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ASSESSING THE ADVERSE EFFECTS OF IMMUNIZATION AFTER COVAXIN AND COVISHIELD VACCINE IN HEALTH CARE WORKERS OF INDIA

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Abstract

Background: The highly contagious COVID-19 disease or Corona Virus disease is caused by a novel coronavirus. It is a pandemic affecting a large population globally concerning both health and financial aspect. Vaccination has emerged to be a vital measure to control COVID-19. However, fear of side effects is a major concern with these vaccines warranting further studies.

Aim: The present study aimed to evaluate the adverse effects after vaccinations with either Covishield or Covaxin for COVID-19 infection.

Methods: The study included 1160 health care professionals who received either Covaxin or Covishield for COVID-19 infection prevention. The adverse effects were noted following the first and second dose of vaccines at different time intervals of less than 24 hours, 24-48 hours, and between 3 to 7 days post-vaccination. WHO (World health organization) questionnaire was used for recording the side-effects where 720 subjects took Covishield and 440 subjects Covaxin.

Results: The study results showed that most of the subjects reported side effects within 24 hours of first dose vaccination with 85% and 90% for Covishield and Covaxin respectively, and after 2nd dose were 74.16% and 89.09% respectively. The most common side effects reported after both vaccines were myalgia, chills, fever, headache, and general weakness. All adverse effects were self-limiting and subsided with no need for hospitalization.

Conclusion: The present study concludes that no significant difference is seen concerning side effects with either Covaxin or Covishield in two doses and the two vaccines separately.

Further studies are warranted in different populations and age groups to get details on the safety data of these vaccines.

Keywords: COVID-19 vaccine, covaxin, covishield, post-vaccination effect, side-effects

Introduction

COVID-19 or coronavirus disease 2019 is caused by SARS-COV-2 (severe acute respiratory syndrome corona virus-2) where the first case was reported in late 2019s in China which later spread to nearly all the countries of the World making it a pandemic disease posing a high financial and health care burden on the global level.[1] To control and prevent the spread of COVID-19, various preventive measures and treatment strategies are employed worldwide. However, all the measures were found to be ineffective due to the high infectivity rate, high spread, and mutation ability of the SARS-COV-2 virus as reported by previous literature data.[2]

The development of various vaccines as a preventive strategy for COVID-19 has been advocated and suggested by various national and global health regulatory authorities and researchers and scholars. Due to this rapid involvement of different authorities, various vaccines have become available in a short span.[3] These vaccines were comprised of inactivated viral vaccines, mRNA, and spike proteins. Few of these vaccines were approved by FDA (food and drugs administration) for EUA (emergency utilization authorization) due to possible protective effects provided by these vaccines and COVID-19 being a medical emergency needing urgent intervention.[4]

In India, the two most common vaccines used were Covaxin by Bharat biotech limited and Covishield by AstraZeneca and Serum Institute of India. These vaccines were approved to be used by the Indian regulatory authority. Based on the 3rd phase interim clinical trials, the efficacy of Covaxin and Covishield was reported to be 90% and 81% respectively. For the management of COVID-19, health care professionals are on the front line and at a high risk of getting infected with COVID-19 which makes them a prior candidate for vaccine intake and protection. Hence, the vaccines were first given to the health care personnel as suggested by the Government of India.[5]

Various side effects have been reported following the vaccination for COVID-19 including chills, joint pain, myalgia, redness, pain at the injection site, fatigue, headache, and/or fever. Most of these side effects were reported within a few days of receiving these vaccinations. The previous literature data has reported that the most common cause of vaccine refusal and hesitancy is the fear of encountering adverse effects.[6]

Different literature studies are done since the introduction of these vaccines to assess the safety profiles of the two most common Indian vaccines namely Covaxin and Covishield. A fact sheet was released by the serum institute of India after a post-marketing analysis done by the various studies. However, owing to COVID-19 being a relatively new disease and scarce data comparing side effects caused by Covaxin and Covishield available in the literature, further studies are warranted concerning the use of these vaccines.[7] Hence, the present study was done to evaluate the adverse effects after vaccinations with Covishield and Covaxin after either the first or second dose or between these two vaccines given for COVID-19 infection.

Materials and Methods

The present prospective observational study was done to evaluate the adverse effects after vaccinations with Covishield and Covaxin after either the first or second dose or between

these two vaccines given for COVID-19 infection. The study population was comprised of subjects who were health care professionals and received the COVID-19 vaccine in India.

The inclusion criteria for the study were health care personnel who received the two doses of either Covaxin or Covishield in India and were willing to participate in the study. The exclusion criteria were subjects who were not willing to participate in the study or received any other vaccine apart from Covaxin or Covishield, history of present or past infection with COVID-19, hospitalized within the past 2 weeks for reasons other than COVID-19 infection, and subjects who did not receive the two complete doses of the vaccines.

The study tool was a questionnaire developed by WHO (World Health Organization) guidelines to collect data concerning the side effects felt by the subjects after either the first or second dose of either Covaxin or Covishield as per WHO 2021. After explaining the detailed study design, informed consent was taken from all the subjects in both verbal and written format.

The study recruited a total of 1220 subjects for inclusion in the study. Among these 1220 subjects, 1160 gave consent to participate in the study where 720 health care personnel subjects received Covishield and 440 subjects received Covaxin.

The study questionnaire comprised of details concerning demographic data, duration of onset of side-effects, adverse effects of the vaccine, and the type of vaccine received by the study participants were self-filled by all the study subjects. The questionnaire comprised the lists of the adverse effects seen following either the first or second dose of the vaccine which was marked by the subjects experiencing it. The questionnaire also assessed the measures taken by the participants when they experienced any side effects related to vaccination including the need for hospitalization.

The data collected were assessed statistically using logistic regression and multivariate statistical techniques. The data were presented in tabulated and descriptive formats. SPSS version 22.0, 2013, Armonk, NY: IBM Corp and chi-square test were utilized. The data were expressed as mean and standard deviations and as percentages and numbers with a 0.05% significance level.

Results

The present prospective observational study was done to evaluate the adverse effects after vaccinations with Covishield and Covaxin after either the first or second dose or between these two vaccines given for COVID-19 infection. The study included 1160 subjects where 720 health care personnel subjects received Covishield and 440 subjects received Covaxin. Concerning the intake of Covishield vaccine in 72 study subjects, side effects following the first dose were seen in 85% (n=612) subjects within 24 hours, in 10% (n=72) subjects in 24-48 hours after the first dose of Covishield, and 5% (n=36) subjects after 3 days of Covishield 1^{st} dose. After the 2^{nd} dose of Covishield, 74.16% (n=534) subjects experienced adverse effects during the first 24 hours, 18.05% (n=130) subjects within 24-48 hours, and 7.77% (n=56) subjects after 3 days of 2^{nd} dose of Covishield as shown in Table 1.

For adverse effects seen following either 1^{st} or 2^{nd} dose of Covishield in the study subjects, after 1^{st} dose, rashes were reported by 2 subjects, giddiness by 64 subjects, joint pain in 156 subjects, myalgia in 318 subjects, vomiting in 18 subjects, nausea in 22 subjects, fatigue in 78 subjects, fever in 396 subjects, chills in 220 subjects, headache in 306 subjects, and general weakness in 404 study subjects respectively. After 2^{nd} dose of Covishield, rashes, giddiness,

joint pain, myalgia, vomiting, nausea, fatigue, fever, chills, headache, and general weakness was reported by 6, 10, 58, 168, 0, 4, 24, 148, 60, 116, and 194 study participants respectively. Vomiting following 2nd dose of Covishield was not reported by any study subject. These findings were statistically significant for giddiness, joint pain, myalgia, fatigue, fever, chills, headache, and general weakness with p<0.001. These findings were also significant for vomiting and nausea with p=0.002 and 0.01 respectively after Covishield intake as shown in Table 2.

Concerning the intake of Covaxin, after vaccination by the first dose, 90% (n=396) subjects reported adverse effects within the first 24 hours, 7.95% (n=35) subjects within 24-48 hours, and 2.04% (n=9) subjects after 3 days of immunization. Following the 2nd dose of Covaxin, 89.09% (n=392) subjects reported adverse effects within the first 24 hours of vaccination, 7.04% (n=31) subjects reported adverse effects within 24-48 hours of vaccination, and 3.86% (n=17) subjects reported that they felt adverse effects after 3 hours of 2nd dose of Covaxin as shown in Table 3.

In 440 subjects, who received Covaxin as a COVID-19 immunization modality, after 1st dose, rashes were not reported by any subject, giddiness by 24 subjects, joint pain by 86 subjects, myalgia by 176 subjects, vomiting in 10 subjects, nausea in 8 subjects, fatigue in 30 subjects, fever in 216 subjects, chills in 120 subjects, headache in 168 subjects, and general weakness in 200 study subjects respectively. After 2nd dose of Covaxin in 440 study subjects, rashes were seen in 2 study subjects, giddiness, joint pain, myalgia, vomiting, nausea, fatigue, fever, chills, headache, and general weakness was reported by 6, 30, 80, 2, 12, 90, 30, 60 and 112 study subjects respectively. These results were statistically significant for giddiness, fatigue, and headache with p-values of 0.01, 0.02, and 0.01 respectively. Also, the results were statistically significant for joint pain, myalgia, fever, chills, and general weakness with p<0.001 for each adverse effect as summarized in Table 4. All the adverse effects of both the

Discussion

The study included 1160 subjects where 720 health care personnel subjects received Covishield and 440 subjects received Covaxin. Concerning the intake of Covishield vaccine in 72 study subjects, side effects following the first dose were seen in 85% (n=612) subjects within 24 hours, in 10% (n=72) subjects in 24-48 hours after the first dose of Covishield, and 5% (n=36) subjects after 3 days of Covishield 1st dose. After the 2nd dose of Covishield, 74.16% (n=534) subjects experienced adverse effects during the first 24 hours, 18.05% (n=130) subjects within 24-48 hours, and 7.77% (n=56) subjects after 3 days of 2nd dose of Covishield. These findings were consistent with the studies of Mohakuda et al[8] in 2021 and Zhu et al[9] in 2020 where authors reported a comparable proportion of subjects reporting adverse effects following the 2 doses of Covishield.

The study results showed that for adverse effects seen following either 1st or 2nd dose of Covishield in the study subjects, after 1st dose, rashes were reported by 2 subjects, giddiness by 64 subjects, joint pain in 156 subjects, myalgia in 318 subjects, vomiting in 18 subjects, nausea in 22 subjects, fatigue in 78 subjects, fever in 396 subjects, chills in 220 subjects, headache in 306 subjects, and general weakness in 404 study subjects respectively. After 2nd dose of Covishield, rashes, giddiness, joint pain, myalgia, vomiting, nausea, fatigue, fever, chills, headache, and general weakness was reported by 6, 10, 58, 168, 0, 4, 24, 148, 60, 116, and 194 study participants respectively. Vomiting following 2nd dose of Covishield was not

reported by any study subject. These findings were statistically significant for giddiness, joint pain, myalgia, fatigue, fever, chills, headache, and general weakness with p<0.001. These findings were also significant for vomiting and nausea with p=0.002 and 0.01 respectively after Covishield intake. These reported incidences of adverse effects following Covishield agreed with the studies of Lazarus et al[10] in 2021 and Shrestha S et al[11] in 2021 where authors reported prevalence of similar side-effects as reported by the present study after 1st and 2nd dose of Covishield.

For the intake of Covaxin, after vaccination by the first dose, 90% (n=396) subjects reported adverse effects within the first 24 hours, 7.95% (n=35) subjects within 24-48 hours, and 2.04% (n=9) subjects after 3 days of immunization. Following the 2nd dose of Covaxin, 89.09% (n=392) subjects reported adverse effects within the first 24 hours of vaccination, 7.04% (n=31) subjects reported adverse effects within 24-48 hours of vaccination, and 3.86% (n=17) subjects reported that they felt adverse effects after 3 hours of 2nd dose of Covaxin. These times of experiencing these side-effects after 1st and 2nd dose of Covaxin were comparable to the studies of Polack et al[12] in 2020 and Menni et al[13] in 2021 where authors reported similar times of experiencing different side-effects after 1st and 2nd dose of Covaxin.

The study results depicted that in 440 subjects, who received Covaxin as a COVID-19 immunization modality, after 1st dose, rashes were not reported by any subject, giddiness by 24 subjects, joint pain by 86 subjects, myalgia by 176 subjects, vomiting in 10 subjects, nausea in 8 subjects, fatigue in 30 subjects, fever in 216 subjects, chills in 120 subjects, headache in 168 subjects, and general weakness in 200 study subjects respectively. After 2nd dose of Covaxin in 440 study subjects, rashes were seen in 2 study subjects, giddiness, joint pain, myalgia, vomiting, nausea, fatigue, fever, chills, headache, and general weakness was reported by 6, 30, 80, 2, 12, 90, 30, 60 and 112 study subjects respectively. These results were statistically significant for giddiness, fatigue, and headache with p-values of 0.01, 0.02, and 0.01 respectively. Also, the results were statistically significant for joint pain, myalgia, fever, chills, and general weakness with p<0.001 for each adverse effect. These findings were similar to the studies of Lee et al[14] in 2021 and Jaiswal KM et al[15] in 2021 where authors reported similar incidences of different side effects following 1st and 2nd doses of Covaxin vaccination as in the present study.

Conclusion

Within its limitations, the present study concludes that no significant difference is seen concerning side effects with either Covaxin or Covishield in two doses and the two vaccines separately. Further studies are warranted in different populations and age groups to get details on the safety data of these vaccines. The limitations of this study were smaller considered population, shirt monitoring, and biased related to the geographic location warranting further long-term studies planned longitudinally.

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TABLES

Side effects (time)	**%**	**N=720**
After 1st dose		
Within 24 hours	85	612
24-48 hours	10	72

After 3 days	5	36
After 2nd dose		
Within 24 hours	74.16	534
24-48 hours	18.05	130
After 3 days	7.77	56

Table 1: Subjects experiencing side-effects following 1st and 2nd dose of Covishield

Adverse Effect	Covishield (n=720)		p-value
	1st dose	2nd dose	
Rashes			
Yes	2	6	0.33
No	718	714	
Giddiness			
Yes	64	10	**<0.001**
No	656	710	
Joint Pain			
Yes	156	58	**<0.001**
No	564	662	
Myalgia			
Yes	318	168	**<0.001**
No	402	552	
Vomiting			
Yes	18	0	**0.002**
No	702	720	
Nausea			
Yes	22	4	**0.01**
No	698	716	
Fatigue			
Yes	78	24	**<0.001**
No	642	696	
Fever			
Yes	396	148	**<0.001**
No	324	572	
Chills			
Yes	220	60	**<0.001**
No	500	660	
Headache			
Yes	306	116	**<0.001**
No	414	604	
General weakness			
Yes	404	194	**<0.001**
No	316	526	

Table 2: Subjects reporting adverse effects following either 1st or 2nd dose of Covishield

Side effects (time)	%	N=440
After 1st dose		
Within 24 hours	90	396
24-48 hours	7.95	35

After 3 days	2.04	9
After 2nd dose		
Within 24 hours	89.09	392
24-48 hours	7.04	31
After 3 days	3.86	17

Table 3: Subjects experiencing side-effects following 1st and 2nd dose of Covaxin

Adverse Effect	Covaxin (n=440)		p-value
	1st dose	2nd dose	
Rashes			
Yes	0	2	0.33
No	440	438	
Giddiness			
Yes	24	6	**0.01**
No	416	434	
Joint Pain			
Yes	86	30	**<0.001**
No	354	410	
Myalgia			
Yes	176	80	**<0.001**
No	264	360	
Vomiting			
Yes	10	2	0.12
No	430	438	
Nausea			
Yes	8	2	0.15
No	432	438	
Fatigue			
Yes	30	12	**0.02**
No	410	428	
Fever			
Yes	216	90	**<0.001**
No	224	350	
Chills			
Yes	120	30	**<0.001**
No	320	410	
Headache			
Yes	168	60	**0.01**
No	272	380	
General weakness			
Yes	200	112	**<0.001**
No	240	328	

Table 4: Subjects reporting adverse effects following either 1st or 2nd dose of Covaxin