Myths and misbelieves regarding COVID vaccines in India

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Abstract

Background: - COVID-19 is the most important public health problem of recent time. Many people require hospitalization after infection. COVID vaccination is the most effective way to prevent the disease. Due to extensive negative publicity through social media channels/platforms, significant number of individuals are not coming forward for vaccination. Therefore, study is needed to evaluate adverse effects associated with different vaccines available in India. Objectives: - To assess the adverse effects associated with COVID-19 vaccination and compare the side effect of two most commonly used COVID vaccines in India. Methods:- In the current report, a cross sectional study was conducted among beneficiaries of COVID-19 vaccines at the vaccination center of the LLRM Medical college, India. After institutional ethical clearance and informed consent, patients were asked about the symptoms they experienced after vaccination. A very simple random sampling approach was used to select beneficiaries. Information was collected on predesigned Google form and total 391 patients submitted the responses. Results:- Out of total respondents 77 % individuals reported one or more symptoms. Fever was reported to be most common problem (59.3%) followed by body ache (57.5%). Out of total beneficiaries, 68.3% experienced mild symptoms while 23% remain asymptomatic. Only few subjects reported moderate adverse effects (8.7%). None of the respondent reported severe and serious adverse effect. Conclusions:- Vaccine associated adverse effects were found less than 3 days and of mild variety in most of the beneficiaries. There was no difference in adverse effect profile of two commonly used vaccines in India. People must come forward for vaccination in mass without fearing of adverse effects of vaccines.

Keywords

COVID-19; COVID vaccination; Vaccine adverse effects; vaccine beneficiaries; Cross sectional Study

Introduction

COVID -19 is the most import public health problem of recent time. It is the disease caused by a new corona virus called SARS-CoV-2 (Severe Acute Respiratory SyndromeCoronaVirus-2) (1). Corona viruses are a large family of viruses which may cause illness in animals or humans. In humans, several corona viruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and SARS. The World health organization (WHO)has been reported about this new

virus on December 31, 2019, following a report of a cluster of cases of 'viral pneumonia' in Wuhan, People's Republic of China(2). The outbreak was declared a pandemic by WHO on 11 March 2020(3).

The spread of SARS-CoV-2 has resulted in an unprecedented global public health and economic crisis(4). According to reports, 1 out of every 6 individuals who infected with SARS-CoV-2, became seriously ill and developed difficulty in breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to

develop serious illness(1). Being a new virus, having high infectivity and producing severe illness in some people, all people are susceptible to contact disease. In most of countries productive age group which is having higher mobility for various economic activities is the easy prey for this viral illness.

Initially to protect their vulnerable population almost each and every country of world imposed countrywide lockdown. In India lockdown was imposed by Indian Government from 24 March 2020 (first phase) which was subsequently extended till May31, 2020 and again in April-June, 2021. Lockdown had slowed down rate of transmission and broken chain of transmission. Government also advertised advised many COVID Appropriate behaviors to slow down rate of transmission(5).

Meanwhile mammoth efforts were started by scientist all over the world for search of vaccines who can protect the individuals from severe COVID illness. These efforts paid off and many countries had a success to make vaccine in a record 9 month to 1 year time. The process was fast tracked which otherwise would have taken 8-10 years of time. Fortunately, India was among leading countries who developed its indigenous COVID vaccine.

As of December 2020, there were over 200 vaccine candidates for COVID-19 vaccines. Of these, at least 52 candidate vaccines are in human trials. Many of them are currently in phase III trials. (6,7) All vaccines have shown promising result in terms of protection from COVID infections. Vaccines have shown efficacy up to 90-98 % for prevention of severe disease in phase 2 of trial. There are three main approaches to design a vaccine i.e. use a whole virus, the parts of the germ that triggers the immune system; or the genetic material that provides the instructions for making specific proteins and not the whole virus(6).

Currently most of the vaccines are being injected under emergency authorization throughout the world. As on 30.04.21 WHO has listed the Pfizer/ BioNTech, AstraZeneca, Serum Institute of India, Moderna and Janssen vaccines for emergency use(7).

In India, Government has approved four vaccines for emergency use i.e. Covishield, Covaxin and SPUTNIK V, mRNA-1273. Government of India has introduced vaccination in phased manner based on risk profile of people. Presently vaccines are being injected for all aged 18 years or more(8).

In India use of social media is very prevalent. There were 624.0 million internet users in India in January 2021(9). Social media, while providing an unprecedented capacity for the public to communicate, has also been a major factor in the rise of fringe opinions damaging to public health. Reconciling principles of free speech with the policing of social media for damaging falsehoods remains a conundrum for democracies. Vaccine hesitancy is not a new phenomenon, but the proliferation of anti-

vaccination misinformation through social media has given it new urgency, especially in light of the corona virus pandemic and hopes for rapid development and deployment of a vaccine(10). Thus, there is some unprecedented believe that vaccines are causing harm. Social media forwards are also aggravating the situation. With the background of above facts, a study has been planned to evaluate adverse effects of COVID vaccines. The results may be first step towards removing myths and misbelieve regarding adverse effect of vaccines and subsequently it may mitigate vaccine hesitancy.

Aims & Objectives

- To evaluate adverse effects associated with different COVID vaccines
- 2. Association of adverse effects of COVID vaccines with different demographic variables.
- Comparison of adverse effects associated with different vaccines.
- 4. To assess the perception of people regarding various aspects of COVID vaccines.

Material & Methods

Present cross-sectional study was conducted in Meerut. The study period was from Jan 2021 to June 2021. The respondents of the study were vaccination beneficiaries (received either one or both doses). Beneficiaries list was obtained from COVID vaccination centre L.L.R.M. Medical College. All beneficiaries of vaccination centre L.L.R.M. medical college irrespective of age sex religion and who gave consent were included in the study. Institutional ethical clearance was taken to conduct study.

Sample size was calculated assuming prevalence of post-vaccination symptoms as 50%, 5% allowable error and 95% confidence interval using the formulae $N=(1.96)^2$ PQ/D2. Sample size thus calculated came out to be 384.

A total of 384 beneficiaries were selected randomly. A Google form regarding various parameters related to adverse effect following immunization was developed in Hindi.

Thereafter all the selected beneficiaries were contacted telephonically and explained in detail about motive of study and information regarding filling and submitting Google form. Response thus collected were analyzed statistically. Few respondents who initially refused to provide information, filled and submitted the form later on. Thus, total respondents in the study became 391.

Results

In present study total 391 vaccine beneficiaries were interviewed. Out of 391 respondent 58.8 % were females and 41.2% were males.

In the study 89% of the participants belong to age group 18-45 years, 8.6% participants belong to age group 45-60 years while rest 2.4% belong to age group more than 60 years. No beneficiary was below 18 years of age.

Total 349, (89.3%) beneficiaries received Covishield while 42, (10.7%) received Covaxin. Covishield was the main supply at L.L.R.M. Medical college when vaccination centre was started.

Our study showed that 77% of beneficiaries reported one or more symptoms. Fever was most common reported symptom (60.3%) followed by Body ache (59.1 %). Uneasiness (12.8%), Sleep disturbance (7.9%), Palpitation (6.9%), Gastric upset (5.6%) and Headache (2.6%) were next in order. When we compared the symptoms in relation to vaccines, fever was commonest symptom (66.3%) in recipients of Covishield followed by body-ache, while Body-ache was commonest symptom in recipients of Covaxin (50%). More than 25% of beneficiaries of Covaxin remained asymptomatic (28.6%). In the study 23% of the beneficiaries developed no symptoms following COVID vaccination (Table 1).

As explained in previous paragraph a total of 77% vaccine recipients experienced one or more symptom after COVID vaccination while 23% remained asymptomatic. In males 31.1% were asymptomatic while 17.4% of female beneficiaries were asymptomatic. Similarly, when compared symptomatic following vaccination, 68.9% of males developed symptoms while 82.2% of females developed symptoms. So apparently asymptomatic males while symptomatic females were more common in study and the difference was statistically significant (p <0.05) (Table 2).

Regarding duration of symptoms, 86.4% of male beneficiaries experienced symptoms for less than 3 days while 90.1% of females had symptoms for less than 3 day. The trends in those who suffered from symptoms for more than 3 days were 13.6% and 9.9% in males and females respectively. So apparently duration of symptoms was more in male population. Although this difference was statistically not significant (Table 3).

Comparison of symptoms severity in relation to gender was estimated next. As described earlier (Table 1) 77 % of beneficiaries reported some sort of symptoms post vaccination. Out of these 88.7% of the beneficiaries reported mild symptoms while rest 11.3 % reported moderate symptoms. None of the beneficiary reported severe and serious side effects in either sex. Amongst males mild and moderate symptoms were reported by 86.4% and 13.6% of the beneficiaries respectively. In contrast in females, mild symptoms were reported by 90.1% while rest 9.9% reported moderate symptoms. So apparently mild symptoms were reported more in females while moderate symptoms in males. Although this difference was statistically not significant (Table 4)

The comparison of symptoms in relation to different age group was calculated in the study. In the study 89% of the participants belong to age group 18-45 years, 8.6% participants belong to age group 45-60 years while rest 2.4% belong to age group more than 60 years. When we talked about mild symptoms following COVID vaccination,

the trends found were like- in age group 18-45 years, 89.2 %, in 45-60 years 92.3%, while in age group >60 years, 57.1% of beneficiaries reported mild symptoms. Similarly when we assessed moderate symptoms development following vaccination- in age group 18-45 years 10.8%, in age group 45-60 years 7.7 % and in age group >60 years 42.9% of beneficiaries reported moderate symptoms. From the results it is evident that mild symptoms were slightly more in age group 45-60 while moderate symptoms were slightly more in >60 years age group. These differences were statistically significant (Table 5). In the study 349 beneficiaries were injected Covishield. In Covishield group 22.3% beneficiaries were asymptomatic, 68.5% of the beneficiaries reported mild symptoms and 9.2% reported moderate symptoms. In comparison Covaxin group 28.6% of the beneficiaries were asymptomatic, 66.7% reported mild and 4.8% reported moderate symptoms. Thus there seems that following vaccination asymptomatic beneficiaries were more in Covaxin group while mild and moderate symptoms were reported more by beneficiaries who received Covishield vaccine. However, these differences were not statistically significant in two vaccine group (Table 6).

When perception regarding various aspects of vaccines was studied among beneficiaries it was observed that almost 63% person were aware that COVID vaccines give protection while 52% were aware that it gives protection against severe disease. In this connection 35.8% of beneficiaries think that vaccinated person will not spread infection to others. Further 10% of beneficiaries also think that vaccines saves from COVID infection by 100% while 4.9% reported that vaccine gives protection against all flu virus (Figure 1).

Discussion

In present study total 391 vaccine beneficiaries were interviewed. Total 349 (89.3%) beneficiaries received Covishield while 42 (10.7%) received Covaxin. This was due to the fact that initially Covishield was the main supply at vaccination centre L.L.R.M. Medical Colllege. Out of these 391 beneficiaries 58.8 % were females and 41.2% were males. Similar trends were reported by Ke'alaAkau. Who in an article informed that in February, the CDC released data on adverse effects during the first month of the COVID-19 vaccine rollout, finding that while women received 61 % of vaccine doses, 72% of the side effects were reported from women(11).

In contrast to present study, Mostafa Abohelwa et al (12) in Texas, quoted that as per report of CDC, 50.6% were males and 49.4 % were females were among vaccine beneficiaries. Further (77.8 %) were between 25 and 35 years old. However the study was amongst medical post graduate.

In present study 89% of the participant belongs to age group 18-45 years, 8.6% participants belong to age group 45-60 years while rest 2.4% belong to age group more

than 60 years. No beneficiary was below 18 years of age. These trends were due to the fact that COVID vaccination was opened initially for health care workers and front-line workers and among these younger population turned up more for vaccination. Almost similar trends were reported by Mostafa Abohelwa et(12) in Texas where 77.8% of beneficiaries were in age group 25-35 years.

Regarding symptoms following vaccine administration present study showed that Fever was most common reported symptom 60.3% followed by Body ache 59.1 %. Uneasiness (12.8%), Sleep disturbance (7.9%), Palpitation (6.9%), Gastric upset (5.6%) and Headache 2.6% were next in order. 23% of the beneficiaries were Asymptomatic. Fever was commonest symptom in recipients of Covishield (66.3%) while Body-ache (50% of total 42 recipients) was common in recipients of Covaxin.

In contrast to our study Cristina Menni in U.K reported that 30% of users complained of injection site pain and less than 25% of fatigue and headache after the first dose of vaccine. Fever was not among main symptoms (13). Covishield was used in the study. Various news reports also show that 70% of Indians developed either mild or no adverse effect following vaccination. (14).

Next, we compared development of symptoms following vaccination, 77% participants experienced one or more symptom after vaccine administration while 23% were asymptomatic. In males 31.1% remained asymptomatic following vaccination while rest 68.9% developed one or more symptoms. In contrast, 17.4% of the females remained asymptomatic while rest 82.2% developed symptoms following vaccination. Thus, apparently asymptomatic males while symptomatic females were more common in study and his difference was statistically significant p <0.05.

These trends of study were supported by CDC data released in Feb on adverse effects during the first month of the COVID-19 vaccine rollout, which says that while women received 61 % of vaccine doses, 72% of the side effects were reported from women(12).

Further in study, comparison was made regarding duration of symptoms. 88.7% of the beneficiaries experienced symptoms for less than 3 days following vaccination while rest 11.3% for more than 3 days. Among male beneficiaries 86.4% experienced symptoms for less than 3 days while 13.6% for more than 3 days. In comparison to this 90.1% of female recipients had symptoms for less than 3 day while 9.9% for more than 3 days. So apparently duration of symptoms was seen more in male population. Although this difference was statistically not significant.

These study findings were in accordance withthe WHO information series regarding COVID Vaccination. As per WHO website, post vaccination side effects usually occur within the first few days of getting a vaccine(13). Similar information is available on MOHFW Government of India

website regarding COVID vaccines. Which says post vaccination side effect last for first few days only(14). In present study comparison was made regarding severity following vaccination. symptoms symptomatic group mild and moderate symptoms were reported by 88.7% and 11.3% of the beneficiaries respectively. None of the beneficiary reported severe and serious side effects. Further amongst males mild and moderate symptoms were reported by 86.4% and 13.6% of the beneficiaries respectively. In females, mild symptoms were reported by 90.1% while rest 9.9% reported moderate symptoms. So apparently mild symptoms were more in female beneficiaries while moderate symptoms were more in male beneficiaries. Although this difference was statistically not significant. These results could not be compared with other studies.

However, WHO website informs that the effect of the COVID-19 vaccine varies from person to person, like it does for most vaccines. As more people get vaccinated, we may be able to determine patterns. This information continues to be collected and will be shared, but for now, we cannot anticipate who may have side effects(13).

The comparison of symptoms in relation to different age group was made in the study. In the study 89% of the participant belongs to age group 18-45 years, 8.6% to age group 45-60 years while rest 2.4% to age group more than 60 years. It is evident from table 6 that after COVID vaccinations 88.7% of participants reported mild symptoms while 11.3% showed moderate symptoms. None of the participant reported severe and serious side effects. Further in the study in relation to age group, in age group of 18-45 years, mild symptoms were reported by 89.2% participants, while rest 10.8% had moderate symptoms. Similarly in age group of 45-60, 92.3% of the beneficiaries reported mild symptoms while rest 7.7% reported moderate symptoms. In age group more than 60 years 57.1% of the participants reported mild symptoms while rest 42.9% of the participants reported moderate symptoms. From the results it is evident that mild symptoms were more in age group 45-60 while moderate symptoms were slightly more in >60 years age group. These differences were statistically significant (p<.05).

In contrast to our findings Cristina Menni in U.K calculated the proportion of participants who reported at least one systemic effect after the first dose. It was significantly higher among people aged 55 years or younger than among those older than 55 years. Covishield was used in study(15).

Next, we compared the two vaccines, 349 beneficiaries were injected Covishield. Out of these 68.5% patients reported mild symptoms, 9.2% moderate symptoms while 22.3% patients were asymptomatic. When assessment was done in Covishield group, 22.3% beneficiaries were asymptomatic, 68.5% reported mild symptoms and 9.2% reported moderate symptoms. In comparison in Covaxin group, 28.6% of the beneficiaries were asymptomatic

while 66.7% reported mild and 4.8% of beneficiaries reported moderate symptoms. Thus, it seems that following vaccination asymptomatic beneficiaries were more in Covaxin injected while mild and moderate symptoms were reported more by beneficiaries who received covishield vaccine. However, the differences were not statistically significant. A comparative study in relation to this could not be searched. (16)

Further in study awareness regarding vaccine benefits were assessed. It was observed that almost 63% person were aware that COVID vaccines give protection while 52% were aware that it gives protection against severe disease. In this connection 35.8% of beneficiaries think that vaccinated person will not spread infection to others. Further 10% of beneficiaries also think that vaccines saves from COVID infection by 100% while 4.9% reported that vaccine gives protection against all flu virus. We could not find any reference for comparison.

Conclusion

In the study fever was the commonest symptom in recipients of Covishield while body-ache was reported mostly by Covaxin beneficiaries. Most of the beneficiaries reported that they either developed mild symptoms or remained asymptomatic following vaccination. Post vaccination adverse effects are more prevalent in younger age group i.e. 18-45 years.

Both vaccines are comparable in terms of adverse effects following vaccinations. Fever, body ache and irritability restlessness were most reported symptoms following vaccination. Mild and moderate adverse effects were reported more in Covishield beneficiaries while asymptomatic following COVID vaccination reported more in Covaxin recipients, however differences are not statistically significant. The most common perception amongst study population was that these give protection from COVID infection by 60-80%.

Recommendation

As most beneficiaries remained asymptomatic or developed mild adverse effects after vaccination so these vaccines can be administered safely without fear.

Limitation of the study

The study compares only Covishield and Covaxin so results can not be generalized to other vaccines used in India.

Relevance of the study

As vaccination is presently ongoing in India and Government of India is using various mass media tools for increasing COVID vaccination so this study is very much relevant in present scenario.

Authors Contribution

All authors are contributed equally.

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Tables

TABLE 1 ADVERSE EFFECTS (SYMPTOMS) OF VACCINES FOLLOWING VACCINATION*

Symptom	No. and % (n=391)	Covishield	Covaxin
Fever	236 (60.3%)	228 (66.3%)	8 (19.0%)
Body ache	231(59.1%)	210 (60.2%)	21(50%)
Ghavrahat and Restlessness	50(12.8%)	50(14.3%)	0 (0%)
Sleeping disturbance	31(7.9%)	31(8.9%)	0 (0%)
Palpitation	27(6.9%)	27(7.7)	0 (0%)
Gastric upset	22(5.6%)	21(6.0%)	1(2.4%)
Headache	10(2.4%)	9 (2.6%)	1 (2.4%)
No symptoms	90 (23%%)	78(22.3%)	12 (28.6%)
Base =391	349(100%)	42 (100%)	

^{*}Multiple response

TABLE 2 ADVERSE EFFECTS OF COVID VACCINES IN RELATION TO GENDER

S.no	Adverse Effects	Male n (%)	Females n %	Total n(%)
1	Asymptomatic following vaccination	50 (31.1)	40 (17.4)	90 (23)
2.	Symptomatic following vaccination	111 (68.9)	190 (82.6)	301 (77)
	Total	161 (100)	230 (100)	391(100)
$df = 1 \chi^2 = 9.97 (p < .05 = significant)$				

TABLE 3 DURATION OF SYMPTOMS FOLLOWING COVID VACCINATION AND THEIR RELATION WITH GENDER.

S.no	Duration of symptoms	Male n(%)	Females n(%)	Total n(%)	
1	Symptoms for less than 3 days	102 (86.4)	165 (90.1)	267 (88.7)	
2	Symptoms more than 3 days	16 (13.6)	18 (9.9)	34 (11.3)	
Total		118(100)	183 (100)	301 (100)	
df = 1, χ^2 = 0.99 p>.05, not significant					

TABLE 4 SEVERITY OF SYMPTOMS FOLLOWING COVID VACCINATION AND THEIR RELATIONSHIP WITH GENDER

	Severity of symptoms	Male n (%)	Females n (%)	Total n (%)
S.no				
1	Mild symptoms	102 (86.4)	165 (90.1)	267 (88.7%)
2	Moderate symptoms	16 (13.6)	18 (9.9)	34 (11.3%)
Total		118(100)	183 (100)	301(100)
$df=1 \chi^2=0.99 p>.05$ not significant				

TABLE 5 SEVERITY OF SYMPTOMS IN RELATION TO AGE

S. no.	Age group	Adverse effects		Total n(%)	
		Mild n (%)	Moderate n (%)		
1	18-45 years	239 (89.2)	29 (10.8)	268 (100)	
2	45-60 years	24 (92.3)	2 (7.7)	26 (100)	
3	>60 years	4 (57.1)	3 (42.9)	7 (100)	
Total		267 (88.7)	34 (11.3)	301(100)	
$df=2 \chi^2 = 7.3563$, p<.05 significant					

TABLE 6 COMPARISON OF TWO VACCINES IN RELATION TO SYMPTOMS PRODUCED

S. no	Severity and duration of symptoms	Type of Vaccine and number of beneficiaries		Total	
		Covishield n(%)	Covaxin n(%)	n(%)	
1	Asymptomatic	78 (22.3)	12 (28.6)	90 (27)	
2	Mild symptoms	239 (68.5)	28 (66.7)	267 (68.3)	
3	Moderate symptoms	32 (9.2)	2 (4.8)	34 (8.7)	
Total		349 (100)	42 (100)	391(100)	
$df=2 \chi^2=1.4859 p>.05 not significant.$					

Figures

FIGURE 1 PERCEPTION REGARDING COVID VACCINES IN STUDY POPULATION. *

