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Post-vaccination side effects following the second dose of COVID-19 vaccine among health care workers

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ABSTRACT

The coronavirus disease 2019 (COVID-19) vaccines were launched after granting them 'emergency use authorization' approval. Beyond the clinical trial, there was very limited data on the side effects following vaccination This is a longitudinal study among health care workers (HCWs) in a tertiary care hospital. Information was also collected using a pre-tested semi-structured questionnaire which included their demographic details, first dose and second dose. Post-vaccination follow-up was done at the centre which was then followed up by telephonic monitoring after 48 hours. In the present study 1,034 (65.6%) health care workers (HCWs) did not report any serious reactions/symptoms. Pain and tenderness were the most commonly reported side-effects in more than half. The severity of the symptoms following the second dose of vaccine was compared with the first dose and it was found that the majority 653 (41.4%) had reported no symptoms/reactions following both doses of vaccine. Every vaccine will have some side effects but it is important to understand that in the ongoing pandemic, vaccines are our "best shot" to fight against this virus.

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1. INTRODUCTION

The world health organization (WHO) had declared the coronavirus disease 2019 (COVID-19) as a public health emergency due to the rapid spread from Wuhan to neighbouring parts of China and other countries in 2020 [1], [2]. The new virus has challenged the economy, medical, and public health cadre of countries globally. There is an epidemiological burden that is constantly evolving concerning the number of people infected, hospital admissions, morbidity, and mortality [3], [4]. Vaccines were developed for this new virus and vaccination drives were carried out in various countries to slow down the spread of this infection.

The Government of India had initially approved two vaccines, namely Covishield (ChAdOx1 nCoV-19) and Covaxin (BBV152) for use from January 2021 [5]–[7]. Health care and frontline workers were given the priority to be vaccinated first. This was followed by the elderly population, then followed by people aged more than 45 [8]. Recently vaccination has been opened up for all people aged 18 and above. As of 30th June 2021 India's cumulative vaccination coverage exceeded 33.57 crores with the union government committed to accelerating the pace and expanding the scope of COVID-19 vaccination throughout the country [9]. An interim data from the trial done in Brazil, the UK, and South Africa showed that most of the adverse reactions were mild to moderate in severity and got resolved within a few days following the vaccination [10]. Beyond this, there was very limited data on the side-effects following

vaccination in our country and thus this study was carried out to determine the same. This paper in particular focuses on the side effects after the second dose of Covishield vaccination and the severity of the symptoms in comparison to that of the first dose among the recipients of Covishield vaccines.

2. RESEARCH METHOD

This was longitudinal study among those who have received their Covishield vaccine at a tertiary care hospital in Thiruvallur, Tamil Nadu, India. The study participants included all healthcare workers (HCWs) at the hospital who had taken their vaccine at this centre. The participants were followed up after the first and second doses respectively. The first dose of vaccination had begun on January 20, 2021 and the second dose of vaccination had begun on February 19, 2021 in the hospital. This particular paper is a follow-up study that focuses on the second dose side effects after vaccination. A total of 1,659 participants had taken their second dose during the study period between February 15 to April 30, 2021. All the HCWs who received the Second dose were followed at the vaccination centre. Only the Participants who attended the follow-up calls were included in the final analysis and thus we ended up with a sample size of 1,577.

Information was also collected using a pre-tested semi-structured questionnaire which included their demographic details, date of first dose vaccination, any delay in the second dose of COVID-19 vaccination and the reasons for the same, severity of the reactions if any, and comparing them to the first dose reactions and medications taken to alleviate the symptoms. At the vaccination centre, the patients were first screened and then their height, weight, and vitals were noted before the vaccination. Post-vaccination, the HCWs were observed at the vaccination centre for a brief period of 30 minutes, and their vitals were noted again.

Any reaction that occurred at the moment of vaccination was termed as "immediate reactions" and those that occurred during the 30 minutes (observation period) were termed as "reactions during observation". Participants were followed up with the help of phone calls, 48 hours post-vaccination, and reactions occurring then were termed as "delayed reactions" and symptoms if any, were treated adequately. Perception of the vaccine reactions was termed as mild, moderate, and severe. If the reactions did not affect or interfere with their daily activities, they were termed as 'mild reactions' and if it interfered with their daily activities, were termed as 'moderate reactions'. Any reactions that required hospital admission were termed as a 'severe reaction' [10].

Data collected were entered into an Excel spreadsheet (Microsoft, Redmond, WA, USA). Data were analyzed using statistical package for the social sciences (SPSS) version 20 (IBM, Armonk, NY, USA). Proportions were used to describe the socio-demographic variables and the Chi-square test was used to measure the association between the study variables, p-values<0.05 were considered statistically significant. Ethical clearance for this study has been obtained from the institutional ethical committee.

3. RESULTS AND DISCUSSION

In the present study, 1,577 vaccine recipient HCWs were observed for reactions following vaccination. The majority of the subjects were females 933 (59.2%) and more than half 845 (53.6%) of the study participants belong to less than 25 years of age. Obesity was observed in nearly 1/3rd (496) of the participants as shown in Table 1.

Among the 1,577 participants who took the vaccines, it was observed that 453 participants delayed their gap of second dose vaccination in which the majority of the participants had a delay of fewer than seven days (Mean 6.9, SD=7.67). Scheduling issues (63.3%) was found to be the main reason for vaccination delay. 38 (8.3%) HCWs felt that they would have a better immune response if they delayed their dose.

3.1. Immediate reactions

We observed that 37/1,577 (2.34%) of the HCWs reported 'immediate reactions' following vaccination and 26/37 (70.2%) were females. Non-obese individuals (83.7%) experienced more reactions than obese (16.3%) individuals and this difference was found to be statistically significant ($p<0.05$) as presented Table 2. Pain and tenderness (59.4%) were the most commonly reported side-effects in this period as shown in Table 3. On grading the severity of symptoms, it was found that 31/37 (83.7%) of the vaccine recipients reported 'mild' reactions', while one female participant experienced severe allergic reactions for which she was treated appropriately as described in Table 4. The present study revealed 1,034 (65.6%) HCWs did not report any reactions/symptoms following their second dose of vaccination.

Table 1. Socio-demographic details of the study participants

No	Variable	Frequency (N)	Percentage (%)
1	**Age**		
	<25 years	845	53.6
	26-40	463	29.4
	41-55	151	9.6
	>55	118	7.5
2	**Gender**		
	Female	933	59.2
	Male	644	40.8
3	**Designation**		
	Doctor	248	15.7
	Nursing staff	381	24.2
	Student	646	41
	Other hospital staff	302	19.1
4	**Body mass index**		
	Underweight	17	1.1
	Obese	496	31.4
	Normal	1,064	67.5

Table 2. Association between timing of adverse reactions following COVID-19 vaccination and related variables among study participants

No	Variable	Immediate reaction n=37 n (%)	Reaction within 30 mins n=106 n (%)	Reaction after observation period n=400 n (%)	Total N=1,577 n (%)
1	**Gender**				
	Female	26 (2.7)	72 (7.7)	265 (28.4)	933 (59.16)
	Male	11 (1.7)	34 (5.2)	135 (20.96)	644 (40.84)
		$\chi2$=1.935	$\chi2$=3.611	$\chi2$=12.96	
		p=0.103	p=0.057	p=0.02*	
2	**Age**				
	<25 years	25 (2.8)	65 (7.6)	239 (28.3)	845 (53.6)
	26-40	11 (2.4)	23 (4.9)	100 (21.6)	463 (29.4)
	41-55	1 (0.66)	13 (8.6)	36 (23.8)	151 (9.6)
	>55	0	5 (4.2)	24 (20.3)	118 (7.4)
		$\chi2$-5.62	$\chi2$-2.681	$\chi2$-2.763	
		p=130	p=0.443	p=0.838	
3	**Designation**				
	Doctor	6 (2.4)	12 (4.83)	57 (23)	248 (15.7)
	Nursing staff	11 (2.9)	30 (7.9)	106 (27.8)	381 (24.2)
	Student	13 (2.01)	52 (8.04)	160 (24.7)	646 (41)
	Other hospital staff	7 (2.31)	12 (3.97)	76 (25.16)	302 (19.1)
		$\chi2$=0.808	$\chi2$=7.664	$\chi2$=7.387	
		p=0.84	p=0.053	p=0.287	
4	**Obesity**				
	Yes	6 (1.2)	25 (5.1)	135 (27.2)	496 (31.4)
	No	31 (2.86)	81 (7.46)	265 (24.5)	1,081 (68.6)
		$\chi2$=4.079	$\chi2$=0.129	$\chi2$=1.564	
		p=0.043*	p=0.719	p=0.457	

*p-value<0.05. (Statistically Significant)

Table 3. Side effects after COVID-19 vaccination among study participants (multiple response)

No	Variable	Immediate reaction n=37 N (%)	Reaction within 30 mins* n=106 N (%)	Reaction after observation period n=400 N (%)
1	Headache	2 (5.4)	8 (7.5)	50 (12.5)
2	Pain/Tenderness at injection site	22 (59.4)	63 (59.4)	180 (45)
3	Giddiness/Dizziness	4 (10.8)	10 (9.4)	6 (1.5)
4	Fever	3 (8)	8 (7.5)	98 (24.5)
5	Swelling/Lump on site of injection	0 (0)	1 (0.9)	3 (0.75)
6	Unwell/Tiredness	0 (0)	1 (0.9)	3 (0.75)
7	Body pain	1 (2.7)	4 (3.8)	85 (21.25)
8	Stomach pain	2 (5.4)	0	7 (1.75)
9	Nausea/Vomiting	0	6 (5.6)	12 (3)
10	Anxiety	0	1 (0.9)	2 (0.5)
11	Allergic reaction	1 (2.7)	2 (1.8)	5 (1.25)

*Observation period

Table 4. Severity of reactions following COVID-19 vaccination

No	Variable	Total N=1,577	Severity of reaction
1	Immediate reaction	37 (2.34%)	Mild – 31 (83.7%) Moderate – 5 (13.5%) Severe – 1 (2.7%)
2	Reaction in waiting room (<30 mins)	106 (6.78%)	Mild – 88 (83%) Moderate – 16 (15%) Severe – 2 (2%)
3	Reaction after observation period	400 (25.3%)	Mild – 336 (84%) Moderate – 63 (15.7%) Severe – 1 (0.3%)

3.2. Reactions during the observation period

The 106/1,577 (6.7%) HCWs reported reaction during the 'observation period' after vaccination. Among them, it was found that the females (68%) and non-obese (76.4%) individuals reported the most symptoms. However, this was not found to be statistically significant as shown in Table 2. Pain and tenderness was the most commonly reported side-effects in more than half (59.4%) of the vaccine recipients during this period, which was followed by giddiness/dizziness (9.4%) as shown in Table 3.

The grading of severity during the observation period (within 30 mins) showed that 88/106 (83%) had mild reactions, while 2/106 (1.8%) of study participants experienced severe reactions. Among them, one male individual was found to have palpitations and high blood pressure for which electrocardiogram (ECG) was taken and found to be normal. He was kept under observation for another 30 minutes after which his blood pressure came to normal and there was one more female, who had nausea and vomiting with giddiness for which antiemetic and IV fluids were given.

3.3. Delayed reactions after vaccination

Only 1/4th (400/1,577) HCWs experienced 'delayed reactions' after the vaccination and among them females (66.3%), non-obese individuals (66.3%), and those aged less than 25 (59.8%) reported symptoms. Statistical significance was observed only in females as presented Table 2. Less than half (45%) of the vaccine recipients reported pain and tenderness, while nearly 1/4th (24.5%) complained of fever and 85 (21%) complained of body pain. Only 3 (0.75%) reported a lump at the site of injection as shown in Table 3. The grading of symptoms revealed that 336/400 (84%) had mild reactions and only one female recipient experienced a severe reaction. She was a known case of bronchial asthma and had shortness of breath after eight hours of vaccination for which she underwent treatment in a hospital and was under observation for two hours as shown in Table 4. Overall, 111/1,577 study participants (7%) took medications following COVID-19 vaccination among which antipyretics (95.4%) were most commonly used to alleviate the symptoms

3.4. Comparison of first dose versus second dose severity

The severity of the symptoms following the second dose of vaccine was compared with the first dose and it was found that the majority 653 (41.4%) had reported no symptoms/reactions following both doses of vaccine and 456 (29%) reported that they had symptoms following the first dose of vaccination. The 280 (17.8%) reported their symptoms to be mild compared to their first dose of vaccination and only 54 (3.4%) reported that their symptoms were 'more severe' when compared to their first dose symptoms. Finally, there were no deaths related to COVID-19 vaccination as shown in Table 5.

Table 5. First dose versus second dose severity comparison of COVID-19 vaccine side effects

Severity	N-1,577 Frequency (N)	Percentage
No symptoms for both doses	653	41.4
Symptoms only for the first dose	456	29
Symptoms only for the second dose	63	4
Mild symptoms compared to the first dose	280	17.8
Severe symptoms compared to the first dose	54	3.4
Same severity as the first dose	71	4.4

Vaccines of varied origin have adverse events which are mainly due to the immune response and not the allergic reaction [11], [12]. This implies that every vaccine is associated with side effects which is not a new phenomenon. Though the development of the COVID-19 vaccine was fast, it did not skip the steps of testing its safety and efficacy. Covishield is based on viral vector technology and this has been used earlier in

the production of the Ebola virus vaccine [13]. This implies that the Covishield vaccine was not developed in a hurry and the safety and efficacy were not compromised. Nevertheless, there is a misinterpretation regarding the COVID-19 vaccines and their adverse effects. Hence this study was done to explore the extent of adverse events related to the second dose of COVID-19 vaccination.

3.5. Incidence and side-effects after vaccination

In the present study, the overall incidence of adverse events following vaccination was found to be 29.8% which is in contrast to a study conducted in Bangladesh [14]. The incidence of adverse events following vaccination was found to be 2.47% immediately following vaccination, 6.78% experienced adverse reactions in the observation room, and 25.3% experienced reactions after the observation period. Many reported the adverse reactions to be between mild to moderate severity and had subsided within one or two days of vaccination with adequate rest or medications. This was consistent with the ChAdOx1 nCoV-19 vaccine trial done in Brazil, the UK, and South Africa [15]. Among other demographic factors, non-obese individuals and younger age group individuals had documented to have experienced more reactions when compared to the others. Further research is required to elicit both immune response and adverse effects among obese and non-obese individuals. In this study, the prevalence of side effects was more in females when compared to males. This was similar to another study reported in South India [16].

Pain and tenderness at the injection site were the most common events following vaccination which were found to be consistent with several studies in many parts of the world [17]–[20]. In the present study among the participants who had side effects majority reported that they had milder side effects after getting the second dose of Covishield than compared to the first dose. This finding is however in contrast to the recipients of the Pfizer-BioNTech COVID-19 vaccine who showed that the number of persons who reported symptoms after receiving the second dose of the vaccine is more compared to the number of persons who reported after receiving the first dose in Saudi Arabia [21].

3.6. Hesitancy and delay in the second dose of vaccination

The gap between the first and second dose of the Covishield vaccine was initially decided as four weeks by the Government of India at the time of the launch of the vaccine. However, the guidelines were later on changed to 4-8 weeks and then 8-12 weeks [22]. Various studies have reported better vaccine efficacy if the gap between two doses is more than 8 weeks [23].

In our institution, we followed the guidelines by the Government of India regarding the gap between the two doses of Covishield. In this study, we observed that 28.7% of the participants had delayed the second dose of the vaccine, and a majority of them delayed the vaccine because of scheduling issues. Delay was found to be highest among nurses. Only 4.8% of participants delayed the second dose vaccination for more than 21 days. This negligible percentage in delay could be due to the active vaccination drive, prompt response at the vaccination centre, and motivation by the institutional infection control department which had led to the decrease in vaccination delay.

Initially, there was vaccine hesitancy among in India as opposed to other countries due to various factors. This was present in all the strata of the population [24]–[27]. This hesitancy was also observed among HCWs of our institute and has been alleviated with frequent follow-up, counselling, and reassurance. Trials in June 2020 have shown that recommendation of the vaccine was only 61.4% which had later shown an increasing trend with the decrease in vaccine hesitancy [28]. In this study, 91.3% of HCWs would recommend the vaccine to their friends and family which infers that there's now vaccine acceptance among this population which in turn will influence the vaccine uptake in the community. A similar study done in the UK in February 2021 showed nearly four-fifths of HCWs would recommend the vaccine, while a study among the French-speaking HCWs showed only 48.6% would 'highly recommend' the vaccine to others [29], [30]. The strengths of our study include the large sample size and the robust follow-up protocol of the vaccinated participants. The major limitation of the study however is that the study is limited to only one vaccination site and thus the external validity may be limited.

4. CONCLUSION

Every vaccine will have some side effects but it is important to understand that in the COVID-19 pandemic, vaccines are our "best shot" to fight against this virus. Though no vaccine is 100% effective, they do play a major role in limiting the severity of the illness. On weighing the pros and cons of the vaccine side effects, these symptoms contribute to a smaller percentage or severity when compared to the disease outcome.

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