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ADVERSE EVENTS FOLLOWING ChAdOx1 nCoV-19 (COVISHIELD) VACCINE IN KASHMIR VALLEY: FINDINGS FROM FOLLOW-UP OF VACCINE RECIPIENTS USING ACTIVE SURVEILLANCE.

Community Medicine

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ABSTRACT

Introduction: Surveillance for adverse events after the rollout of a new vaccine is of paramount importance. This study was conducted to estimate the frequency and characteristics Of Adverse Events Following Immunization with ChAdOx1 nCoV-19 vaccine.

Methods: An observational follow-up study design was used for vaccine recipients in the first quarter of 2021. Using non-randomized method, alternate subjects coming for vaccination were included. Baseline sociodemographic and any immediate AEFIs were recorded at the vaccination site followed by computer-assisted telephonic interviews on days 1,3,7 and 30. The same protocol was followed after second dose. Sample size was calculated using formula for prevalence studies. Standard case definitions were used for AEFIs. Chi-square test was used to test for significance and P-value of less than 0.05 was considered significant

Results: A total of 652 subjects with a mean age of 59.1 ± 9.2 years were included. 3/4th of subjects were males and 1/4th were healthcare workers. The most common systemic side effects after first dose were fever (49.4%), Fatigue (43.6%) headache (38.6%), and chills/shivering (28.4%). Myalgia/arthralgia developed in around 10% and diarrhea in around 3% of subjects. Among local symptoms, tenderness at the injection site, pain at the site were reported by almost half whereas warmth and swelling were reported by 1/5th of participants. Second dose had a similar AEFI profile. h/o COVID-19 and younger age had a significant association with incidence of AEFI.

Conclusion: Although around half of subjects developed any AEFI, most of these were minor and self-limiting.

KEYWORDS

AEFI, ChAdOx1 nCoV-19, Surveillance, Vaccination.

INTRODUCTION:

Adverse events following immunization (AEFI) is defined as 'any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the use of the vaccine (1). Vaccines contain antigens that stimulate our immune system leading to activation of various immunological mediators (2) (3). Consequently, all vaccines are usually associated with a range of systemic and local adverse effects, the frequency and pattern depending on the type of vaccine and the characteristics of recipients (4)(5). The enormity of the COVID-19 pandemic led to accelerated vaccine development and approvals by regulatory bodies (6). One of the early vaccines to be approved was the Oxford vaccine (ChAdOx1 nCoV-19), which is based on viral vector technology and was manufactured by AstraZeneca (7)(8)(9). In India, the Serum Institute of India developed a variant of the same vaccine, which was initially approved by the national drug regulator of India and is one of the vaccines globally with emergency use authorization from the World Health Organization (WHO) (10)(11). This was the first vaccine to be made available in India under the name COVISHIELD (12). Due to shortages at the initial stage, a staggered approach of the rollout was planned with healthcare workers, persons aged above 60 years, and persons aged above 45 years with comorbidities prioritized for vaccination initially(13). An inbuilt system for recording of AEFI was also put in place before vaccine rollout but that system is primarily passive and past evidence has shown that passive reporting systems suffer from underreporting (14)(15). Considering the importance of having local data on the adverse event profile after immunization, the present study was conducted to estimate the frequency and characteristics of AEFIs after immunization with the COVISHIELD vaccine and identifying socio-clinical factors associated with its occurrence.

METHODS:

Study design/Setting: India rolled out its COVID-19 vaccination campaign in January 2021 for healthcare workers. Two more subgroups, the elderly population and persons with comorbidity were included in the prioritized population(13). The health facility in which this study was conducted also started vaccination in January. The subjects were selected from those coming to the health facility for vaccination. A prospective observational study design was used. Using a non-randomized method, alternate subjects coming for vaccination were enrolled in the study starting from the 2nd week of February. The enrollment for new subjects continued for one month. This period was the nadir in the epidemic curve of India as well as locally in J&K where this study was conducted (16). The vaccination was conducted in a hospital setting by a dedicated healthcare worker and vaccine recipients were kept under observation for a minimum period of 30 minutes post-vaccination (17).

Participants: The participants were adults aged more than 18 years who received the first dose of vaccine at the hospital and did not have any exclusion criteria. The subjects were explained about the purpose of the study and their informed consent sought. Socio-demographic characteristics, past medical, allergic history of subjects were recorded on a pretested schedule. Following this their height and weight were recorded and their contact numbers recorded. The subjects were observed for 30 minutes after vaccination for any immediate AEFI. The subjects were then contacted telephonically on day 1, Day 3, day 7, and day 30 of vaccine administration. Computer-assisted telephonic interviews were conducted to record any new symptoms among the participants. The same protocol was followed after the second dose.

EXCLUSION CRITERIA:

Subjects who had any disease affecting recall and/or cognitive function.

Study Questionnaire: The study schedule included three sections. The first section was filed in person when the subject received his/her vaccine and included socio-clinical details, history of allergies, weight, and height. The second part was filled during computer-assisted telephonic interviews on the 1st, 3rd, 7th, and 30th days. Questions regarding symptoms were open-ended. The same set of questions were repeated after 2nd dose.

Sample method and size: The sample size was estimated based on an estimated population parameter of 1.5%, which was the incidence of

the least reported symptom in one previous study (18). The sample size needed was estimated to be 568 for 95% CI and a 1% acceptable margin of error. The sample size was increased by 10% to accommodate for any non-response or incomplete data resulting in a required sample size of 625 (19). The total number of subjects included in the study was 652.

Study variables: Proportion of recipients who developed any AEFI after 1st and 2nd dose of vaccine, Proportion of different types of AEFIs after 1st and 2nd dose.

Case definitions used:
AEFI: In the current study, any new symptom which developed among vaccine recipients from vaccine administration till one month was categorized as AEFI (20) (21).

Minor AEFI: It included symptoms that were mild and did not require hospitalization. The symptoms included local ones like tenderness/ pain at the injection site, mild fever, myalgia, and headache which were managed at home(17) (22).

Severe AEFI: AEFI was categorized into severe as per national AEFI guidelines and included cases of high-grade fever (>102) and cases that were not minor but did not result in death or hospitalization (22).

Serious: AEFI was considered serious if it resulted in death, required hospitalization, resulted in persistent or significant disability, or a cluster of AEFIs (22) (23).

The categorization was done independently by two authors based on available data on symptoms. Cases in which different categories were assigned by the authors were discussed with an independent public health expert and a consensus was achieved.

STATISTICAL METHODS: The data was first collected on an excel spreadsheet and then exported to SPSS 23. Proportions and means were calculated depending on the data. The Chi-square test was used to test for significance. A P-value of less than 0.05 was considered statistically significant.

RESULTS:
A total of 652 subjects who received the first dose of vaccine were included in the study. Of these subjects, 646 subjects received the second dose as well. The subjects had a mean age of 59.1 ± 9.2 years and comprised of 72% males. One-fourth of subjects were healthcare workers. A total of 91 (13.9%) subjects had a history of past COVID-19 infection. The socio-clinical profile of study participants is described in Table 1.

The most common systemic adverse effects after the first dose were fever (49.4%), Fatigue (43.6%) headache (38.6%), and chills/shivering (28.4%). Other systemic symptoms included myalgia and arthralgia which developed in around 1/10th of subjects and the least reported symptom was diarrhoea. Among local symptoms, tenderness at the injection site, pain at the site were reported by almost half of the subjects. Warmth and swelling locally were reported by 1/5th of participants. An allergic reaction was reported by one participant and comprised of generalized itching which needed injectable antihistaminic. The detailed breakup of symptoms is depicted in Table 2. The incidence proportion following the second dose was not significantly different from the first dose and included the same symptoms which are described in Table 2.

Table 1: Socio-clinical characteristics of study subjects

		N	%
Gender	Male	473	72.55%
	Female	179	27.45%
Age	Overall Mean ± SD	59.1 ± 9.2	
	18 -44	109	16.72%
	45-60	196	30.06%
	60 years and more	347	53.22%
BMI	Underweight	38	5.83%
	Normal	481	73.77%
	Overweight/obese	133	20.40%
Category of recipient	HCW	160	24.54%
	Age more than 60	324	49.69%
	45-59 with comorbidity	168	25.77%
Marital status	Currently married	523	80.21%
	Unmarried	72	11.04%
	Widowed/divorced	57	8.74%
Comorbidity	Yes	335	51.38%
	No	317	48.62%
h/o drug allergy	No	21	3.22%
	Yes	631	96.78%
Previous h/o covid	Yes	91	13.96%
	No	561	86.04%
Education	Illiterate	82	12.58%
	primary	134	20.55%
	secondary or more	436	66.87%

Table 2: Profile of AEFI after the first and second dose of COVISHIELD Vaccine

	First dose No received= 652		Second dose No received= 646	
Systemic side effects	**N**	**%**	**N**	**%**
Any	348	53.37	367	56.81
Fever	322	49.39	353	54.64
Fatigue	284	43.56	304	47.06
Headache	252	38.65	201	31.11
Chills and shiver	185	28.37	214	33.13
Myalgia	92	14.11	128	19.81
Arthralgia	64	9.82	86	13.31
Nausea	47	7.21	53	8.20
Diarrhoea	22	3.37	13	2.01
Local side effects	**N**	**%**	**N**	**%**
Any	408	62.58	423	65.48
Tenderness	383	58.74	405	62.69
Pain	347	53.22	368	56.97
Warmth	134	20.55	104	16.10
Swelling	124	19.02	146	22.60
Redness	90	13.80	76	11.76
Itch	34	5.21	21	3.25
Bruising	14	2.15	12	1.86
Swollen armpit glands	3	0.46	5	0.77
Allergic reaction				
Rash	1	0.15	0	0.00
Skin burning	0	0.00	0	0.00
swelling of face lips	0	0.00	0	0.00

The AEFIs were broadly classified into three groups as per the national guidelines and the proportion of subjects with mild AEFI, severe AEFI, and serious AEFI after the first dose were 63.3%, 8.9%, and 0.2%. 27.6% did not develop any AEFI. The corresponding figures for the second dose were 67.3%, 11.5%, and 0%. The same is depicted in Figure 1.

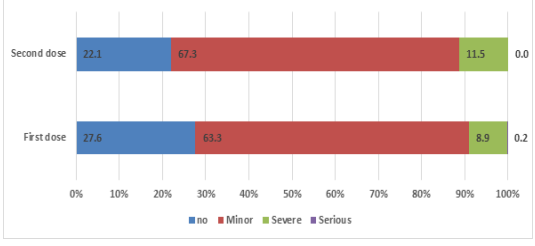

Figure 1: Types of AEFI after the first and second dose of Vaccine

Time duration for AEFI: Most of the AEFI started on the next day of vaccination and almost all resolved by the 5th day of vaccination. All symptoms except injection site tenderness peaked in terms of the proportion of subjects with symptoms on the 2nd day. The time trend of the most common symptoms is depicted in Figure 2.

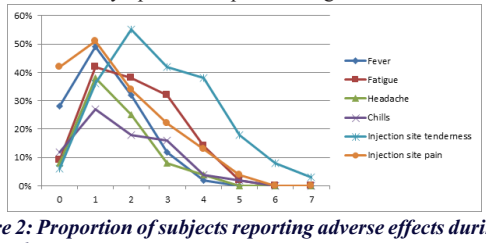

Figure 2: Proportion of subjects reporting adverse effects during the first week

Determinants of AEFI: Younger age and history of COVID-19 infection were associated with a higher incidence of systemic AEFIs. Other socio-clinical factors including gender, type of recipient, h/o comorbidity had no significant association with the occurrence of AEFI. The association of all socio-clinical factors with the incidence of AEFI is described in Table 3.

Table 3: Association of systemic and local AEFIs with socio-clinical factors

		N	Any Systemic AEFI		Local AEFI	
			Number	%	Number	%
Gender	Male	473	251	53.07	295	62.37
	Female	179	97	54.19	113	63.13
	P-value		*0.864*		*0.927*	
Age	< 55 years	236	142	60.17	151	63.98
	>55 years	416	206	49.52	257	61.78
	P-value		***0.0091****		*0.6137*	
Type of recipient	HCW	160	93	58.13	103	64.38
	Age more than 60	324	167	51.54	198	61.11
	45-60 with comorbidity	168	88	52.38	107	63.69
	P-value		*0.376*		*0.738*	
Comorbidity	No	335	186	55.52	216	64.48
	Yes	317	162	51.10	192	60.57
	P-value		*0.272*		*0.331*	
BMI	Underweight	38	21	55.26	24	63.16
	Normal	481	256	53.22	295	61.33
	Overweight/o	133	71	53.38	89	66.92
	P-value		*0.058*		*0.498*	
h/o COVID-19	No	561	289	51.52	345	61.50
	Yes	91	59	64.84	63	69.23
	P-value		***0.0231****		*0.1634*	
h/o drug allergy	Yes	21	12	57.14	14	66.67
	No	631	336	53.25	394	62.44
	P-value		*0.825*		*0.82*	
	*Significant p values**					

DISCUSSION:

Surveillance for AEFI after vaccination is an important public health intervention as fear of AEFIs is one of the primary reasons for vaccine hesitancy(24) (25). Most AEFIs are the side effects of immunological response mounted against antigens in the vaccine whereas some like allergic reactions depend on multiple host factors(26). Still, providers need to be aware of the frequency and distribution of expected AEFIs for counselling vaccine beneficiaries.

The present study estimated the incidence of AEFIs after the first and second dose of the COVISHIELD vaccine in the Indian Kashmir Valley. A total of 652 subjects were enrolled in the study with a mean age of 59.1 ± 9.2. Around 1/6th had a history of COVID-19 infection and 25% were healthcare workers. Half of the subjects were suffering from any comorbidity.

The most common systemic adverse effects included Fever and fatigue which were reported by half of the subjects followed by headache and Chills. Diarrhoea was the least reported systemic adverse event reported by around 3% of subjects. Symptoms like myalgia or arthralgia were reported by around 10%. Among local adverse events, injection site tenderness and pain were the most common symptoms reported by more than half of the subjects. Around 1/5th of subjects reported injection site swelling and warmth. Injection site itching and bruising were less common. One subject developed an immediate allergic reaction. The subject developed generalized itching without any signs of anaphylaxis and was treated by parenteral antihistaminic at the health facility. Two similar studies have been conducted in India with one conducted in Kerala state and another in Maharashtra state. The incidence proportion of this study correlates well with the study done in Kerala as around 50% of subjects in that study also reported fever, headache and myalgia (27). The other study conducted in Maharashtra reported less frequency of AEFIs but the pattern was similar to this study(28). In addition, both these studies only had healthcare workers as their study participants and the present study included a higher proportion of subjects with comorbidities.

Globally the largest post-marketing surveillance study was conducted in the United Kingdom in which 33% of subjects had experienced systemic adverse events and around 60% had experienced local adverse events(18). Our study subjects found a higher incidence of systemic adverse events but comparable local ones. That study had a lesser proportion of subjects with a history of COVID-19 disease and had a higher average age of subjects. the two study populations also have vast genetic and racial differences which can also be a reason for the higher proportion of systemic adverse events in this study.

The incidence of adverse events particularly systemic adverse effects is higher when compared with other vaccines like the flu vaccine. It could be due to vaccine composition but there are also chances of it being high due to the apprehensions among recipients as the COVID-19 vaccine is new.

Although the rates for AEFI may seem high as evidenced by the fact that around half of subjects experienced any symptom, most of these were minor AEFIs which either resolved on their own or needed simple symptomatic treatment. Of the severe ones, most had a high-grade fever which was managed at home settings and only 1 subject needed a short stay at the hospital. The subject also recovered by parenteral antihistaminic.

Younger age and history of COVID-19 had a statistically significant association with the incidence of systemic adverse effects. There was no significant association of local AEFIs with any sociodemographic factor. The has been much debate on the impact of age and AEFIs after the ChAdOx1 nCoV-19 vaccine and two previous studies conducted also found a significant relation(27)(29). More studies with a bigger sample size may be needed to explore this further. History of COVID-19 and higher systemic adverse effects may be due to the presence of a primed immune system among previously infected subjects and the UK study also found higher rates of AEFIs in previously positive subjects(18).

The onset of all symptoms was usually on the 1st day of vaccination and it peaked on the 2nd and 3rd days. Fever, headache, fatigue, and injection site pain were most common on the next day of immunization whereas injection site tenderness was reported by most subjects on 3rd day of vaccination. Only injection site tenderness persisted in more than 10% of subjects beyond the 5th day. So even if around half of the subjects developed on or other adverse events, these were self-limiting and remained for around 2 days.

The present study consisted of 2/3rd males. This correlated with the gender breakup of overall vaccine recipients as 75% of vaccine recipients for the entire study duration were males. The same was true for the overall subregion in which 2/3rd of those who received the vaccine were males. This points to a broader issue of higher vaccine hesitancy among females in the region.

Even a small loss to follow-up in AEFI surveillance studies can severely impact the validity of the study as the follow-up loss could be due to any vaccine adverse event. The study team planned an in-person follow-up with the six subjects who did not turn up for the second dose. In-depth interviews were conducted and AEFIs were explored in detail. Two out of these six subjects had developed only minor AEFI which were similar in pattern to the rest of the subjects. The reasons for not receiving 2nd dose were not related to AEFIs from the first dose. Two believed that only one dose is sufficient as they had previously been infected with COVID-19. Rest four wanted to delay the second dose further.

Strengths and limitations: the primary limitation of this study was that the study is not powered enough to estimate serious AEFI and AEFIs of special concern. The study also did not have any control group to estimate the size of any placebo effect as there are high chances of overreporting when any new vaccine is administrated to subjects due to fear and anxiety. That said keeping a control group would have been unethical. The primary strengths lie in the fact that there was no loss to follow-up, as one reason for attrition could have been any serious AEFI post-vaccination.

Ethics statement: Informed consent was taken from all subjects and the study was approved by the institutional review committee of the institute.

Conflict of interest: The authors declare that they have no competing interests.

Authors' contribution: AJ was involved in conceptualizing, data analysis and writing of the manuscript. MM was involved in designing study protocols, data collection, collation and analysis and provided inputs to the manuscript. SA was involved in developing study protocols data analysis and manuscript writing. WR provided support in collation analysis and writeup. SK provided inputs in developing study protocols and in manuscript writing.

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