



## “Vaccine Coverage and Adverse Effect Evaluation Following First Dose of Covid-19 Vaccine among Healthcare Workers in a Tertiary Care Hospital in Jammu”

Dr. Aakriti Khajuria<sup>1</sup>, Dr. Sunny Babber<sup>2</sup>, Dr. Shalini Sobti<sup>3</sup>

<sup>1</sup>(Intern, ASCOMS&H, J&K, INDIA)

<sup>2</sup>(Assistant professor, ASCOMS&H, J&K, INDIA)

<sup>3</sup>(Associate professor, ASCOMS&H, J&K, INDIA)

Submitted: 25-04-2021

Revised: 06-05-2021

Accepted: 08-05-2021

**ABSTRACT: Background:** COVID-19 emerged as epidemic in Wuhan city of china (animal food market). The first case of the COVID-19 pandemic in India was reported on January 30th, 2020. The COVID vaccine in India was launched on 16<sup>th</sup> January, 2021. The first group to receive vaccine (Covishield) in the 1<sup>st</sup> phase includes healthcare and frontline workers. **Objective:** The aim of this study was to determine the distribution and types of adverse events reported following immunization of healthcare workers at ASCOMS AND HOSPITAL, in Jammu, from the day vaccination for 1<sup>st</sup> dose of Covishield started until 1 week after the end of vaccination and To find relation of AEFI with prior Covid exposure, taking paracetamol prophylactically, age and co morbid status of vaccine beneficiary and to analyse the vaccine coverage in our hospital. **Methods:** A questionnaire was prepared and data was collected during the Covishield vaccination of health workers at the ASCOMS AND HOSPITAL from random 200 health care workers who got vaccination and all those health care workers were more than or equal to 18 years of age and the data was compiled by using the appropriate statistical analysis. **Result and Conclusion:** The most prominent adverse events reported were injection-site pain, fatigue, fever, myalgia, headaches, dizziness, abdominal pain, nausea, sweating, vomiting, diarrhoea in decreasing order. Majority of adverse events observed were mild to moderate and usually resolved within a few days. Total vaccine coverage of 1<sup>st</sup> dose in our hospital was 80%. The incidence of fever was reported less in the vaccine beneficiaries who had prior Covid exposure, had taken paracetamol prophylactically or had both diabetes and hypertension. In this paper, we also analysed that as the age increases the incidence of fever decreased by using chi square test.

**Key words:** Covid 19, Covishield, Health workers, AEFI, Vaccine coverage.

### I. INTRODUCTION

Covid 19 (Corona virus) emerged as pandemic starting from china (Wuhan city) [1]. On 31<sup>st</sup> December 2019, cases of pneumonia with unknown aetiology were reported to World Health Organization (WHO) [2]. On 30<sup>th</sup> Jan 2020, this virus was labelled as PHEIC (public health emergency of national concern) by WHO [3]. Also, on 30<sup>th</sup> Jan 2020, 1<sup>st</sup> case was reported from India from the Kerala state [4]. on 11<sup>th</sup> march 2020, it was labelled as Global pandemic by WHO. The agent of Covid is SARS COV-2 (SS-RNA) [5]. The origin was said to be from bat [6]. Camel, civet cat and pangolin were said to play the role of intermediate host. Mode of infection was found to be droplet method and incubation period is 2-14 day [7]. Clinical features are fever, myalgia, cough, headache, runny nose, loss of taste and smell sensation [8]. Many drugs were under trial and are used to treat patients, but seeing the fast spread of this infectious disease, the need of Covid vaccine was most important. Many countries tried to make vaccines and India among few other countries successfully made the vaccine and completed the trials and finally the vaccine for Covid in India was launched on 16<sup>th</sup> January, 2021 [9]. Thereafter the vaccination process was started in 3 phases, 1<sup>st</sup> phase of healthcare workers and frontline workers (army, police, revenue, sanitation dept.), 2<sup>nd</sup> phase for old >60 years and >45 years with specific co morbid conditions given by the government of India. And 3<sup>rd</sup> phase for all the government employees followed by the entire general public. 2 vaccines, Covishield and Covaxin are in use [10].

In ASCOMS and Hospital, Covishield was supplied for vaccination of health workers and all the health care workers were registered for the same. The vaccination in this hospital started on 28<sup>th</sup> Jan 2021. It is globally acknowledged that vaccination is one of the most important steps especially in the fight against the spread of communicable diseases. There is inoculation of the killed or attenuated form of microorganisms



through vaccination, and then the body's immune system is stimulated to produce antibodies which will then protect against infections.

Adverse events following immunization (AEFIs) may occur due to any error during vaccine preparation, handling of vaccine, during administration of vaccines or due to inherent properties of the contents of vaccine. Local, systemic, or allergic reactions usually occur as a result of reactions to inherent properties of a particular vaccine even when the vaccine is prepared, handled, transported or administered correctly. In some cases, AEFIs occur from unknown causes.

In ASCOMS and hospital, Covishield vaccine was administered. Covishield Vaccine is developed by Oxford University and AstraZeneca. The Covishield (AZD1222) vaccine is a replication-deficient simian adenovirus vector, and it basically contains the coding sequence of SARS-CoV-2 spike protein. It also has tissue plasminogen activator (tPA) leader sequence. The spike S1 protein is an external protein which enables the SARS-type corona virus to enter cells through the enzymatic domain of ACE2. The spike protein is produced after vaccination prompting the immune system to attack the corona virus if it anytime in future infects the body. Covishield is Liquid, preservative-free, multi-dose suspension. There are 10 doses per vial (each dose of 0.5 mL) and given with Auto-disable (AD) syringe: 0.5 mL, intramuscularly on left deltoid. It is recommended for 18 years of age and above, including persons 65 years of age and older recommended schedule 2 doses (0.5 mL each) can be administered with an interval of 4-12 weeks. WHO recommends an interval 8-12 weeks, where Dose 1 is given making it the start date followed by Dose 2 which is given 4 to 12 weeks after first dose. Route and site of administration is Intramuscular (I/M) administration and the preferred site is deltoid muscle. Dosage is 0.5 mL (single dose). no diluents are needed. Vaccine is stored in the original carton in a refrigerator at +2 to +8 °C

#### **METHOD OF VACCINATION DONE IN THE HOSPITAL**

Through short message service (SMS), all health workers were informed about their vaccination slot one day before the vaccination. The vaccine was administered by well-trained nurses. For uniformity, 0.5 ml of Covishield vaccine was administered intramuscularly into the deltoid muscle of the left arm. Each vaccine was kept in an observation room and was advised to report any adverse events

following immunization [11] to designated health workers on duty. After vaccination, people were advised to wait in the observation room for 30 min to check whether they may experience any pain in arm, altered sensorium, light-headedness, dizziness or any allergic reaction. As per the data collected, no vaccinee had any severe issue in the observation room. After few hours (5-6 hours) of vaccination, few health workers complained that they had some irritability in mood, and after about 6-8 hours after vaccination, some health care workers complained of myalgia, nausea, tenderness at the injection site and feverish feeling. After almost 12 hours, the vaccine beneficiaries experienced high grade fever with chills which required paracetamol to resolve. Some health care workers took paracetamol prophylactically before the onset of fever in order to reduce the chances of fever and headache. No health care worker in this hospital had any major AEFI like allergic reaction or any other adverse effect which may require hospitalization. By about second day of vaccination, fever and headache were resolved after taking paracetamol, however myalgia and tenderness at the injection site persisted in many health care workers. Almost in all individuals, Paracetamol (NSAID) seemed to be required to resolve the AEFI. The second dose of vaccine is planned to be administered after 28 days in all the registered health care workers who received the 1<sup>st</sup> dose.

#### **II. MATERIAL AND DATA COLLECTION:**

A questionnaire was prepared and data was collected from random 200 health care workers who got vaccinated. They were asked about the adverse effects they had after the first dose and basic information about their health status, any immuno-compromised status, previous history of diabetes mellitus and hypertension and prior Covid exposure. They were also asked about intake of paracetamol prophylactically. Everyone was informed that they can share data only if they feel comfortable and it will be used purely for research purpose and names won't be used anywhere.

**PARTICIPANTS:** Random 200 people among the registered health care workers of ASCOMS and hospital who responded to the questionnaire. The data was collected randomly from interns, nurses, doctors, clerks, sweepers, canteen handlers, watchman's and registered health care workers at all levels of the hospital.

**DATA ANALYSIS:** The data thus obtained was compiled and analysis was done in IBM SPSS 21.



In this paper, we use student t- test and chi square test for comparison and the others results are evaluated by calculating different percentages.

### III. RESULTS

Out of total registered staff which is 1500, A total of 1200 healthcare workers got vaccinated for 1<sup>st</sup> dose resulting in coverage of 80%. The coverage of this 1<sup>st</sup> dose in ASCOMS and hospital was not 100%. Many registered health care workers didn't get vaccinated. Some of the challenges to this coverage are vaccine safety and efficacy. Many females who were pregnant or lactating avoided the vaccine. The staff who were currently having Covid also didn't get vaccinated. Also, some health care workers were not well or were in their post-operative period who avoided the vaccine. Vaccine hesitancy and fear of AEFI can be another challenge.

Out of the data collected from 200 random health care vaccine beneficiaries, 58% were males (n=116) and 42 % were females (n=84).

Total mean age of the random 200 people was  $34.95 \pm 10.38$ . Males with a mean age of  $35.66 \pm 10.54$  years were vaccinated and females with a mean age of  $33.96 \pm 10.16$  years were vaccinated. 89% (n=178) vaccinees reported minor adverse events. The mean age among vaccinees reporting minor adverse events was  $31.87 \pm 8.48$  years. No one reported major AEFI like allergic reaction which could lead to hospitalisation (n=0). 11% (n=22) vaccine beneficiaries had no adverse effect. The mean age among vaccinees reporting no adverse events was  $38.13 \pm 10.81$  years, here we find highly statistical significant difference between the mean age among vaccinees reporting minor adverse events and the mean age among vaccinees reporting no adverse events ( $t=3.16$ ,  $p=0.001$ ). Therefore, age has effect on the incidence of AEFI.

Out of total males, 50.86% (n=59) males had some minor AEFI and out of total females, 55.95 % (n=47) females had AEFI. In particular, we found no significant difference in the way males reported AEFI compared to females (Chi-squared  $[\chi^2] = 0.34$ ;  $p = 0.56$ ). Thus, gender has no role in reporting of AEFI.

**Table 1:** Distribution of various AEFI of Covishield first dose.

Vaccinees Beneficiary	Male (%)	Female (%)	Total (%)	p-value
No. of persons	116 (58)	84 (42)	200	-
Mean age	$35.66 \pm 10.54$	$33.96 \pm 10.16$	$34.95 \pm 10.38$	
Minor AEFI	59 (50.86)	47 (55.95)	96 (48)	0.56
Pain at injection site	-	-	125(62.5)	-
Fatigue	-	-	108(54)	-
Fever	-	-	106(53)	-
Myalgia	-	-	89(44.5)	-
Headache	-	-	50(25)	-
Dizziness	-	-	46(23)	-
Abdominal pain	-	-	43(22.5)	-
Nausea	-	-	34(17)	-
Sweating	-	-	22(11)	-
Vomiting	-	-	19(9.5)	-
Diarrhoea	-	-	19(9.5)	-

According to data, 62.5% (n=125) of people had pain at injection site, 54% (n=108) had fatigue, 53% (n=106) had fever, 44.5% (n=89) had myalgia, 25% (n=50) had headache, 23% (n=46) had dizziness, 21.5% (n=43) had abdominal pain, 17% (n=34) had nausea, 11% (n=22) had sweating, 9.5% (n=19) had vomiting, 9.5% (n=19) had diarrhoea. No one had any allergic reaction (n=0).

About 14.5% (n=29) had a history of diabetes mellitus and 19.5% (n=39) had a previous history of hypertension while 10.5% (n=21) had

history of both diabetes and hypertension. And 76.5% (n=153) had no co morbidity. Observed events were generally milder and fever was less frequently reported in patients having hypertension and diabetes mellitus both (42.85%) as compared to the ones who didn't have any co morbidity (53.59%). Thus, co morbid patients had less incidence of fever.

About 19.5% (n=39) of vaccine beneficiaries had a prior Covid exposure. Also, the fever was less frequent in the health care workers



who had a previous history of Covid (25.64%) as compared to the ones who didn't have any covid exposure (54.62%). Therefore, previous Covid infection decreases the chance of fever following immunisation.

Out of 200 people, 86 took paracetamol prophylactically and 114 didn't take paracetamol prophylactically. Out of these 86 people who took paracetamol prophylactically 29.07% (n=25) develop fever and out of 114 people who didn't take paracetamol 71.05% (n=81) didn't develop fever. here we can see that prophylactic paracetamol intake decreases incidence of fever.

About 86.5% (n=173) vaccine beneficiaries of 1<sup>st</sup> dose said that they would go for the 2<sup>nd</sup> dose. About 5.5% (n=11) said that they won't go for the 2<sup>nd</sup> dose and 8% (n=16) said they weren't sure about going for the 2<sup>nd</sup> dose.

Mean no. of days after which the vaccine beneficiaries recovered from the side effects of 1<sup>st</sup> dose are  $2.21 \pm 1.14$  days. the mean no. of days for recovery from AEFI for males was  $2.08 \pm 0.97$  days and that for females is  $2.28 \pm 1.34$  days, (t= 1.22, p=0.22). here we find no statistical significance between the no. of days of recovery for males and females. So, gender has no role in recovery period from the adverse effect.

We divided the whole population in 3 groups according to the age i.e., 18-40 years, 40-60 years and more than 60 years. In the age group of 18-40 years, out of 130 persons, 63.07% (n=82) had fever, for 40-60 years of age, out of 66 persons, 34.84% (n=23) had fever and for the age >60 years, out of 4 persons, 25% (n=01) had fever. On comparing the above data according to different age group, we find that there is highly statistically significant difference between them i.e., as the age increases, the incidence of fever decreases. (Chi-square  $[\chi^2] = 15.28$ ;  $p < 0.001$ )

#### IV. CONCLUSION

The most prominent adverse events that we found in our study were injection-site pain, fatigue, fever, myalgia, headaches, dizziness, abdominal pain, nausea, sweating, vomiting, diarrhoea in decreasing order. Majority of adverse events observed were mild to moderate and usually resolved within 2 to 3 days. The vaccine coverage of 1<sup>st</sup> dose in our hospital was 80 %. The incidence of fever was reported less in the vaccine beneficiaries who had prior Covid exposure, had taken paracetamol prophylactically or had both diabetes and hypertension. Also, as the age increases, the incidence of fever decreases. Gender had no effect on development of AEFI or days of recovery.

#### REFERENCES

- [1]. H. Lu, C. W. Stratton, and Y. W. Tang, "Outbreak of pneumonia of unknown etiology in Wuhan China: the mystery and the miracle," *Journal of Medical Virology*, vol. 92, no. 4, pp. 401-402, 2020.
- [2]. Pranab Chatterjee, Nazia Nagi, Anup Agarwal, Bhabatosh Das, Sayantan Banerjee, Swarup Sarkar, Nivedita Gupta and Raman R. Gangakhedkar. The 2019 novel coronavirus disease (COVID-19) pandemic: A review of the current evidence. *Indian J Med Res.* 2020 Feb-Mar; 151(2-3):147-159.
- [3]. World Health Organization. COVID-19 as a Public Health Emergency of International Concern (PHEIC) under the IHR, 05/19/2020 - 12:00.
- [4]. M.A. Andrews, Binu Areekal, K.R. Rajesh, Jijith Krishnan, R. Suryakala, Biju Krishnan, C.P. Muraly, and P.V. Santhosh. First confirmed case of COVID-19 infection in India: A case report, *Indian J Med Res.* 2020 May; 151(5): 490-492.
- [5]. Anant Parashar. COVID-19: Current understanding of its pathophysiology, clinical presentation and treatment. *Postgraduate Medical Journal (PMJ)*. Available from: <https://pmj.bmj.com/content/early/2020/10/06/postgradmedj-2020-138577>.
- [6]. Ben Hu, Xingyi Ge, Lin-Fa Wang, and Zhengli Shi. Bat origin of human coronaviruses. *Virology* 2015; 12: 221.
- [7]. Hayat Ouassou, Loubna Kharchoufa, Mohamed Bouhrim, Nour Elhouda Daoudi, Hamada Imtara, Noureddine Bencheikh, Amine ELbouzidi, Mohamed Bnouham, "The Pathogenesis of Coronavirus Disease 2019 (COVID-19): Evaluation and Prevention", *Journal of Immunology Research*, vol. 2020, Article ID 1357983, 2020. Available from: <https://doi.org/10.1155/2020/1357983>
- [8]. M. A. Shereen, S. Khan, A. Kazmi, N. Bashir, and R. Siddique, "COVID-19 infection: origin, transmission, and characteristics of human corona viruses," *Journal of Advanced Research*, vol. 24, pp.91-98, 2020 .
- [9]. World Health Organisation. COVID -19 VACCINES <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines>.



- [10]. Ministry of health and family welfare, Government of India Information Regarding COVID-19 Vaccine. Available from=[https://www.mohfw.gov.in/covid\\_vaccination/vaccination/index.html#:~:text=In%20the%20initial%20phase%2C%20COVID,45%20and%2059%20with%20comorbidities](https://www.mohfw.gov.in/covid_vaccination/vaccination/index.html#:~:text=In%20the%20initial%20phase%2C%20COVID,45%20and%2059%20with%20comorbidities)
- [11]. SERUM INSTITUTE OF INDIA. ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) COVISHIELD. Available from=[https://www.seruminstitute.com/product\\_covishield.php](https://www.seruminstitute.com/product_covishield.php)