Assessment of post vaccination symptoms following COVID-19 vaccination in India: A cross-sectional analytical study

ABSTRACT:

INTRODUCTION: The recent examples of newly emerged diseases that causes alarming situation globally include H1N1, Congo Hemorrhagic fever, Ebola virus diseases, Nipah Virus Infection, Lassa Fever and newly declared global emergency pandemic SARS nCOVID-19 infection. Since its emergence, it has spread around the globe. It tends to spread by the inhalation of the respiratory aerosols and direct human contact. ~~and via fomites.~~ (fomites are the objects or materials which are likely to carry infection, such as clothes, utensils, and furniture)

MATERIAL AND METHODS: This analytical study was carried out among the healthcare workers and people who received either of Covishield or Covaxin. The online survey questionnaire was prepared, and data obtained through the responses to the survey proforma. In the paragraph referring to the material and the method I would like to mention how many questionnaires were registered, and a few general demographics.

RESULTS: 86.17% respondents were above 40 years, 69.15% males and 30.85% were females. 89.36% were vaccinated with Covishild and 10.64% by Covaxin. 75.53% respondents experienced post vaccination symptoms; commonest were the local pain at injection site (28.72%), fever (12.76%), Myalgia (12.77%). The symptoms were found more in respondents with any of co-morbid condition.

DISCUSSION: Covishild was used more commonly than Covaxin in study samples. The symptoms following vaccination were more common in 40-60 age group and persons with co-morbid conditions.

Key words: ~~emergency~~, pandemic, healthcare workers, vaccination symptoms, COVID-19

INTRODUCTION:-

In recent years, we are facing various emerging and re-emerging diseases which were never present in the world or presented with totally new symptomatology. The recent examples of newly emerged diseases that causes alarming situation globally includes H1N1, Congo Hemorrhagic fever, Ebola virus diseases, Nipah Virus Infection, Lassa Fever and newly declared global emergency pandemic disease i.e. SARS nCOVID-19 infection. More than 30 new infectious agents are detected worldwide in last three decades and sixty percent of them have zoonotic origin, more than 2/3rd originated in wildlife.[1] Unplanned Urbanization leading to habitat destruction of various animals increased contact of humans with the wildlife animals and arthropod vectors of viral infections.[2] The novel SARS-Cov-2 is also believed to be emerged in Wuhan city in 2019 from bats. Since its emergence, it spread around the globe, despite efforts by World Health Organization and Governments to contain the infection, mainly because of highly infectious nature of the virus. It tends to spread by the inhalation of the respiratory aerosols, direct human contact and via fomites.[3] The World Health Organization on 11 March 2020 declared COVID-19 as pandemic. Since its inception, millions of people were infected with the virus causing some to severe life threatening conditions during its course in human body. Mortality associated with the infection is also alarming as many people around the world lost their lives owing to the COVID-19 infection and complications resulted because of it. According to WHO Corona virus (COVID-19) Dashboard, currently 136,996,364 were infected around the world by COVID-19 infection of which 29,51,832 lost their lives to COVID-19 infection and counting. In India 138,73,825 cases were reported, out of them 172,085 peoples lost their lives to COVID-19[4]. This global pandemic is the centre of research for all the organizations and governments for containment and prevention of mortality morbidity related to the disease. Search for effective drug treatment along with effective vaccine is need of hour to control

the disease from spreading and preventing the lives of human lost to the infection. I would like you to see the figures in this paragraph in a little more detail.

Vaccine is one of the important solutions for enhancing the immunity against disease and containment of infection. Several countries have joined this battle of vaccine development and have speed up the process of clinical trials and are trying to develop an effective and harmless vaccine against Covid- 19 [5]. The effect of an efficacious vaccine on the course of the SARS-CoV-2 pandemic is complex and there are many potential scenarios after deployment. The ability of a vaccine to protect against severe disease and mortality is the most important efficacy endpoint, as hospital and critical-care admissions place the greatest burden on health-care systems[6]. Two vaccines that have been granted emergency use authorization by the Central Drugs Standard Control Organization (CDSCO) in India are Covishield (Recombinant virus vaccine, AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin (Killed virus vaccine, manufactured by Bharat Biotech Limited). These COVID-19 vaccines were launched in India on 16 January, 2021. The first group includes healthcare and frontline workers. The second groups to receive COVID 19 vaccine are persons over 60 years of age and persons under 45 years with co-morbid conditions started from 1st March 2021. This study aims at to assess the post vaccination symptoms perceived by the vaccine recipients after 1st dose and after completion of the course of vaccination.

MATERIAL AND METHODS:

This is a cross sectional analytical study carried out among the healthcare workers and individuals who received the course of either of Covishield (AstraZeneca's vaccine manufactured by Serum Institute of India) or Covaxin (manufactured by Bharat Biotech Limited) vaccine. After taking ethical clearance from Institutional Ethical Committee, the online survey questionnaire was prepared and sent to the vaccine recipients. The data was obtained through the responses to the survey proforma and was used for analyse. A total 94 people responded to the online questionnaire within 16 days span starting from 10th March 2021 to 26th March 2021.

STATISTICAL ANALYSIS:

Collected data on predesigned proforma was coded and tabulated using MS Excel data sheet and Statistical analysis were performed on tabulated data using the Statistical Package for Social Sciences (SPSS) version 20. Mean and percentages were calculated and tables and graphs were prepared using the data. Chi square test was used to draw statistical significance ($p=<0.05$).

RESULTS:

A total 94 participants responded to the online questionnaire sent to them. 86.17% participants who responded to online questionnaire were above 40 years, 69.15% males and 30.85% were female respondents. 77.66% participants were either Consultant or Faculty of medical college, study also had 14.89% non health workers. 89.36% respondent participated in study were vaccinated with Covishild vaccine (AstraZeneca's vaccine manufactured by Serum Institute of India), and 10.64% vaccinated by Covaxin (manufactured by Bharat Biotech Limited). (Figure 1).

44.68% participants received only one dose and 55.32% both the doses at the time when responded to the questionnaire. 75.53% respondents had post vaccination symptoms, commonest were the local pain at injection site (28.72%), fever (12.76%), Myalgia (12.77%), tiredness (8.51%) and Headache (5.32%) (Figure 2).

The time duration for occurrence of post vaccination symptoms was most commonly 12-24 hours (32.98%) followed by 6-12 hours (22.34%). 10.64% respondents started experiencing post vaccine symptoms within 6 hours and 10.64% after 24 hours. The symptom lasted for 12-24 hours in 28.72% of participants, 24-48 hours in 20.21% and 10.64% participants experienced symptoms for less than 6 hours.

68.09% vaccine recipient immediately resumed their work post vaccination, 24.47% resumed work one day after vaccination. Out of the respondent who received vaccine, 23.40% were Hypertensive, 11.70% were diabetics and 55.33% had no co-morbid conditions. (Table 1).

The chances of post vaccination symptoms were seen increasing with the increased age. Most common age group affected was between 41-50 years age group (85.18%) followed by 51-60 years (80.64%). After 60 years, the symptoms were shown decreasing with 64.28% of the participants experienced post vaccination symptoms. (Figure 3).

86.21% female respondents experienced the post vaccination symptoms compared to 72.31% Males. The symptoms were seen to have occurred late in females (20%) as compared to Males (10%). In most of the Male respondents, the duration of symptoms lasted less than 24 hours (72.73%) while in female respondents, 52.17% experienced symptoms for more than 24 hours. The time to resume work was also somewhat more in females (34.49%) as compared to males (24.62%). This shows that the late occurrence of symptoms, duration of suffering and time to resume work is more in female vaccine recipients than other counterpart. There was no statistical significant association between male and females found with respect to post vaccination symptoms, time of occurrence, duration of symptoms and time to resume work. (Table 2)

When assessed the post vaccination symptoms with associated Co-morbid conditions, the symptoms were found more in respondents with any of co-morbid conditions than the respondents with no associated co-morbidity (67.31%). Statistically significant association between co-morbidity and post vaccination symptoms was found (p=0.017). (Table 3) The assessment of post vaccination symptoms with number of doses received by the respondents, it was found no statistical significant association (p value > 0.5). It reflects that the chances of post vaccination symptoms are almost similar after first and second doses. (Table 4)

Comparison of the post vaccination symptoms with the type of vaccine used for COVID-19 prevention, it was observed that COVISHILD (84 respondents) had more vaccine related symptoms (79.76%) as compared to the (10 respondents) COVAXIN (50%). Comparison is not feasible as only 10.63% respondents vaccinated by Covaxin, the association was also not found statistically significant (p=0.879) very targeted comment!!! Excellent!! (Table 5).

Figure 1: Type of vaccine used for vaccination

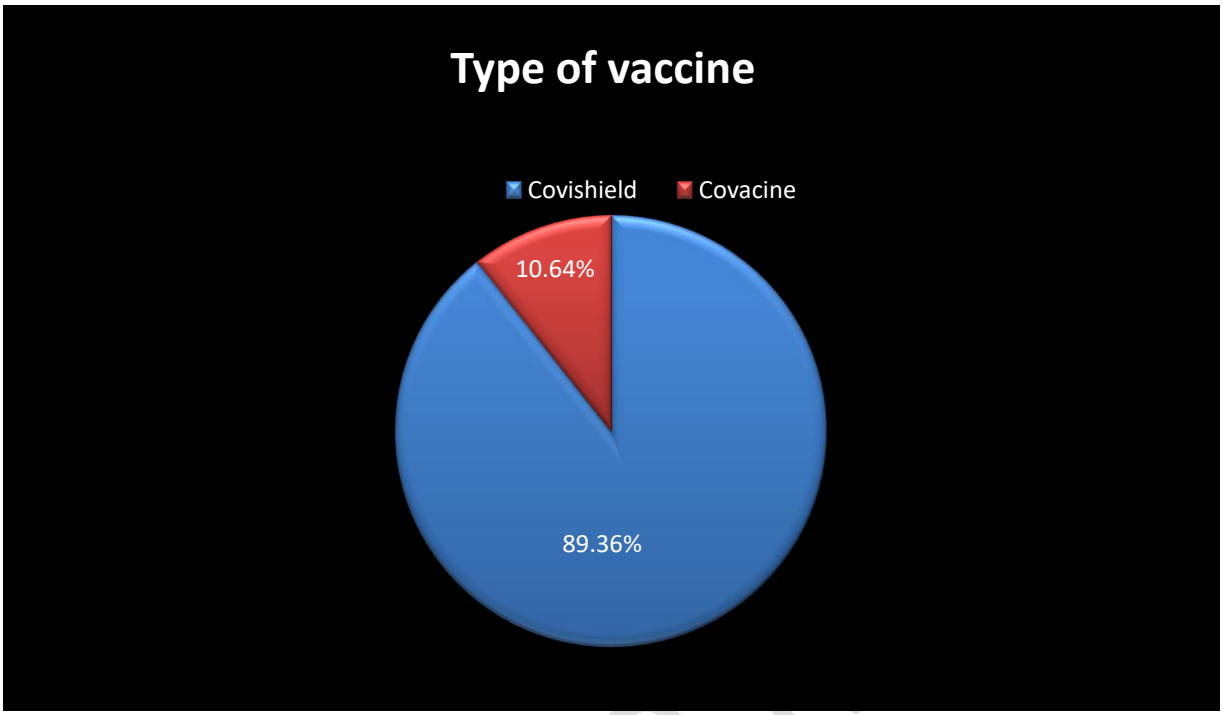


Figure 2: Post vaccine symptoms perceived by vaccine recipients.

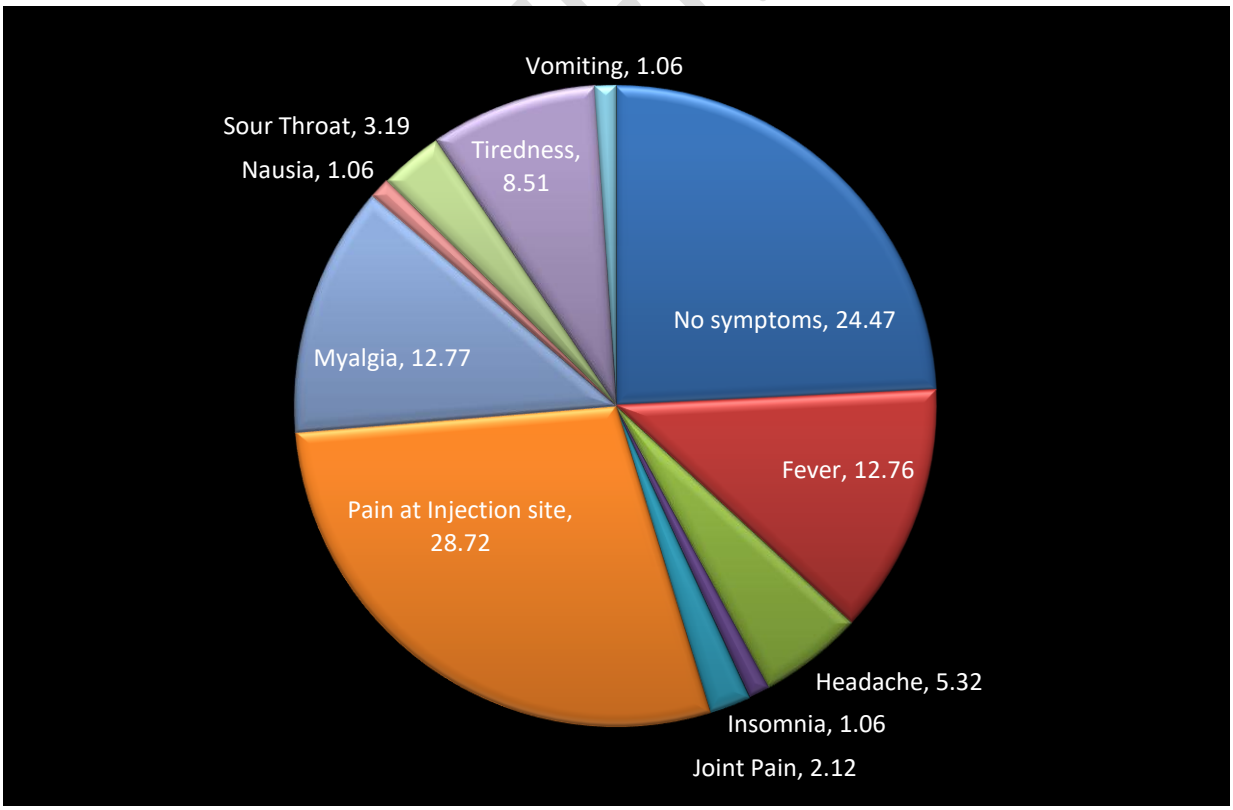
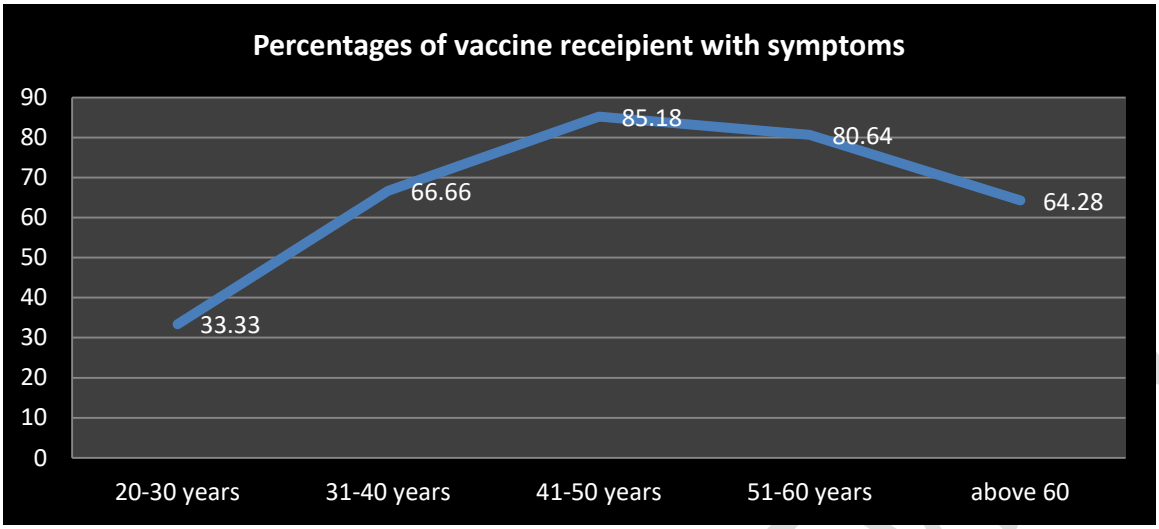


Figure 3: Percentages of vaccine recipients with symptoms according to age group



I would prefer a little more aligned tables and maybe a white background behind the graphs

Table 1: Demographic Profile of study participants

Socio-demographic Profile	Total	Percentages
Age		
20-30 Years	03	3.19
31-40 Years	10	10.64
41-50 Years	26	27.66
51-60 Years	27	28.72
>60 Years	28	29.79
Gender		
Male	65	69.15
Female	29	30.85
Occupation		
Consultant / Faculty	73	77.66
Residential Doctor	06	6.39
Office staff	01	1.06
Non Healthcare Worker	14	14.89
COVID-19 Vaccination		
One dose	42	44.68
Both doses	52	55.32
Reasons for Delay		
No Delay	81	86.17

Delayed call for vaccination	05	5.32
COVID positive	03	3.19
Other	05	5.32
Time of Occurrence of post vaccination symptoms		
No symptoms	22	23.40
Immediate	05	5.32
Within 6 hours	05	5.32
6-12 hours	21	22.34
12-24 hours	31	32.98
After 24 hours	10	10.64
Duration of Symptoms		
No symptoms	26	27.66
< 6 hours	10	10.64
6-12 hours	07	7.45
12-24 hours	27	28.72
24-48 hours	19	20.21
> 48 hours	05	5.32
Time to Resume Work		
Immediately	64	68.09
Within 6 hours	04	4.25
After a day	23	24.47
More than a day	03	3.19
Associated Co-morbid Condition		
No Co-morbidity	52	55.33
Diabetes	11	11.70
Hypertension	22	23.40
Heart Diseases	04	4.26
Respiratory Problems	01	1.06
Cancer	01	1.06
Other	03	3.19

Table 2: Assessment of symptoms following vaccination among men and women

Post Vaccination Symptoms		**Gender**		**P value**
		Male	**Female**	
Symptoms Present		47 (72.31)	25 (86.21)	0.1336
Symptoms Absent		18 (27.69)	04 (13.79)	
Time of Occurrence	<24 hours	42 (89.36)	20 (80.00)	0.274
	>24 hours	05 (10.64)	05 (20.00)	

Duration of symptoms	<24 hours	32 (72.73)	11 (47.83)	0.801
	>24 hours	12 (27.27)	12 (52.17)	
Time to Resume Work	<24 hours	49 (75.38)	19 (65.51)	0.264
	>24 hours	16 (24.62)	10 (34.49)	

Table 3: Assessment of Post vaccination symptoms with associated Co-morbid conditions

Associated Co-Morbid Conditions	**Symptoms following vaccination**		**P value**
	Yes	**No**	
No Co-morbidity	35 (67.31)	17 (32.69)	P=0.017 (p<0.05)
Diabetes	09 (81.82)	02 (18.18)	
Hypertension	21 (95.45)	01 (4.55)	
Heart Diseases	04 (100)	00 (00.00)	
Respiratory Problems	00 (00.00)	01 (100)	
Cancer	01 (100)	00 (00.00)	
Other	02 (66.67)	01 (33.33)	

Table 4: Assessment of post vaccination symptoms following no of vaccine doses

	Post Vaccination Symptoms	

No of Vaccine dose	Present	Absent	P value
One dose	34 (80.95)	08 (19.05)	0.369
Both doses	38 (73.08)	14 (26.92)	

Table 5: Assessment of Post vaccination symptoms with Type of Vaccine used

Type of Vaccine	Symptoms following vaccination		Total P=0.879
	Yes	No	
Covishield	67 (79.76)	17 (30.24)	84
Covaxin	05 (50.00)	05 (50.00)	10

DISCUSSION:

The Indian Vaccination drive against COVID-19 vaccination started from 16st January 2021 and till date, most of the Health Workers, front line workers and people aged more than 60 years and 45 Years people with co-morbid conditions were the population included in for the vaccination against the infection. In India, Covishield (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin (manufactured by Bharat Biotech Limited) are the vaccines used for the immunization purpose. The study was directed to analyse the vaccination experience and post vaccination symptoms perceived by the vaccine recipient. A total of 94 respondent shared their experiences through online questionnaire.

The study found that around 75.53% respondents experienced the post vaccination symptoms following immunization with either of COVID-19 vaccine. 24.47% vaccine recipient had no symptoms following vaccination. The study conducted by Jayadevan R[7]

titled 'Survey of Symptoms Following COVID-19 Vaccination in India' found around 65.92% participants with post vaccination symptoms.

75.53% respondents were had post vaccination symptoms, commonest were the local pain at injection site (28.72%), fever (12.76%), Myalgia (12.77%), tiredness (8.51%) and Headache (5.32%). Jayadevan R[7] reported tiredness as most common symptom in 45% respondents, it followed by Myalgia (44%), Fever (34%) and headache (28%) and local pain at injection site by 27% of the respondents.

When compared the post vaccination symptoms with the type of vaccine used, COVISHILD had more vaccine related symptoms (79.76%) as compared to the COVAXIN (50%) in our study. The study conducted by Jayadevan R[7] showed vaccine related symptoms i.e. 66% with COVISHIELD, 53% with COVAXIN, 70.7% for PFIZER and 24.4% with SINOPHARM.

The time of occurrence of post vaccination symptoms was most commonly 12-24 hours (32.98%) followed by 6-12 hours (22.34%). The duration of symptom was 12-24 hours in 28.72% participants, 24-48 hours in 20.21% and 10.64% participants experience symptoms for less than 6 hours. Jayadevan R[7] reported that 79% respondents who experienced symptoms were within first 12 hours.

86.21% female experienced the post vaccination symptoms compared to 72.31% Males. The symptoms also occurred late in females (20%) as compared to Males (10%). Most female respondents (52.17%) experienced symptoms for more than 24 hours. The time to resume work was also somewhat more in females (34.49%) as compared to males (24.62%). The results were found consistent with study conducted by Jayadevan R[7-9].

In our study, symptoms were found more common in respondents with any of the co-morbid conditions than the respondents with no associated co-morbidity (67.31%). This suggests that extra precaution is necessary for the individuals aged more than 60 years and people with co-morbid conditions[10-14].

CONCLUSION:

Most of the participated in online questionnaire was above 40 years. Covishild was used more commonly than Covaxin in study samples. The symptoms following vaccination were more common in 40-60 age group and persons with co-morbid condition, commonest were the local pain at injection site, fever, Myalgia, tiredness and Headache. The symptoms were most commonly occurred in 12-24 hours followed by 6-12 hours and lasted for 12-24 hours in 28.72% of participants, 24-48 hours in 20.21%.

LIMITATIONS:

The study sample of this online questionnaire based cross sectional analytical study is small. Along with it, the online survey is also interest based, so the persons who experienced some post vaccination symptoms following vaccination to prevent COVID-19 may be more interested in participation in the study than the other vaccine takers (Volunteer Bias). Also the comparison between the vaccines is difficult as only few peoples taken COVAXIN as compared to the COVISHILD vaccine. The symptoms following vaccination is also taken as the vaccine recipient perceived in short duration after vaccination, studies are needed to explore the long term post vaccination symptoms.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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