International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 12, December 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.12.2024.90

ORIGINAL RESEARCH

Adverse Events Following Covid-19 vaccination: A prospective study from GMC Anantnag, J&K

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Received Date: 18 November, 2024 Accepted Date: 14 December, 2024

Abstract
Aims and Objectives: To find out the incidence of adverse events following immunization (AEFIs) after COVID-19 vaccination**.**
Material and Methods: This is a prospective study of the AEFIs associated with COVID-19 vaccine (Covishield) at the Government Medical College Anantnag. The volunteers after getting vaccinated were asked to wait in the ADR surveillance room of vaccination centre for at least 30 minutes for any immediate unexpected adverse reaction before leaving the vaccination centre.
The demographic as well as other necessary health details were received and entered on a predesigned Covid-19 vaccine safety surveillance form (CVSSF) developed by the department of pharmacology, GMC Anantnag. These participants were telephonically called for any possible AEFI after the gap of 24 hours and 72 hours after receiving the vaccination dose (for both first and second dose).
Results: A total of 1765 individuals got vaccinated whose mean age was 46.8 years ranging from17 years to 93 years out of which 38% were females and 62% were males. Total of 422 participants showed AEFI out of which 379 (49.8%) developed AEFI after first dose of vaccination while only 43 (7.4%) developed AEFI after 2nd dose of vaccination. The most common AEFI after first and 2nd dose of vaccine were fever, chills, local pain, fatigue and myalgia. None of the participants who developed the AEFI required hospitalization.
Conclusion: We conclude that the AEFIs associated with COVID-19 vaccination are mostly mild and can be managed without hospitalization.
Keywords: Covid-19 Vaccination, AEFI, Covishield

INTRODUCTION:

Coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an infectious disease. Vaccination against coronavirus disease2019 (COVID-19) is underway globally to prevent the infection caused by the severe acute respiratory syndrome coronavirus.[1] After its outbreak in Wuhan, China (December 2019), the rapid spread of the virus sparked alarm worldwide. The World Health Organization declared this outbreak a pandemic, and countries around the world are grappling with a surge in confirmed cases. As the virus spreads through close contact and by small droplets produced during cough, sneeze or talk,[2,3] most of countries have responded with preventive measures through health advocacy campaigns, lockdowns and restricting public gatherings. Meanwhile, scientists are exploring potential treatments, testing new therapies and vaccines to contain the virus.[4]

In India, the first SARS-CoV-2 positive case was reported in the state of Kerala on Feburary 03, 2020.[5] Subsequently, in Kashmir too the number of COVID-19 cases drastically increased. The first case in Kashmir was reported on 18th March 2020 when the lady had an international travel history.[6]

Vaccines against COVID-19 have been recognized as one of the most effective public health interventions to control the pandemic.[7] Vaccines are intended to produce active immunity to specific antigens. Adverse events following immunization (AEFIs), including any untoward medical occurrences, does

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not necessarily have a causal relationship with the vaccine. [8]

It is important to improve the inoculation rate of the COVID-19 vaccine to achieve the national goal of herd immunity. However, several adverse events associated withCOVID-19 vaccines have been reported, including anaphylaxis, transverse myelitis and deep vein thrombosis.[9,10,11]

Misrepresentation spread through the various media outlets have caused substantial anxiety among the large population about the safety of vaccine.[12] . Furthermore, no large-scale research studies are available yet about the adverse event following immunization (AEFI) associated with the COVID-19 vaccine in the general population.

AEFIs may be related not only to the vaccine itself, but also to the vaccination procedure (vaccine quality defects, immunization errors or anxiety) and coincidental events (not linked to the vaccine). Most of the reported AEFIs are not serious and are mediated by non-immunological mechanisms.[13] However, these events can cause fear and loss of confidence in the safety of vaccines among the public. A good understanding of AEFIs will help alleviate fears about the current COVID-19 vaccines.

AEFI AGAINST COVID-19: NON-ALLERGIC AEFI

Local injection site reactions (swelling, redness, and/or soreness) and systemic symptoms, especially fever, are common after administration of most vaccines and are usually non-allergic reactions.[14] Clinical trial data from the various studies of different vaccines suggest that the most common adverse effects following immunization were pain at the injection site, fatigue, headache, myalgia, chill, arthralgia, sore arm, nausea, dizziness, weakness, aching muscle and rapid heart beat.[9,12,15]

These reactions seem to reflect the body's normal immune response to vaccines. They are typically seen with most vaccines and tend to resolve within a few days. These types of AEFI associated with COVID-19 vaccines are broadly similar across age groups, although they may be slightly more frequent in younger adults.[16]Some non-allergic systemic reactions may be complicated by the onset of syncope (vasovagal or vasodepressor reaction),[16] which can occur after many types of vaccination and is most common among adolescents and young adults. In particular, the Vaccine Adverse Event Reporting System (VAERS) in the US has detected a trend toward increasing syncope reports linked to three shots specifically for adolescents with different ingredients: human papillomavirus vaccine, meningococcal conjugate vaccine, and Tdap (tetanus, diphtheria, and pertussis).[15,16] According to the Centers for Disease Control and Prevention (CDC), 80% of the reported syncope episodes occur within 15 minutes of vaccine administration.[16]A vasovagal syncope episode is usually triggered by pain and anxiety, but not by the vaccine itself, causing sudden drops in heart rate and blood pressure. Many experts have concluded that syncope may result from the temporary pain of vaccination rather than the COVID-19 vaccine itself. Syncope itself is generally not serious, but syncope-related falls or other accidents can cause injury.[8,14] Although syncope itself may or may not be preventable, it is important to prevent injuries when people faint. An interesting study estimated the baseline incidences of several AEFIs, including syncope. The mean predicted monthly incidence of vasovagal syncope was 23.89 (19.81-27.98) cases per 100,000 in 2021, suggesting that it is possible that cases could develop at COVID-19 vaccination sites, so thorough preparations are required.[17] Till date, frequent non-allergic AEFIs associated with COVID-19 vaccines generally appear to be the same as those associated with other existing vaccines. There is also a safety issue regarding thrombosis, which has yet to be resolved.[18]

We aimed to evaluate the incidence and severity of AEFI associated with the COVID-19 vaccine at a single center during the six (06) month among the general population and the front line workers (FLW) as well as health care workers (HCW) from south kashmir and to provide a basis to ensure safety during the future national vaccination against COVID-19. In this study, we collected the adverse effect following immunization by directly making the phone calls tothe study participants.

Methodology:

This was a prospective study (for the period of six months from 16th January 2021 to 16th July 2021) of the AEFIs associated with the First and Second dose of the COVISHIELD vaccine (Manufactured by Serum Institute of India) at the Government Medical College Anantnag. We aimed to find out the incidence of adverse events following immunization (AEFIs) after COVID-19 vaccination among the general population from the South Kashmir. The volunteers after getting vaccinated were asked to wait in the surveillance room for at least 30 minutes for any unexpected adverse reaction before leaving the vaccination centre.

The demographics as well as other necessary details along with the contact numbers of the volunteers who got vaccinated were received and entered on a predesigned Covid-19vaccinesafetysurveillance form (CVSSF) developed by the department of pharmacology, GMC Anantnag. These details were collected from the vaccination centre of GMC Anantnag and the nodal officer of the adverse drug reaction reporting centre stationed in the department of Pharmacology GMC Anantnag could make a list of those volunteers whom they will call for any possible AEFI after the gap of 24 hours and then again after 72 hour gap after receiving the vaccination dose (for both first and second dose). Recipients were also advised to voluntarily report to us in case if they

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noticed any untoward adverse reaction following immunization on the common helpline number given to them. If any call regarding the AEFI was received at the nodal centre, then depending on the severity of AEFI the patient was advised to visit the nearest health centre as soon as possible.

Government of India initially set up the age limit for the volunteers who want to get vaccinated. HCW and FLW followed by the general population with the age group more than 45 years were eligible first to be vaccinated. Information about the COVISHIELD vaccine and vaccination was notified to all the eligible volunteers who were recommended for vaccination, and informed consent was obtained before the vaccination. The HCWs were asked to fill a preliminary form that captured the previous history of vaccination, COVID-19, and allergies. The vaccine was administered in the deltoid region by well-trained nurses, and adverse events were monitored for 15–30 minutes. Every HCW who had a history of allergic reaction was monitored for at least 30 minutes. After monitoring, vaccinated HCWs were advised to report to the outpatient clinic of the department of infectious diseases (IDs) or the emergency room (ER) if the adverse events persisted.

RESULTS:

A total of 1765 individuals got vaccinated of which 38% were females and 62% were males. The mean age was 46.8 years ranging from 17 years to 93 years. Highest number of participants (48.7%) were in the age group of 40-59 years. A total of 358 (20.3%) of our participants had some form of comorbidity. Majority of the participants (64.5%) received first of vaccine and 35.5% received second dose of vaccine during the study period. Total of 422 (23.9%) participants observed some type of AEFI following vaccination. **(Table 1)**

Table 1: General characteristics of Study Participants

Participant Characteristics		Frequency	Percent
Gender	Male	1094	62.0
	Female	671	38.0
Total		1765	100.0
Age	17-39 Years	518	29.3
	40-59 Years	860	48.7
	≥ 60 Years	387	21.9
Total		1765	100.0
Mean Age in Years = 46.82±14.206, Min. age = 17 Years & Max. age = 93 Years			
Comorbidity	Yes	358	20.3
	No	1407	79.7
Total		1765	100.0
Vaccination Dose	1st	1139	64.5
	2nd	626	35.5
Total		1765	100.0
AEFI	Yes	422	23.9
	No	1343	76.1
Total		1765	100.0

DOI: 10.69605/ijlbpr_13.12.2024.90

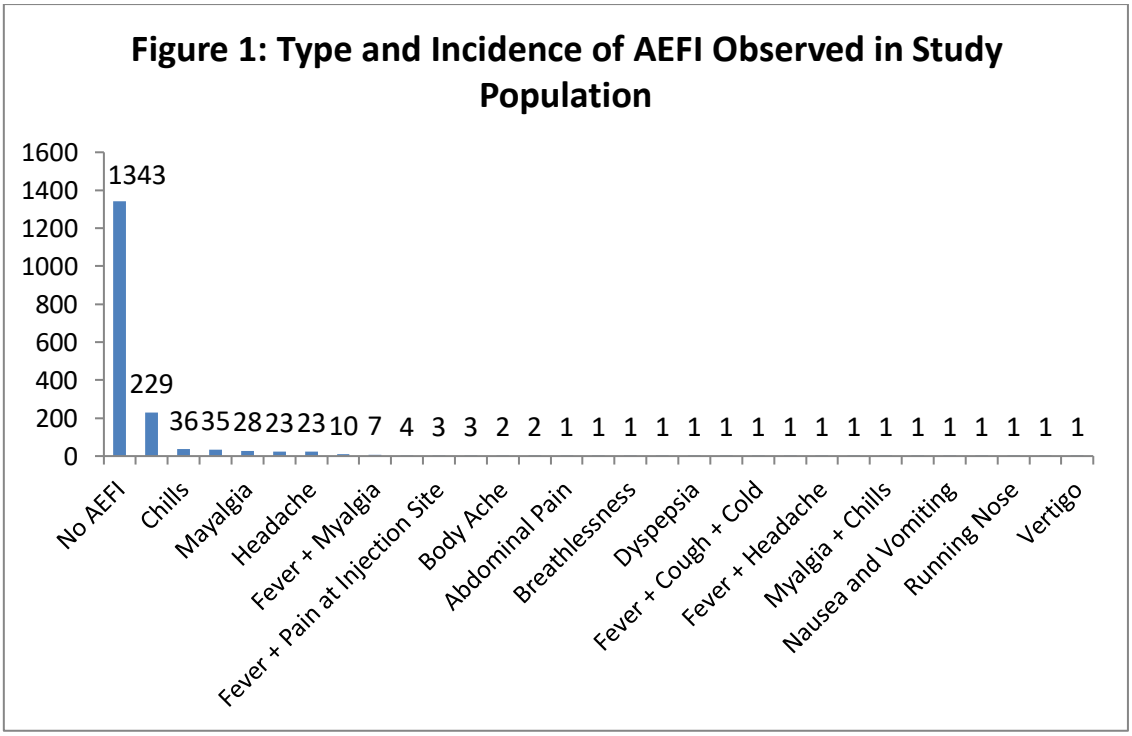

Figure 1 shows type and incidence of AEFI following COVID-19 vaccination in our study population. The most common AEFI observed in our study was fever only in 229 subjects followed by chills (36), pain at the site of injection (35), general mayalgia (28), fatigue (23) and others as shown in figure 1.

Table 2: Risk factor assessment for AEFI after COVID-19 Vaccination

		AEFI		Total	Relative Risk (95% CI)	P-Value
		Yes	No			
Dose	1st	379	760	1139	4.844 (3.589-6.538)	<0.0001
		33.3%	66.7%	100.0%		
	2nd	43	583	626		
		6.9%	93.1%	100.0%		
Gender	Male	267	827	1094	1.056 (0.888-1.256)	0.532
		24.4%	75.6%	100.0%		
	Female	155	516	671		
		23.1%	76.9%	100.0%		
Age	17-59 Years	352	1026	1378	1.412 (1.122-1.778)	0.002
		25.5%	74.5%	100.0%		
	≥ 60 Years	70	317	387		
		18.1%	81.9%	100.0%		
Comorbidity	Yes	88	270	358	1.035 (0.844-1.270)	0.738
		24.6%	75.4%	100.0%		
	No	334	1073	1407		
		23.7%	76.3%	100.0%		

The risk factors assessment for the development of AEFI in COVID -19 vaccination is shown in **table 2**. The most commonly AEFI occurred after first dose of vaccination in 33.3% of the subjects and only in 6.9% of the subjects following second dose. The difference was found to be statistically significant (p <0.0001). The relative risk for the development of AEFI following first dose as compared to second dose of COVID-19 vaccination was found to be 4.844 (95% CI = 3.589-6.538).

No statistically significant difference was found in AEFI among males (24.4%) and females (23.1%).

The 25.5% of the subjects within the age bracket of 17-59 Years developed AEFI while as only 18.1% developed AEFI who had age above 59 years. The difference was found to be statistically significant (p=0.002). The relative risk for development of AEFI in age group 17-59 years was 1.412 (95% CI = 1.122-1.778) as compared to the subjects with age more than 59 years. 24.6% of the subjects with comorbidity and 23.7% of the subjects without any comorbidity developed AEFI. However, the difference was found to be statistically not significant (p value = 0.738).

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DISCUSSION:

In this study the total number of individuals who got vaccinated were 1765 which included health care workers, frontline security workers and the local residents of the northern part of Kashmir. Out of these beneficiaries 1139 individuals received first dose of covishield vaccine among whom 379 (33.3%) individuals produced adverse affects following immunization (AEFI). Among the individuals who showed AEFI only 24.4% were males and 23.1% were females. The individuals who recieved the 2nd dose of covishield were 626 among whome only 43 (7.4%) individuals (27 Males; 16 females) developed AEFI as shown in **table 1 & 2**. The reduction of AEFI after 2nd dose of vaccination could be due to the increased immune response in the individuals by the covishield vaccine after its first dose. [22]

As shown in table 2, we also found that 88 (24.6%) individuals developed AEFI also had some comorbidities while as 334 (23.7%) individuals without any comorbidity also developed AEFI. The most common comorbity found among the vaccinated people was hypertension followed by diabeties mellitus but there was no statistically significant difference observed in development of AEFI in individuals with comorbididty.

The most commonly AEFI found in our study after first and 2nd dose of covishield were fever, chills local pain, fatigue and myalgia. None of the participant who developed the AEFI required hospitalization. All the AEFIs which developed among the vaccinated individuals got resolved within 3 to 4 days after taking the necessary medication prescribed after consulting the physician. In the study it was also found that most of the AEFI which were found in the participants within the age group of 17-59 years and least among the age group above 59 years. Hence the older people were not at risk for development of AEFI but instead had lower risk than the younger individuals.

In the literature it was found that most of the frequently reported adverse reactions were tenderness and pain at the injection site, headache and fatigue and the majority of these adverse reactions in severity were mild to moderate which got resolved within days ofter vaccination.[9, 19] But in contrast to these previous studies, the data from our study showed that the most commonly reported AEFIs after the first and 2nd dose of the covishield vaccine were fever, chills, pain and tenderness, fatigue, myalgia and headache respectively. There were no serious events which required hospitalization, and most AEFIs improved within a few days after vaccination. Earlier one of the study showed that the incidence of anaphylaxis associated with vaccination tended to increase in Korea.[17] As of March 26,2021, according to the status of reports of adverse reactions after vaccination against COVID-19 in Korea, 96 suspected cases of anaphylaxis were reported (96/771284 i.e. 0.01% incidence). [20] In our study we did not found any case of anaphylaxis and no serious adverse events who required hospitalization were reported from our study. Similar results as found in our study were also seen from the research articles published from Nepal and Korea. [8,21]

The limitations from our study must be considered. Firstly, since this study was conducted at a single center, the results might not be generalizable. So the multicentric study involving many vaccination centers could be suggestive.

CONCLUSION:

The most frequently reported AEFI were fever, chills, pain and tenderness, fatigue, myalgia and headache after covishield vaccination. The severity of all the AEFI reported were from mild to moderate and no death was reported due to post vaccination complications from our study. The number of AEFI reported after 2nd dose of vaccination drastically reduced to 7.4% which was almost 49.8% after first dose of vaccination. The abundant information to fill the surveillance forms of individuals who are getting vaccinated and by involving multiple vaccination centers to obtain the large pool of AEFIs after vaccination are still required.

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