questionnaire was self-developed and pre-validated consisting of nine questions. It was pretested on a group of Healthcare workers. An online survey was performed to get the response from Healthcare workers. The participants were contacted with the digital Questionnaire through various networking systems. In this study, online social media platforms (WhatsApp Group, Facebook, email) were used to recruit participants. Categorical variables were present as numbers and percentages, while continuous variables were present as median [interquartile range]. An independent Mann-Whitney U test for continuous variables and a Chi-square test for categorical variables, as required, was used for the univariate analysis.

RESULT

The present study was carried out among 316 healthcare workers who received the first dose of the Covishield covid-19 vaccine. According to age we divided the

participants into three groups in which 205(64.87%) were in the 18-24 year age group, 95 (30.06%) were in the 24-40 year age group and 16(05.36%) were in >40 year age group (Figure 1).

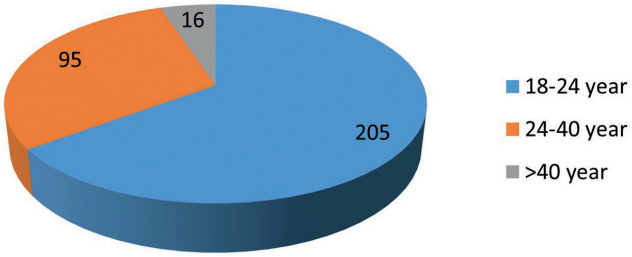

Figure 1. Age wise distribution of participants

The median age of participants was 23 year of which 179 (56.64%) were male and 137(43.35%) were female (Figure-2).

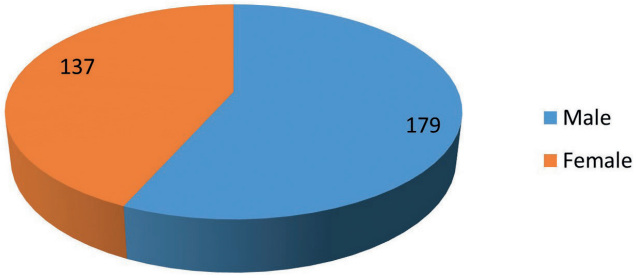

Figure 2. Gender wise distribution of participants

About 72% were undergraduate medical students, 14% were doctors, 6% were postgraduate medical students, 3% were nursing staff and paramedics each (Table 1).

Table 1. Demographic details of study participants (n=316)

Variables		N (%)
1.	Age (Years) 18-24 Years 24-40 Years >40 Years	 205(64.87%) 95(30.06%) 16(05.86%)
2.	Gender Male Female	 189(56.64%) 137(43.35%)
3.	Qualification Undergraduate Students Postgraduate Students Doctors Nursing Staff Paramedics	 228(72.15%) 20(06.32%) 46(14.55%) 11(03.48%) 10(03.16%)
4.	Side effects appear Yes No	 83(26.26%) 233(73.73%)
5.	Side Effects Fatigue Fever Body ache Swelling At Vaccination Site Head Ache Pain In Limb Others	 64(20.25%) 52(17.64%) 40(12.65%) 35(11.07%) 25(07.91%) 18(05.69%) 24(07.59%)
6.	Degree Of Severity Side Effects Mild Moderate Severe	 53(16.77%) 26(08.22%) 04(01.26%)
7.	Side Effects Appear In Within 24 Hours After 24 Hours	 67(20.59%) 16(05.06%)

In this study out of 316 health care workers, 83 (26.26%) participants complained of side effects after receiving the first dose of the Covishield vaccine (Figure 3).

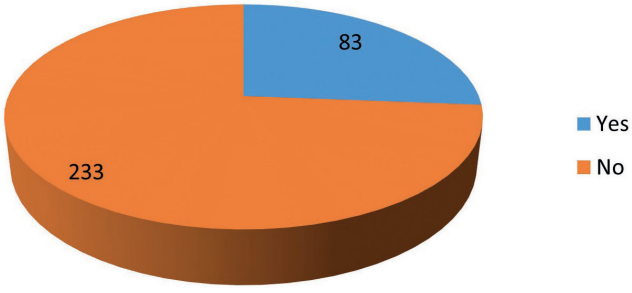

Figure 3. Side effects appear after the Covishield vaccination

A significant difference was found in the side effects reported by undergraduate, postgraduate, doctors, nursing staff, and paramedics ($p<0.001$). Undergraduate students had higher chances of showing side effects as compared to other groups. There was no statistical difference between different age groups and genders ($p>0.05$) (Table 2).

Table 2. Side effect due to the Covishield Vaccine (n=316)

FACTORS	YES N (%)	NO N (%)	TOTAL N (%)
Age (Years)			
18-24 Years	59(28.7)	146(71.2)	205
24-40 Years	22(23.1)	73(76.8)	95
>40Years	02(12.5)	14(87.5)	16
p Value	**0.258**		
Gender			
Male	43(24)	136(76)	179
Female	40(29.2)	97(70.8)	137
p Value	**0.364**		
Qualification			
Undergraduate Students	57(25)	171(75)	228
Postgraduate Students	12(60)	8(40)	20
Doctors	13(28.3)	33(71.7)	46
Nursing Staff	0(0.0)	11(100)	11
Paramedics	1(9.1)	10(90.9)	10
p Value	**0.001(S)**		

The most common reported side effect was fatigue, a total of 64 cases reported fatigue after the first dose of vaccination followed by fever (52), body ache (40), swelling at the vaccination site (35), headache (25), pain in limb (18) and other (24) (Figure 4).

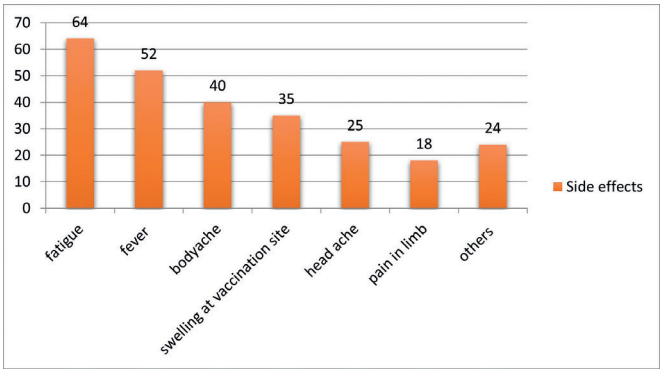

Figure 4. Reported cases of different types of side effects of the Covishield vaccine

Fatigue was found to be significantly more prevalent among less than 24 years of age group and undergraduate participants ($p<0.005$) (Table 3).

As shown in Figure 5, 53(16.77%) participants showed a mild degree of side effects followed by 26(8.22%) and 4(01.26%) showed moderate and severe degree side effects after vaccination respectively.67(20.59%) participants showed side effects of vaccination within 24 hours while 16(5.06%) showed side effects after 24 hours (Figure 6)

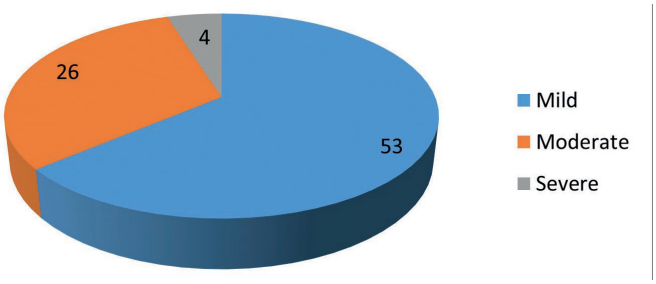

Figure 5. Severity of side effects of the Covishield vaccine

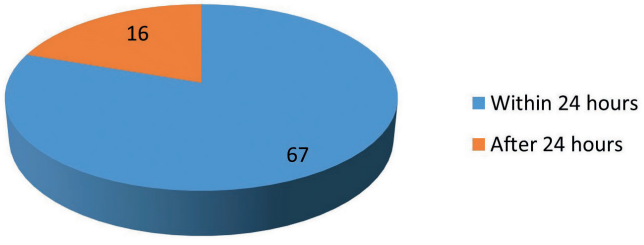

Figure 5. Time interval after which Side effects appear due to vaccination

Table 3. Different side effects due to Covishield vaccine (n=83)

Factors	Fatigue (N%)	Fever (N%)	Swelling (N%)	Headache (N%)	Body Ache (N%)	Pain In Limb (N%)	Others (N%)
AGE							
18-24	36(17.6)	32(15.6)	24(11.7)	16(07.8)	24(11.7)	08(3.9)	17(8.3)
24-40	28(08.86)	20(21.1)	(11.6)	09(09.5)	15(15.8)	09(9.5)	07(7.4)
>40	00(0.0)	00(0.0)	00(0.0)	00(0.0)	01(6.3)	01(6.3)	00(0.0)
p value	**0.007(S)**	**0.094**	**0.350**	**0.428**	**0.448**	**0.153**	**0.481**
GENDER							
MALE	36(20.1)	26(14.5)	18(10.1)	10(5.6)	18(10.1)	07(3.9)	12(6.7)
FEMALE	28(20.4)	26(19)	17(12.7)	15(10.9)	22(16.1)	11(8.0)	12(8.8)
p value	**0.944**	**0.366**	**0.632**	**0.124**	**0.156**	**0.187**	**0.693**
QUALIFICATION							
UNDER-GRADUTE STU-DENTS	44(19.3)	38(16.7)	27(11.8)	18(7.9)	29(12.7)	10(04.4)	18(7.9)
POSTGRADUATE STUDENTS	09(45.2)	08(40)	02(10)	02(10.0)	06(30.0)	03(15.0)	01(5.0)
DOCTOR	10(21.7)	06(13)	06(13)	05(10.9)	05(10.9)	05(10.9)	05(10.9)
NURSING STAFF	00(0.0)	00(0.0)	00(0.0)	00(0.0)	00(0.0)	00(0.0)	00(0.0)
PARAMEDICS	01(9.1)	00(0.0)	00(0.0)	00(0.0)	00(0.0)	00(0.0)	00(0.0)
p Valve	**0.022(S)**	**0.012(S)**	**0.544**	**0.633**	**0.676**	**0.109**	**0.604**

There was no statistical difference between different age groups gender and qualification for the severity of side effects and side effects appearing duration (Table-4 and Table-5)

Table 4. Degree of severity of side effects of Covishield vaccine (n=83)

Factors	Mild N (%)	Moderate N (%)	Severe N (%)	p value
AGE				
<24	37(62.7)	18(30.5)	04(06.7)	**0.736**
24-40	15(37.5)	07(62.5)	000(0.0)	
>40	01(50)	01(50)	00(0.0)	
GENDER				
MALE	29(69)	13(28.6)	01(2.4)	**0.505**
FEMALE	24(60)	13(32.5)	03(7.5)	
QUALIFICATION				
UNDERGRADUTE STUDENTS	37(64.9)	16(28.1)	04(7.0)	**0.764**
POSTGRADUATE STUDENTS	07(58.3)	05(41.7)	00(0.0)	
DOCTOR	09(69.2)	04(30.8)	00(0.0)	
NURSING STAFF	00(0.0)	00(0.0)	00(0.0)	
PARAMEDICS	00(0.0)	01(100)	00(0.0)	

Table 5. Time intervals after which side effects appear due to vaccination (n=83)

Factors	Within 24 hours N (%)	After 24 hours N (%)	p-value
AGE			
<24	47(79.6)	12(28.8)	**0.764**
24-40	18(81.8)	04(18.1)	
>40	02(100)	00(0.0)	
GENDER			
MALE	34(79.1)	09(20.9)	**0.907**
FEMALE	33(82.5)	07(17.5)	
QUALIFICATION			
UNDERGRADUTE STUDENTS	43(75.4)	14(24.5)	**0.469**
POSTGRADUATE STUDENTS	11(91.7)	01(83.3)	
DOCTOR	12(92.3)	0197.7)	
NURSING STAFF	00(0.0)	00(0.0)	
PARAMEDICS	01(100)	00(0.0)	

DISCUSSION

COVID-19 infection arose in Wuhan, China in December 2019 and affected human health globally. In order to combat the COVID-19 pandemic, urgent efforts had to be made to develop and test vaccines to ensure their efficacy and safety. Before the traditional steps of clinical trials were finished, the emergency use approval for COVID-19 vaccinations was granted. COVID-19 vaccines have been rolled out recently in several parts of the world. Although the protective efficacy is frequently discussed, little is known about the real-world post-vaccination experience outside of clinical trial conditions[17]. Concerns about the safety and side effects of coronavirus SARS CoV2 vaccines have been raised among many communities worldwide. The most often reported local side effects of the COVID-19 vaccination were discomfort, swelling, and redness at the injection site. Fever, exhaustion, myalgia, and headache were some of the systemic responses. [16]

316 Healthcare professionals who received the first dose of the Covishield covid-19 vaccine took part in the survey and described their immediate post-vaccination experience. The median age of participants was 23 years of which 56.64% were male and 43.35% were female. Out of 316 healthcare workers, 83 (26.26%) participants complained of side effects after receiving the first dose of the Covishield vaccine. The remaining three-fourths did not report any symptoms. The chance of having symptoms decreased with advancing age. In the youngest age group (18-24 years) 59 developed symptoms, while only 02 of those over 40 years reported any symptoms. Some previous studies also showed the same correlation[17, 18]. Post-vaccination symptoms were statistically insignificant between men and women. Undergraduate students were more likely to develop post-vaccination symptoms as compared to postgraduates, doctors, nursing staff, and paramedics ($p<0.001$).

In our study, most of the symptoms were mild in nature. Fatigue (64 cases) was the most common symptom after the first dose of vaccination followed by fever (52), body ache (40), swelling at the vaccination site (35), and headache (25). Local pain at the injection site was reported by 18 of the respondents. Many respondents showed more than one type of symptom. None of the symptoms were serious or required hospitalization. Most of the symptoms appeared within 24 hours after the Covishield vaccination. Therefore,

this survey would give an insight into the actual adverse effects experienced by the recipients of the COVID19 vaccine and will help us understand the nature of the adverse effects of the Covishield vaccine. This would also help instill confidence in people on getting vaccinated against COVID-19.

CONCLUSION

The study showed that one-fourth of participants complained of side effects after receiving the first dose of the Covishield vaccine. Most of participants experienced mild post-vaccination symptoms. Most common symptoms were fatigue, fever, and body ache. However, none of the reported symptoms were serious or required hospitalization. This study provides valuable insight into the real-world post-vaccination experience of the COVID-19 vaccine and can help instill confidence in people about getting vaccinated. It also emphasizes the need for continued monitoring and surveillance of adverse effects related to the COVID-19 vaccines.

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Availability of data and materials
Data will be available by emailing punm.jakhar@gmail.com.

Authors' contributions
PJ and KKT are the principal investigator of the study who designed the study and coordinated all aspects of the research, including all steps of the manuscript preparation. Both are responsible for the study concept, design, information collection, statistical analysis, as well as writing, reviewing, editing, and approving the manuscript in its final form. RC contributed to the study design, information collection with analysis, reviewed and approved the manuscript. LS AB and MM contributed in the interpretation of data, drafting the work, writing the manuscript, reviewed and approved the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate
We conducted the research following the Declaration of Helsinki. The protocol of study was approved by the Institutional ethics committee of RUHS College of Medical Sciences Jaipur, Rajasthan (EC/P-42.1/2021). Confidentiality was assured with signed informed consent.

Consent for publication
Not applicable

Competing interest
The authors declare that they have no competing interests.

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