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Original Research Article

The occurrence of adverse events following immunization after first and/or second dose of Covishield or Covaxin vaccine at a tertiary care hospital: An observational study

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ABSTRACT

Background: With the introduction of the COVID-19 vaccine, many cities of India are reporting minor, mild, and severe AEFI cases during half an hour of observation and after that. No vaccine can protect everyone receiving it and is safe too for everyone. Effective vaccines could produce a few unwanted side effects mainly mild and clear up frequently.
Methods: After the COVID-19 vaccination, everyone was asked to wait for 30 minutes in the observation room to check for any type of AEFI. While waiting, all second dose beneficiaries were asked to fill a printed case record form with all demographic details, including AEFI events experienced after their first dose of the COVID-19 vaccine. Phone calls were made to all 500 beneficiaries after seven days of vaccination to know about the type of AEFI experienced after the second dose.
Results: Safety of product is of paramount importance and in this study, we actively captured adverse events post-vaccination. Fever, headache, weakness, body pain, were the most common adverse events along with pain at the injection site. In our study, the younger age group was associated with minor AEFIs. However, we did not find any supporting evidence for high reactogenicity among women, and this may be due to an almost similar proportion of men and women in our sample.
Conclusions: The advantages of immunization in disease prevention have significantly exceeded the risks of immunization-associated adverse events. COVID vaccines have their largest potential to end the COVID-19 pandemic if they are widely accepted and used. As we all want to get rid of the diseases which are not curable easily and spread with very large intensity, now is the time to get vaccinated and control them.

Keywords: Adverse reactions, COVID-19 vaccine, Covishield, Covaxin

INTRODUCTION

The SARS-CoV-2 pandemic has severely impacted health systems, economic and social progress globally. 2020 has been a difficult year for all as COVID-19 disease has arisen with unprecedented speed. But a hope against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is only vaccines. The rollout of vaccines in several parts of the world is being hailed as a solution to the crisis. However, there is a long series of communicable diseases in which vaccines are only partially effective and we have a series of sensational vaccine defeats. So, the evaluation of the safety and efficacy of vaccines that have to be used against the SARS-CoV-2 virus in different populations is essential because it is an RNA virus, and generally has a high mutation rate.[1-2]

AEFI (Adverse Events Following Immunization) is the term that helps to know these risk factors. It is an

inappropriate medical incident occurring after vaccination or immunization and does not have any relationship with the administration of a vaccine. These incidences of adverse events could be of any non-favorable, abnormalities, symptoms, or disease. If not dealt with frequently and effectively can lead to undermining of vaccine confidence and eventually have a drastic consequence for coverage of immunization and disease prevalence. As there is nothing perfect in the world like that there is no vaccine that can protect everyone receiving it and safe too for everyone. Effective vaccines could produce a few unwanted side effects mainly mild and clear up frequently. Many of the events associated with vaccine administration are not due to the vaccine, few of them happen due to coincidental events or due to program or human error. As we all will accept that it is impossible to attribute every person having a mild to serious reaction to a vaccine. Therefore, there are some contradictions regarding a few vaccines. Further, contraindications and the risk of serious adverse effects can be minimized for proper functionality. Therefore, a systematic data collection, evaluation, and analysis of all the minor or major medical events that occurred after vaccination was ordered to perform in the immunization program by World Health Organization (WHO).[3,4] India has played a central role in the COVID-19 vaccination globally. India's Drug Regulatory Authority has given emergency approval of two vaccines for restricted use against COVID-19, on 3 January 2021, however, phase III clinical trials for Covishield and Covaxin were still ongoing in India.[5,6] Covishield, which is being manufactured by the Pune-based Serum Institute of India (SII), the world's largest vaccine manufacturer; and Covaxin, which is the Hyderabad-based Bharat Biotech (BB) has developed in conjunction with the Indian Council of Medical Research.[7] The rollout of vaccines in several parts of the world is being hailed as a solution to the crisis. With newer and more virulent serotypes on the horizon and limited vaccines available, evaluation of safety and immunogenicity is critical for the rationalization of vaccine use in public health.[8] This study aims to establish a practical workflow to define the causal relationship between adverse events following immunization (AEFI) and COVID-19 vaccination.[5]

Rationale

AEFI means any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease. All of us need to take health and safety precautions concerning the COVID-19 vaccine. With the introduction of the COVID -19 vaccine, many cities of India are reporting minor, mild, and severe AEFI cases during half an hour of observation and after that. AEFI included Lymphadenopathy, decreased appetite, Headache, Dizziness, Nausea, Vomiting, Abdominal pain, Hyperhidrosis, Injection site bruising including injection site hematoma, rash, Myalgia, arthralgia, Injection site tenderness, injection site pain, injection site warmth, injection site erythema, injection site pruritus, injection site swelling, fatigue, malaise, pyrexia, chills, etc. A serious AEFI is an event that results in death, hospitalization, or prolongation of existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, or is life-threatening; The clinical manifestations of AEFI profile are heterogeneous. COVID-19 vaccine AEFI include a wide range of symptoms and conditions that may vary from minor symptom to critical conditions.

Aim of the study was to assess the occurrence of adverse events following immunization after first and/or second dose of Covishield/covaxin vaccine at the COVID Vaccination Centre of a tertiary care hospital: An observational study. Objectives of the study were to determine the occurrence of manifestations after getting the first and/or second dose of the Covishield/covaxin vaccine and to assess the type of AEFI concerning other factors such as age group, sex, presence of co-morbidities

METHODS

The data includes 500 beneficiaries from the vaccination center of a tertiary care hospital. On the day of the vaccination, the beneficiaries waited for their turn to verify their identification card. The vaccine was administered in the deltoid region by the well-trained nurses with the Covishield/covaxin vaccine. After the COVID-19 vaccination, everyone was asked to wait for 30 minutes in the observation room to check for any type of AEFI. While waiting, all second dose beneficiaries were asked to fill a printed case record form with all demographic details, including AEFI events experienced after their first dose of the COVID-19 vaccine. Phone calls were made to all 500 beneficiaries after seven days of vaccination to know about the type of AEFI experienced after the second dose. Out of 500 beneficiaries, 250 took covishield and the other 250 took Covaxin. Data analysis was done from the above data sources to provide insights into the situation post-vaccination in tertiary care hospital.

RESULTS

Covishield

A total of 155 adverse events were reported in covishield and 73 in Covaxin as seen in Tables 1 and 2. The most common adverse events in covishield were Pain at the injection site, fever, body pain, Weakness, Headache, fever with body pain. The fewer common symptoms were Shivering, Fever with chills, Giddiness, Vomiting, rash, Acidity, and anosmia. There were 3 hospital admissions, all 3 were after getting 1st dose of Covishield. The majority of AEFI symptoms lasted for 1–2 days. Co-morbidities were present in 59 (23.6%) of the recipients of Covishield.

Table 1: Age-wise occurrence of symptoms, co-morbidities, duration of symptoms in covishield vaccine (n= 250).

Variables	Age groups					
	18-44 years		45-60Years		> 60 years	
	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Symptoms						
Fever	98 (73.13)	19 (14.18)	12 (8.95)	2 (1.49)	3 (2.23)	0
Fever with chills	36 (92.3)	0	2 (5.1)	0	1 (2.6)	0
Fever with body pain	67 (77.01)	7 (8.04)	10 (11.49)	0	3 (3.34)	0
Headache	60 (60.60)	22 (22.22)	5 (5.05)	9 (9.09)	1 (1.01)	2 (2.02)
Vomiting	7 (50)	1 (7.14)	4 (28.57)	1 (7.14)	1 (7.14)	0
Body pain	83 (70.33)	19 (16.10)	10 (8.47)	5 (4.23)	0	1 (0.84)
Shivering	34 (79.06)	3 (6.97)	5 (11.62)	1 (2.32)	0	0
Rash	2 (40)	0	2 (40)	0	0	1 (20)
Weakness	87 (84.46)	5 (4.85)	8 (7.76)	1 (0.97)	2 (1.94)	0
Hospital admission	3 (100)	0	0	0	0	0
Others*	112 (58.94)	49 (25.78)	23 (12.10)	0	6 (3.15)	0
Co-morbidities	18 (30.50)		33 (55.93)		8 (13.55)	
Duration of symptoms (days)						
1	99 (58.92)	44 (26.19)	11 (6.54)	8 (4.76)	3 (1.78)	3 (1.78)
2	40 (63.49)	6 (9.52)	12 (19.04)	4 (6.34)	1 (1.58)	0
3	0	0	2 (100)	0	0	0
4	0	0	1 (100)	0	0	0

Others include symptoms such as pain at the injection site, giddiness, anosmia, acidity

Table 2: Age-wise occurrence of symptoms, co-morbidities, duration of symptoms in Covaxin vaccine (n=250).

Variables	Age groups					
	18-44		45-60		60-90	
	1st dose	2nd dose	1st dose	2nd dose	1st dose	2nd dose
Symptoms	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Fever	52 (69.33)	10 (13.33)	10 (13.33)	0	3 (4)	0
Fever with chills	3 (75)	1 (25)	0	0	0	0
Fever with Body pain	17 (85)	2 (10)	1 (5)	0	0	0
Headache	25 (59.19)	17 (36.17)	2 (4.25)	1 (2.12)	1 (2.12)	1 (2.12)
Vomiting	3 (75)	1 (25)	0	0	0	0
Body pain	45 (67.16)	13 (19.40)	5 (7.46)	2 (2.98)	2 (2.98)	0
Shivering	4 (57.14)	0	1 (14.28)	0	2 (28.57)	0
Rash	3 (100)	0	0	0	0	0
Weakness	31 (73.80)	8 (19.04)	2 (4.76)	0	1 (2.38)	0
Hospital Admission	0	0	0	0	0	0
Others*	184 (66.90)	24 (8.72)	45 (16.36)	4 (1.45)	16 (5.81)	2 (0.72)
Co-morbidities-	2 (4)	29 (58)	19 (38)			
Duration of symptoms (days)						
1	56 (57.14)	29 (29.59)	9 (9.18)	1 (1.02)	3 (3.06)	0
2	21 (55.26)	9 (23.68)	2 (5.26)	1 (2.63)	4 (10.52)	1 (2.63)
3	5 (62.5)	3 (37.5)	0	0	0	0
4	0	2 (66.66)	1 (33.33)	0	0	0

Others include symptoms such as pain at the injection site, giddiness, anosmia, acidity.

Covaxin

Adverse events in Covaxin included Pain at injection site, giddiness, fever, body pain, headache, weakness (N-42, 16.8%), fever with body pain (N-20.8%), shivering (N- 7, 2.8%), fever with chills (N-4, 1.6%), vomiting (N-4, 1.6%) and rash (N-3, 1.2%). There were no hospital admissions among the recipients of Covaxin and the AEFI symptoms lasted for 1-2 days in most of the study participants. 50 (20%) of them had co-morbidities.

AEFI in different sexes

A total of 155 adverse events were reported in Covishield of which 76 (49%) were reported in males and 79 (51%) in females.

A total of 73 adverse events were reported in Covaxin in which 33 (13.2%) were reported in males and 40 (16%) in females. Adverse events in both males and females included pain at the injection site, fever, body pain, weakness, fever with body pain, headache, shivering, fever with chills, vomiting, giddiness, rash, acidity, and anosmia. There were 2 (0.8%) hospital admissions in Covishield (2 in males and 1 in females) and 1(0.4%) hospital admission in Covaxin (male).

AEFI with co-morbidities

93 beneficiaries were having co-morbidities and took the vaccine. Out of which, 51 took Covishield and 42 took Covaxin. The adverse events which occurred in those beneficiaries were fever with chills, pain at the injection site, fever, fever with body pain, headache, weakness, shivering, giddiness, vomiting, rash, acidity, and anosmia. No hospital admissions were seen in beneficiaries with co-morbidities. In this study, all the symptoms were mild.

However, the significant symptoms in covishield were fever, fever with chills, fever with body pain, headache, shivering, weakness, and other symptoms like pain at the injection site, giddiness, anosmia, and acidity.

The significant symptoms in covaxin were rash weakness and other symptoms like pain at the injection site, giddiness, anosmia, and acidity. Symptoms were also significant in patients with co-morbidities like angina, asthma, diabetes mellites, hypertension, hyperthyroidism, and sickle cell anaemia.

Table 3: Sex-wise occurrence of symptoms, co-morbidities, duration of symptoms in Covishield and Covaxin.

Variables	Covishield		Covaxin	
	Male	Female	Male	Female
	N (%)	N (%)	N (%)	N (%)
Symptoms				
Fever	61 (45.52)	73 (54.47)	44 (58.66)	31 (41.33)
Fever+chills	15 (38.46)	24 (61.53)	1 (25)	3 (75)
Fever+Body pain	41 (47.12)	46 (52.87)	8 (40)	12 (60)
Headache	39 (39.39)	60 (60.60)	21 (44.68)	26 (55.31)
Vomiting	10 (71.42)	4 (28.57)	2 (50)	2 (50)
Body pain	52 (40.62)	66 (51.56)	33 (49.25)	34 (50.74)
Shivering	16 (37.20)	27 (62.79)	3 (42.85)	4 (57.14)
Rash	3 (60)	2 (40)	0	3 (100)
Weakness	47 (45.63)	56 (54.36)	18 (42.85)	24 (57.14)
Others	113 (49.47)	77 (40.52)	247 (89.81)	28 (10.18)
Hospital Admission	2 (66.66)	1 (33.33)	0	0
Co-morbidity	27 (45.76)	32 (54.23)	40 (80)	10 (20)
Duration of symptoms (days)				
1	73 (43.45)	95 (56.54)	54 (55.10)	44 (44.89)
2	32 (50.79)	31 (49.20)	13 (34.21)	25 (65.78)
3	2 (100)	0	5 (62.5)	3 (37.5)
4	0	1 (100)	2 (66.66)	1 (33.33)

Table 4: Occurrence of symptoms with co-morbidities in Covishield and Covaxin.

Symptoms	Covishield	Covaxin
	N (%)	N (%)
Fever	26 (10.4)	11 (4.4)
Fever + chills	57 (22.8)	0
Fever + Body pain	25 (10)	0
Headache	19(7.6)	4 (1.6)
Vomiting	4 (1.6)	0
Body pain	22 (8.8)	7 (2.8)
Shivering	6 (2.4)	4 (1.6)
Rash	4 (1.6)	0
Weakness	18 (7.2)	6 (2.4)
Others	38 (15.2)	37 (14.2)
Hospital Admission	0	0

Table 5: AEFI with Co-morbidities in both vaccines.

Symptoms	Angina	Asthma	Diabetes	Hypertension	Hyperthyroidism	Sickle cell anemia
Fever	1 (0.2%)	1 (0.2%)	10 (2%)	16 (3.2%)	6 (1.2%)	3 (0.6%)
Fever + chills	2 (0.4%)	5 (1%)	7 (1.4%)	9 (1.8%)	11 (2.2)	3 (0.6%)
Fever +body pain	1 (0.002)	0	9 (1.8%)	10 (2%)	2 (0.4%)	3 (0.6%)
Headache	1 (0.002)	2 (0.4%)	6 (1.2%)	7 (1.4%)	4 (0.8)	2 (0.4%)
Vomiting	0	0	3 (0.6%)	1 (0.2%)	0	0
Body pain	1 (0.2%)	2 (0.4%)	6 (1.2%)	13 (2.6%)	5 (1%)	3 (0.6%)
Shivering	0	0	2 (0.4%)	5 (1%)	3 (0.6%)	0
Rash	0	0	0	1 (0.2%)	0	0
Weakness	1 (0.2%)	3 (0.6%)	6 ((1.2%)	9 (1.8%)	3 (0.6%)	3 (0.6%)
Pain at inj site	1 (0.2%)	6 ((1.2%)	27 (5.4)	28 (5.6)	6 ((1.2%)	1 (0.2%)
Giddiness	0	1 (0.2%)	5 (1%)	3 (0.6%)	1 (0.2%)	0

Table 6: Significant symptoms in both vaccines.

Symptoms	Significant Symptoms (Chi-Square test P≤0.05)	
	Covishield	**Covaxin**
Fever	Significant	Not-Significant
Fever + chills	Significant	Not-Significant
Fever+ Body pain	Significant	Not-Significant
Headache	Significant	Not-Significant
Vomiting	Not-Significant	Not-Significant
Body pain	Significant	Significant
Shivering	Significant	Not-Significant
Rash	Non- Significant	Significant
Weakness	Significant	Significant
Others	Significant	Significant
Hospital Admission	Non-Significant	Not-Significant
Co-morbidity	Significant	Significant

DISCUSSION

India had granted emergency use of authorization of two COVID-19 vaccines Covishield and Covaxin which are currently being used in the government vaccination drive. Events that are mainly seen after vaccination of COVID-19 include pain at the site of injection, chills, fever, headache, and weakness which are very common after any vaccination. AEFI associated with COVID -19 vaccination is seen in at least 0.005% across the country.[11] Vaccination perceives by the public are 10% unsafe in all vaccines, refusing the vaccination is a worldwide threat in terms of heath known as vaccine hesitancy, it can lead to an increase in the viral spread further which can ultimately lead to the outbreak of the disease.[12] Vaccines are widely recognized as the most important and efficacious in cost interventions for the health of the population. It helps in significantly reducing the morbidity and mortality of various viral or bacterial diseases.

Detection and quantification of mild adverse events are usually missed by passive surveillance (regular disease reporting data by all the institutes). Although, conditions such as under-reporting or difficulty in searching cause among adverse events and administration of vaccine tends to hamper the pharmacovigilance.

Safety of product is of paramount importance and in this study, we actively captured adverse events post-vaccination via case record form. Fever, headache, weakness, body pain, were the most common adverse events along with pain at the injection site. It is important for people to be aware of these minor side effects which are manageable with some symptomatic treatment like paracetamol to resolve the symptoms timely or such medicines can be taken as prophylaxis to avoid the development of post-vaccination symptoms and to increase the acceptance of the COVID-19 vaccine among the mass population while decreasing the psychological fear of any side effect of vaccination, which would certainly help to counter this pandemic disease through the ongoing vaccination program successfully. Vaccines have side effects but they are not as severe as the disease for which that vaccine is prepared.

After rolling out 96 crore doses, the GOI reported an overall AEFI of 0.005%.[11] Most of the symptoms could be due to 'injection-related side effects' and 'immunization anxiety-related reaction. The WHO document defines immunization-anxiety-related reaction as "a range of symptoms and signs that may arise around immunization that are related to 'anxiety' and not to the vaccine product, a defect in the quality of the vaccine or an error of the immunization program".[16] The high prevalence of anxiety (78.9%) is not surprising owing to various reasons. Fast-tracked vaccine development, limited knowledge about long-term effects, controversies on Covaxin's approval without phase-3 trial, and social media could have mounted the anxiety. Anxiety can be one of the main reasons for vaccination hesitancy in our center and the country.

In our study, the younger age group was associated with minor AEFIs. However, we did not find any supporting evidence for high reactogenicity among women, and this may be due to an almost similar proportion of men and women in our sample. Though anxiety is thought to be associated with AEFI, we could not find this association

in our study. There is also a possibility that most people with severe anxiety would have refrained from vaccination.

CONCLUSION

In conclusion, the advantages of immunization in disease prevention have significantly exceeded the risks of immunization-associated adverse events. The AEFI associated observation and reporting system should be thoroughly studied for a longer duration enhancing the faith of the public for being vaccinated with the existing or future vaccines, which are being newly developed for elevating the immunization on large scale all over the world.

COVID vaccines have their largest potential to end the COVID-19 pandemic if they are widely accepted and used. As we all want to get rid of the diseases which are not curable easily and spread with very large intensity, now is the time to get vaccinated and control them.

Vaccines frequently cause adverse events; however, the vast majority of AEFI is due to the protective immune response induced by the vaccine, and not due to an allergic reaction. To assess the AEFI according to age, sex, and co-morbidities in our vaccination center we have analyzed the initial available data. The total number of participants in the study is 500 (250- Covishield and 250 Covaxin). Out of the total beneficiaries of covishield, 146 are males and 104 are females whereas in Covaxin 157 are males and 93 are females. Some reported within 30 minutes mild AEFI like headaches and giddiness. Common symptoms observed were pain at the injection site, fever, fever with chills, fever with body pain, headache, vomiting, body pain, weakness, and shivering which subsided with time. It seems that such mild side effects are acceptable during COVID-19 vaccination as the body will need some time to adapt to the vaccination dose and to trigger the immune system to induce protective antibodies.

AEFI in different sexes

In Covishield, symptoms such as fever, body pain, headache, weakness, fever with body pain, shivering, fever with chills, and giddiness were observed more in females as compared to males.

In Covaxin, symptoms such as body pain, headache, weakness, fever with body pain, shivering, and rash were observed more in males as compared to females.

AEFI in different age groups-

In Covishield, adverse events such as pain at the injection site, fever, body pain, weakness, headache were more commonly seen in the 18-44 age group whereas in the age group 45-60 events such as body pain, fever, and headache were seen. In the elderly age group, symptoms such as pain at the injection site, fever, fever with body pain, and headache were observed. Symptoms were more in the age group of 18-44 as compared to the other age groups.

In Covaxin, adverse events such as pain at the injection site, giddiness, fever, body pain, and weakness were more commonly seen in the 18-44 age group whereas in the age group 45-60 adverse events such as pain at the injection site, giddiness, fever and body pain were seen. In the elderly age group, symptoms such as pain at the injection site, giddiness, and fever. Symptoms were more in the age group of 18-44 as compared to other age groups. Also, more symptoms were observed in covishield as compared to covaxin.

AEFI with co-morbidities

In covishield, the adverse events which occurred in beneficiaries with any co-morbidity were fever with chills, pain at the injection site, fever, fever with body pain, body pain, headache, weakness.

In covaxin, the adverse events which occurred in beneficiaries with any co-morbidity were pain at the injection site, fever, body pain, weakness, giddiness.

Limitations

Some mildly symptomatic cases of AEFI may have been missed due to lack of reporting, lack of transportation, and limited non-COVID healthcare services. However, in the study pregnant and lactating women are not included.

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