Original Research Article

AEFI Related to Covishield and Covaxin: A Comparative Study in Medical College & Hospital, Kolkata

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Abstract

Introduction: Covid 19 Pandemic could be considered as most relevant health crisis throughout the world for last two years and vaccination was an important weapon for winning the battle against this pandemic. Largest vaccination drive against Covid 19 in India was launched on January 2021. But fear and misconceptions regarding AEFI regarding Covid 19 vaccines was an obstacle to this programme. In this context the present study aimed at determining and comparing proportion of AEFI following receiving Covishield and Covaxin. **Method:** Observational Analytic study was conducted in Medical College, Kolkata, among 220 adults (>18 years) were taking Covishield (110 participants) and Covaxin (110 participants) 1st or 2nd dose. History of AEFI related to previous dose (when participants received 2nd dose) was obtained by recall method. All participants were observed for half an hour for immediate AEFI. Telephonic interview of participants were conducted 72 hours of vaccination to obtain any AEFI following present dose. **Results:** Prevalence of any AEFI following present dose (2nd dose) was 58.4%, but in most cases adverse reactions were mild. AEFI following current dose was significantly more in Covishield compared to Covaxin [OR= 5.778 (3.164-10.552)] in unadjusted model, as well as where adjustment done with Demographic, Socioeconomic covariates (AOR= 6.425 (3.421-12.171) and where all comorbidities added [OR= 6.465 (3.423-12.213)]. **Conclusion:** Both Covid vaccines introduced in India were highly safe and well tolerated among study participants. Proportion of any AEFI following receiving present dose of vaccine was significantly less in Covaxin (which was indigenous vaccine prepared in India).

Key words: Covid 19, Covishield, Covaxin, AEFI

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Introduction

Covid 19, caused by SARS-CoV-2, was 1st described in China in December 2019[1] and it was declared a pandemic on March 11, 2020, by the World Health Organization[2]. Since end of 2000 only effective primary prevention of Covid 19 was based on social distancing, wearing of mask, hand and personal hygienic measure, early diagnosis and isolation of cases and quarantine of suspected contacts. But there was need for specific protective measures in form of invention of effective vaccine. Although vaccine development normally takes years due to its stringent administrative requirements, technological checks, and trial protocols, the numerous second and third peaks of COVID-19 across nations had made the world realize the need for a quick and effective vaccine. This had accelerated the process of trials and approvals for the early availability of a vaccine. Currently, more than 250 vaccines against SARS-CoV-2 are in development worldwide, including mRNA vaccines, replicating or nonreplicating viral-vectored vaccines, DNA vaccines, autologous dendritic cell–based vaccines, and inactivated-virus vaccines[3].

The first vaccination drive to be launched across an entire nation began in Russia in December 2020, using the vaccine Gam-COVID-Vac, trade named Sputnik V and developed by Gamaleya Research Institute by the Russian Ministry of Health[4]. This was followed by vaccination drives in other countries like the United States and United Kingdom using vaccines developed by Pfizer/BioNTech, Moderna, and Johnson & Johnson.

Owing to the urgent need, two COVID-19 vaccines were given restricted emergency use approval by the Drugs Controller General of India on January 3, 2021. The government of India subsequently announced that countrywide vaccine rollout would go into effect starting January 16, 2021, in a phased manner[5].

The two vaccines which were used since beginning for this countrywide Covid 19 vaccination drive were:

1. Covishield, a viral vector vaccine, was developed by Serum Institute of India in line with the vaccine developed in the United Kingdom by the Jenner Institute at the University of Oxford and
2. Covaxin, an inactivated virus vaccine, was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research[3].

Under the EUA both vaccines were recommended for adults more than 18 years both vaccines were claimed to be safe with only mild adverse reactions including injection site pain and swelling, fever, headache, bodyache, malaise, myalgia etc[5]. In spite of that, the rapid approval of the vaccines and the myths being propagated have made the general public in India doubt the safety of the vaccine[6,7].

There was lack of sufficient research work comparing AEFI of Covishield and Covaxin. In this backdrop the present study was proposed with following objectives:

- To estimate prevalence of minor, severe and serious adverse reactions following administration of Covishield and Covaxin.

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- To compare AEFI associated with Covishield and Covaxin.

Methodology

Study Type

Observational epidemiological study.

Study Design

Analytic Cross-sectional study.

Study Setting

Covid Vaccination Centre, Medical College Kolkata.

Study Period

3 months (October, 2021- January,2021)

i. Preparatory period: 1 month.
ii. Data collection & compilation: 2 month.
iii. Data analysis& Report writing: 1 month.

Study Population

All adults (>18 years) were taking covid vaccination (Covishield/Covaxin) 1st or 2nd dose from Covid Vaccination Centre, Medical College Kolkata in study period.

Exclusion Criteria

a. Subjects not willing to participate in the study.

Sampling Technique

All adults (>18 years) were taking covid vaccination (Covishield/Covaxin) 1st or 2nd dose from Covid Vaccination Centre, Medical College Kolkata in time period between October 2021 to December 2021 were included in the study until desired sample size was reached, thus convenient sampling was done.

Sample Size

In a multicenter study carried out in northern and eastern India individuals who received the first dose of the Covishield vaccine were followed up for 7 days it was found that over all prevalence of AEFI was 42% [8] which was considered as P1.

In a double-blind, multicenter, randomized, controlled phase 1 trial Maximum Prevalence of AEFI related to BBV 152 (Covaxin) was found to be 21% [9] which was considered as P2

Assuming 95% confidence interval and 80% power sample size in each arm (Those who received Covishield and those who received Covaxin) was 73 by following formula.

$$\text{Sample size in each arm} = \frac{(Z\alpha+Z\beta)^2\,(P1Q1+P2Q2)}{(P1-P2)^2}$$

Where P1= 42%, Q1= 100-P1; P2 = 21%, Q2 = 100-P2; $Z\alpha = 1.96$; $Z\beta = 0.84$

Assuming nonresponse rate 50% Total sample size was each arm was 110.

Study Technique

Study participants was informed about the nature and purpose of study and after ensuring autonomy and confidentiality of study participants informed consent was taken.

After obtaining required permissions and consent from the participants, participants was screened by a questionnaire related to their basic demographic and socioeconomic information presence of any co- morbidity (only co-morbidities reported by participants or elicited by medical records, documents or reports was considered). All participants was observed for 30 minute after vaccination in covid vaccination center. They were monitored for development of any adverse reaction in this time. A telephonic interview of all study participants was done 72 hours after immunization to elicit any mild, severe or serious adverse reaction following immunization.

Study Tool

i. A pre-designed data collection form.

Study variables

A. **Outcome variables**: Adverse events following immunization by Covishield / Covaxin:

AEFI can be classified as

a) **Minor Vaccine reaction**: Mild local pain, swelling and redness not affecting day to day activity. Fever <102 degree F. Mild Systemic reaction including headache, body ache, malaise, irritability etc. not hampering day to day activity.

b) **Serious Vaccine reaction**: AEFI resulting in any of the below:

- death,
- persistent or significant disability/incapacity,
- requiring hospitalization,
- clustering of AEFI cases in community,
- raising community concern.

c) **Severe Vaccine reaction**: AEFI does not fulfill the criteria of serious vaccine reaction but causing severe reactions which is sufficient to hamper day to day activity like

- Severe local pain, swelling and redness affecting day to day activity
- Fever ≥102 degree F
- Severe systemic reaction including headache, body ache, malaise, irritability etc. hampering day to day activity.
- Anaphylaxis, fainting, unconsciousness, severe allergic reaction following immunization
- Other severe systematic reaction including excessive internal or external bleeding

B. **Independent Variables**

I. Socio-Demographic characters:
i. Age and gender
ii. Level of Education
iii. Monthly Income
iv. Marital status (Married/ Unmarried/ Widowed/ Divorced)
v. Socio economic status as per BG Prasad scale

II. Existing Co-morbidities related to:
i. Cardiovascular system
ii. Respiratory system
iii. Nervous system
iv. Hepatic and GI System
v. Endocrine system
vi. Hematological diseases
vii. Renal diseases
viii. Malignancies
ix. Autoimmune diseases
x. HIV/AIDS and other immunosuppressive diseases

Plan for data analysis

Data available will be compiled into SPSS software. Descriptive measures will be reported to characterize study participants in terms of frequencies, percentages for categorical variables. Mean, median and standard deviation will be used to describe the continuous variables. Prevalence of Minor, Serious and Severe vaccine reactions will be estimated separately for Covishield and Covaxin and they will be compared. Association of AEFI with different socio-demographic variables and presence of co-morbidities will be determined.

Ethical Consideration

For the purpose of study no interventions will be undertaken on the subjects. Informed consent will be taken from the participants. In all steps of the study, anonymity and confidentiality will be maintained and participants will be demarcated by serial numbers. Only participants themselves will know their serial numbers, neither the investigators nor other participants will know that.

Source of Funding: Self-funded by the investigators.
Conflict of Interest: None declared by the investigators.

Results

Table 1: Distribution of Study Participants according to their demographic and Socio-economic characteristics:

Variable	Number (%)		
	Receiving Covishield n=110 (%)	Receiving Covaxin n=110 (%)	Total n=220 (%)
Age Group			
18-44 year	82 (74.5)	86 (78.2)	168 (76.4)
45-59 year	19 (17.3)	21 (19.1)	40 (18.2)
60 year and above	9 (8.2)	3 (2.7)	12 (5.4)
Sex			
Male	63 (57.3)	72 (65.5)	135 (61.4)
Female	47 (42.7)	38 (34.5)	85 (38.6)
Marital Status			
Currently Married	88 (80)	79 (71.8)	167 (75.9)
Unmarried	19 (17.3)	31 (28.2)	50 (22.7)
Widow/Separated/Divorced	3 (2.7)	0 (0)	3 (1.4)
Education			
Illiterate	6 (5.5)	9 (8.2)	15 (6.8)
Literate (non formal)	0 (0)	3 (2.7)	3 (1.4)
Upto Primary (Class I-IV)	15 (13.6)	9 (8.2)	24 (10.9)
Upto Middle (Class V-VIII)	35 (31.7)	27 (24.5)	62 (28.2)
Upto secondary and higher secondary (Class IX-XII)			
Graduate	29 (26.4)	37 (33.7)	66 (30)
Post Graduate and above	19 (17.3)	23 (20.9)	42 (19.1)
Occupation	6 (5.5)	2 (1.8)	8 (3.6)
Unemployed			
Homemaker	2 (1.8)	0 (0)	2 (0.9)
Unskilled Worker	29 (26.4)	27 (24.6)	56 (25.5)
Semiskilled Worker	17 (15.5)	15 (13.6)	32 (14.5)
Skilled Worker	18 (16.3)	9 (8.2)	27 (12.3)
Clerk/Shop-Owner	4 (3.6)	1 (0.9)	5 (2.3)
Professional	30 (27.3)	45 (40.9)	75 (34)
Student	2 (1.8)	0 (0)	2 (0.9)
Retired	7 (6.4)	13 (11.8)	20 (9.1)
Social Class [Modified BG Prasad Scale (2021)]	1 (0.9)	0 (0)	1 (0.5)
Social Class I (Rs.-Rs.)			
Social class II (Rs.2786-5570)			
Social class III (Rs.1671-2785)	19 (17.3)	13 (11.8)	32 (14.5)
Social class IV (Rs.836-1670)	25 (22.7)	26 (23.6)	51 (23.2)
Social class V (Rs. <836)	29 (26.4)	32 (29.1)	61 (27.7)
	24 (21.8)	32 (29.1)	56 (25.5)
	13 (11.8)	7 (6.4)	20 (9.1)

Table 1 reveals that most of study participants (76.4%) belonged to 18–44 year age group and larger portion of participants (61.4%) were male.75.9% study participants were married. As per education of study participants was concerned greater portion (30%) were educated upto secondary and higher secondary level followed by 28.2% were educated upto V to VIII level. Occupation wise larger portion of study participants (34%) were clerk/office worker/shop owner/small business owner followed by homemaker (25.5%) and unskilled worker (14.5%). According to Modified B.G. Prasad scale 2021 27.7% study participants belonged to Social class III followed by 25.5% belonged to social class IV and 23.2% belonged to social class II.

Table 2: Distribution of Study Participants according to Presence of Comorbidities

Morbidity	Number (%)		
	Receiving Covishield n=110 (%)	Receiving Covaxin n=110 (%)	Total n=220 (%)
i. Cardiovascular system	9 (8.2)	5 (4.5)	14 (6.4)
ii. Respiratory system	0 (0)	4 (3.6)	4 (1.8)
iii. Hepatic and GI System	2 (1.8)	2 (1.8)	4 (1.8)
iv. Hematological diseases	1 (0.9)	1 (0.9)	2 (0.9)
v. Endocrine disease	3 (2.7)	5 (4.5)	8 (3.6)
vi. Autoimmune diseases	1 (0.9)	0 (0)	1 (0.5)
HIV/AIDS and other immunosuppressive diseases	1 (0.9)	0 (0)	1 (0.5)
viii. Other Comorbidities	6 (5.5)	0 (0)	6 (2.7)
Total persons having morbidity	20 (18.2)	14 (12.7)	34 (15.5)

Table 2 revealed that 15.5% of all study subjects had history of pre-existing comorbidities. 6.4% study subjects had co-morbidity related to Cardiovascular system followed by 3.6% had co-morbidity related to endocrine system. 1.8% study participants gave history related to comorbidity of respiratory system and GI system each.

Table 3: Distribution of Study Participants according to receiving current dose order (1st or 2nd dose) of Covid Vaccine

Dose Order	Number (%)		
	Receiving Covishield n=110 (%)	Receiving Covaxin n=110 (%)	Total n=220 (%)
Receiving1st Dose	17 (15.5)	6 (5.5)	23 (10.5)
Receiving 2nd Dose	93 (84.5)	104 (94.5)	197 (89.5)

Table 3 reveals that most of the study participants (89.5%) received second dose as their current dose of covid vaccine.

Table 4: Distribution and comparison of study participants according to occurrence of AEFI among those receiving covishield and those receiving covaxin:

AEFI	Number (%)			Chi-square value (P value)
	Receiving Covishield	Receiving Covaxin	Total	
AEFI in Previous dose (1st dose) [When current dose of vaccine is 2nd dose] :	45 (48.4%) [n=93]	41 (39.4%) [n=104]	86 (43.7%) [n=197]	1.604 (0.205)
Prevalence of different types of AEFI in previous dose (1st dose) [Multiple Response taken] Mild local pain, swelling and redness not affecting day to day activity :	31 (33.3%) [n=93]	25 (24.0%) [n=104]	56 (28.4%) [n=197]	2.196 (0.334)
Fever (<102^{0}F):	20 (21.5%) [n=93]	11 (10.6%) [n=104]	31 (15.7%) [n=197]	4.494 (0.106)
Mild Systemic reaction including headache, body ache, malaise, irritability etc. not hampering day to day activity:	9 (9.7%) [n=93]	16 (15.4%) [n=104]	25 (12.7%) [n=197]	5.373 (0.068)
AEFI in Current dose (1st dose):	15 (88.8%) [n=17]	3 (50.0%) [n=6]	18 (78.3%) [n=23]	3.811 (0.051)
Prevalence of different types of AEFI in current dose (1st dose) [Multiple Response taken] Mild local pain, swelling and redness not affecting day to day activity	13 (76.5%) [n=17]	3 (50.0%) [n=6]	16 (69.6%) [n=23]	4.135 (0.127)
Fever (<102^{0}F)	7 (41.2%) [n=17]	0 (0.0%) [n=6]	7 (30.4%) [n=23]	5.461 (0.065)
Mild Systemic reaction including headache, body ache, malaise, irritability etc. not hampering day to day activity.	7 (41.2%) [n=17]	0 (0.0%) [n=6]	7 (30.4%) [n=23]	5.461 (0.065)
Fever (>102^{0}F)	1 (5.9%) [n=17]	0 (0.0%) [n=6]	1 (4.3%) [n=23]	3.963 (0.138)
AEFI in Current dose (2nd dose):	73 (78.5%) [n=93]	42 (40.4%) [n=104]	115 (58.4%) [n=197]	29.346 (0.000)*
Prevalence of different types of AEFI in current dose (2nd dose) [Multiple Response taken] Mild local pain, swelling and redness not affecting day to day activity	64 (68.8%) [n=93]	33 (31.7%) [n=104]	97 (49.2%) [n=197]	30.902 (0.000)*
Fever (<102^{0}F)	18 (19.4%) [n=93]	14 (13.5%) [n=104]	32 (16.2%) [n=197]	30.276 (0.000)*
Mild Systemic reaction including headache, body ache, malaise, irritability etc. not hampering day to day activity.	24 (25.8%) [n=93]	23 (22.1%) [n=104]	47 (23.9%) [n=197]	34.261 (0.000)*

*Significant at 95% confidence limit, **Significant at 99% confidence limit

Table 4 revealed that 43.7% participants gave the history of AEFI following their previous dose (1st dose). 73.8% participants reported adverse reaction during telephonic interview following present dose (1st dose) and 58.4% participants reported AEFI during telephonic interview 72 hour following present dose which is 2nd dose. In almost all cases adverse reactions were mild and self-limiting. Only one 25 year old female participant reported severe adverse reaction (Fever >102^0 F lasting for >48 hour) following receiving covishield current dose which was her 1st dose.

As per comparison of AEFI following both covid vaccine were concerned, in all cases proportion of AEFI was more in Covishield than Covaxin. This difference was statistically significant among those participants who received 2nd dose of Covid vaccine as their present dose (Chi-Square value = 29.346, p value <0.01)

Table 5: Effect of type of vaccine on occurrence of adverse reaction following present dose:

Variable		Occurrence of AEFI	
	Unadjusted OR (95% CI)	Model 1 AOR (95% CI)	Model 2 AOR (95% CI)
Type of Vaccine taken	1	1	1
Covaxin	5.778**	6.452**	6.465**
Covishield	(3.164-10.552)	(3.421-12.171)	(3.423-12.213)

*Significant at 95% confidence interval, **Significant at 99% confidence interval

Model 1: Adjusted with demographic and socioeconomic variable
Model 2: Model 1 + adjustment with presence of comorbidities

Table 5 revealed that in present study AEFI following current dose was significantly more in participants taking Covishield compared to those who received Covaxin [OR= 5.778 (3.164-10.552)]. Finally, 2 logistic regression model were prepared to elicit effect of vaccine (Covishield and Covaxin) and other covariates on AEFI within 72 hours of receiving current dose.

Model 1: Effect of type of vaccine on AEFI was adjusted with Demographic, Socioeconomic covariates like age group, gender, marital status, education, occupation, social class and it was seen that in adjusted model also prevalence of prevalence of AEFI following present vaccine dose was significantly more among those received Covishield (AOR= 6.425 (3.421-12.171).

Model 2: In model 2 (which was final model) Covariates related to presence of existing co-morbidities were added with model 1. In this final model also AEFI following current dose was significantly more in participants taking Covishield compared to those who received Covaxin [OR= 6.465 (3.423-12.213)].

Discussion

The main objective of present study was to estimate prevalence of minor, severe and serious adverse reactions following administration of Covishield and Covaxin and to compare AEFI associated with Covishield and Covaxin.

In present study most of the study participants received 2nd dose of vaccine as present dose 88 (89.5%). In case of Covishield this proportion was 84.5% and for Covaxin this proportion was 94.5%. Only 5.5% participants received Covaxin and 15.5% received Covishield first dose as their current dose. Those participants who received 2nd dose of vaccine AEFI history related to their first dose was taken by recall method.

The present study revealed that both the vaccine were safe with very rare incidence of severe adverse reaction. In almost all cases adverse reactions were mild and self-limiting. Only one 25-year-old female participant reported severe adverse reaction (Fever >102^0 F lasting for >48 hour) following receiving Covishield current dose which was her 1st dose for which she required medical attention. No participants require any hospitalization. During observation period of half an hour no participants reported any kind of adverse reaction including anaphylaxis.

78.3% of study participants report any adverse effect following covid vaccination of current dose when current dose was 1st dose. In case of Covishield this proportion was 88.8% and in case of Covaxin this proportion was 50%. But when participants who received 2nd dose as current dose recalled about their AEFI related to previous dose (1st dose) only 43.7% participants reported any AEFI, and this proportion was 48.4% in case of Covishield (recall period was 12 weeks) compared to 39.4% in case of Covaxin (recall period was 4 weeks).

In a study in Togo, where prevalence of adverse rection among health workers was assessed following giving 1st dose of Covishield, it was found that 71.6% study participants reported at least one adverse effect[10].

In present study most common adverse reaction following Covishield 1st dose was mild local pain, swelling and redness followed by fever <102^0F. In case of Covishield 2nd dose also most common AEFI was mild local pain, swelling and redness, but 2nd most common AEFI was mild Systemic reaction including headache, body ache, malaise, irritability etc. Following receiving Covaxin (in both 1st and 2nd dose) most common adverse effect was mild local pain, swelling and redness followed by mild Systemic reaction including headache, body ache, malaise, irritability etc. In a multi-center safety study following Covishield vaccination it was found that myalgia and/or fatigue was the most common effect in 25.7%, followed by fever in 22.0% of individuals[8]. In double blind randomized phase 1 trail of Covaxin it was found that most common solicited adverse events were injection site pain (5%), headache (3%), fatigue (3%), fever (2%)[9], which was almost similar with our present study finding.

When the comparison of AEFI between Covishield and Covaxin was considered, in present study it was found that proportion all forms of AEFI was more following receiving present dose and this difference was statistically significant when present dose was 2nd dose. In an retrospective observational survey of adverse events following immunization comparing tolerability of Covishield and Covaxin vaccines, it was also found that proportion of AEFI was more following receiving Covishield compared to Covaxin[11]. In that study percentage of The AEFI experienced with Covishield vs Covaxin during 1st does was 92.45 % vs 77.27 % and with 2nd dose 86.79 % vs 72.72 % respectively[11].

Finally by multivariate logistic regression, it was established that in our present study proportion of any adverse reaction following current dose of covid vaccine was significantly more in case of Covishield compared to Covaxin and this statistical significance persisted even when adjusted with demographic, socio-economic covariates and presence of comorbidities.

Limitation

1. In our study most of the study participants (89.5%) received 2nd dose of Covid vaccine as their current dose. So for assessing proportion of AEFI following 1st dose of Covid vaccine, sample size may be inadequate.
2. Study participants who received 2nd dose of covid vaccine, history of AEFI of their previous dose of vaccine was collected by recall method and this recall period was 4-6 weeks for Covaxin and 12-16 weeks for Covishield. The difference between proportion of AEFI (mild and self-limiting AEFI) following taking 1st dose of Covid vaccine when it was present dose and receiving 1st dose of Covid vaccine when it was previous dose was might be due to recall bias.
3. Follow up period of study participants for developing AEFI following present dose of Covid vaccine was 72 hours which might be a short observation period.

Conclusion

On 16 Jan 2021, Govt. of India initiated the world's largest vaccination program for COVID-19. Vaccination for COVID-19 is very crucial and necessary as vaccination has proved to prevent the disease or decrease severity and prevent mortality due to COVID-19[11]. But there was lots of fear, myths and misconception among general population regarding safety of Covid vaccines, which prohibit some of them from receiving vaccine[6,7]. The present study revealed that both Covid vaccines recommended in India under EUA, were highly safe, well tolerated with nil hospitalization and death following vaccination and very rare incidence of severe adverse reaction. When we compare mild adverse reaction of both vaccine following receiving present dose it was significantly less in Covaxin (inactivated virus vaccine, was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research) compared to Covishield. But more research work is recommended with larger sample size and longer follow up period.

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