

Post Vaccination Effects Of m-RNA Covid-19 Vaccine & Its Efficacy with Detailed Self-Reported Symptoms from Healthcare Workers and General Population in Central Gujarat

ABSTRACT:

Background & Aim: Concerns are prevailing about the safety and side effects of the mRNA vaccine for coronavirus disease 2019 (COVID-19). Hence a study aiming the effectiveness of vaccine, post vaccination symptoms, natural progression of infection in the individuals was performed.

Methods: A randomized, cross-sectional survey was performed comprising the 757 individuals from the pool of 1000 people, to investigate the side effects of the vaccines using an independent online questionnaire gathering responses from healthcare workers (HCWs) and general population with detailed review of organ systems.

Results: A total of 757 people responded, led us to the point where 476 people (62.87 %) of people experiencing **minimum** one symptom following the first dose of either of the two vaccine, in comparison to 188 responses (24.8%) of people experiencing at least one symptom following second dose of either of the two vaccine.

Conclusions: Commonly reported symptoms (occurrence in descending order) were soreness, fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasm, sweating, dizziness, flushing, feelings of relief, brain fogging, anorexia, localized swelling, decreased sleep quality, itching, tingling, diarrhea, nasal stuffiness and palpitations. Despite this, remarkable acceptance for the second dose of the **m-RNA Covid** vaccine was found among all the individuals.

Keywords: *Covid-19; m-RNA Covid vaccine; efficacy; symptoms*

1. INTRODUCTION

The COVID-19 pandemic had a dramatic health, social, and economic impact. As of the time of this report, the level of uncertainty was extremely high and exacerbated by an excess of contradictory information.^{1,2} Many lay media and websites have unceasingly delivered real-time numbers on new cases and deaths, often also providing unauthorized medical advices, without waiting for confirmation. The amount and variety of news have led to a massive informative overload, generating a real infodemic.

Providing the population with evidence-based scientific data is beneficial and necessary, but does not necessarily lead to individuals correctly understanding or interpreting the information. Evidence-based data runs the risk of being self-defeating if too much information is released and the public become saturated with different facts and contradictory information, leading to emotional reactions and mistrust toward decision-makers.³ Moreover, debates among individuals and organizations who have a strong web and media presence, often provoke conflicting opinions and negative beliefs, as in the current COVID-19 situation.^{4,5} One of the most discussed topics is about prevention of SARS-CoV-2 through the development of vaccines: there is a lot of information from different sources, often conflicting, that have already caused much controversy and, in some cases, been labeled as “fake news.”^{6,7}

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has caused a global pandemic in a short period of time, imposing challenges on medical services, researchers, epidemiologists and policy makers about the nature of the virus; and posing challenges for a successful vaccine outcome. The disease is asymptomatic or mild in most patients. However, a substantial percentage of people have more extensive pneumonia that can progress to hypoxemic respiratory failure, shock, dysfunction of organs and death. Unfortunately, no effective treatment has been demonstrated to radically change the natural history of SARS-CoV-2 infection. As immunization is one of the most successful and cost-effective health interventions to prevent infectious diseases, vaccines against COVID-19 are considered to be of great importance to prevent and control COVID-19. In the month of September 2020 two vaccines produced from Serum Institute of India and Bharat Biotech received approval from the government for vaccination in India. Along with these two, several other vaccines were ongoing trials. This unparalleled initiative in developing vaccines created many uncertainties looming around the efficacy and safety of these vaccines. This study aimed to assess the side effects and efficacy following COVID-19 vaccination.^{8,9}

METHODS

Study comprised of conducting a survey with a detailed questionnaire pertaining to effectiveness of vaccine, post vaccination symptoms, natural progression of infection and treatment modalities during hospital stay or home quarantine facility if infected after getting vaccinated. Our survey was based on the vaccination drive carried out initially for healthcare workers followed by mass

vaccination drive over a period of eight months¹¹. Our survey includes people of all age groups ranging from 18 to 91 years old. The responses were filled by the individuals during follow up interviews. The question set included responses in binary fashion along with descriptive features needed in certain categories. A total of 757 responses were collected and statistical analysis was performed (Table 1).

2. RESULTS & DISCUSSION

A total of 757 people responded to the questionnaire given to them, which lasted for eight months from the month of September 2020 to April 2021. Among those who responded, 59.5% were healthcare workers including doctors, nurses, technicians followed by general population (40.5%). Amongst the vaccine recipients 37.8% were male and 62.2% female. From the survey responders 698 people (92.2%) were administered Covishield (manufactured by Serum Institute, India) vaccine and 59 (7.8%) people were given Covaxin vaccine (manufactured by Bharat Biotech, India).

Table 1: Overall symptomatic response after covid-19 vaccination based on age.

Crosstab					
		Symptomatic overall			Total
		Asymptomatic	Symptomatic		
Age	<20	Count	22	226	248
		% within symptomatic overall	8.3%	46.0%	32.8%
21-30	Count	27	147	174	
		% within symptomatic overall	10.2%	29.9%	23.0%
31-40	Count	22	31	53	
		% within symptomatic overall	8.3%	6.3%	7.0%
41-50	Count	37	26	63	
		% within symptomatic overall	13.9%	5.3%	8.3%
51-60	Count	38	9	47	
		% within symptomatic overall	14.3%	1.8%	6.2%
61-70	Count	69	36	105	
		% within symptomatic overall	25.9%	7.3%	13.9%
71-80	Count	44	14	58	
		% within symptomatic overall	16.5%	2.9%	7.7%
>80	Count	7	2	9	
		% within symptomatic overall	2.6%	0.4%	1.2%
Total	Count	266	491	757	
		% within symptomatic overall	100.0%	100.0%	100.0%
Chi-Square Tests					
		Value	df	P value (<0.05 is significant)	
Pearson Chi-Square		256.345	7	<0.001	

Table 2: Overall symptomatic response after covid-19 vaccination based on gender.

Crosstab				
		Symptomatic overall		Total
		Asymptomatic	Symptomatic	

Gender	F	Count	131	340	471
		% within symptomatic overall	49.2%	69.2%	62.2%
	M	Count	135	151	286
		% within symptomatic overall	50.8%	30.8%	37.8%
Total		Count	266	491	757
		% within symptomatic overall	100.0%	100.0%	100.0%
Chi-Square Tests					
		Value	df	P value (<0.05 is significant)	
Pearson Chi-Square		29.353	1	<0.001	

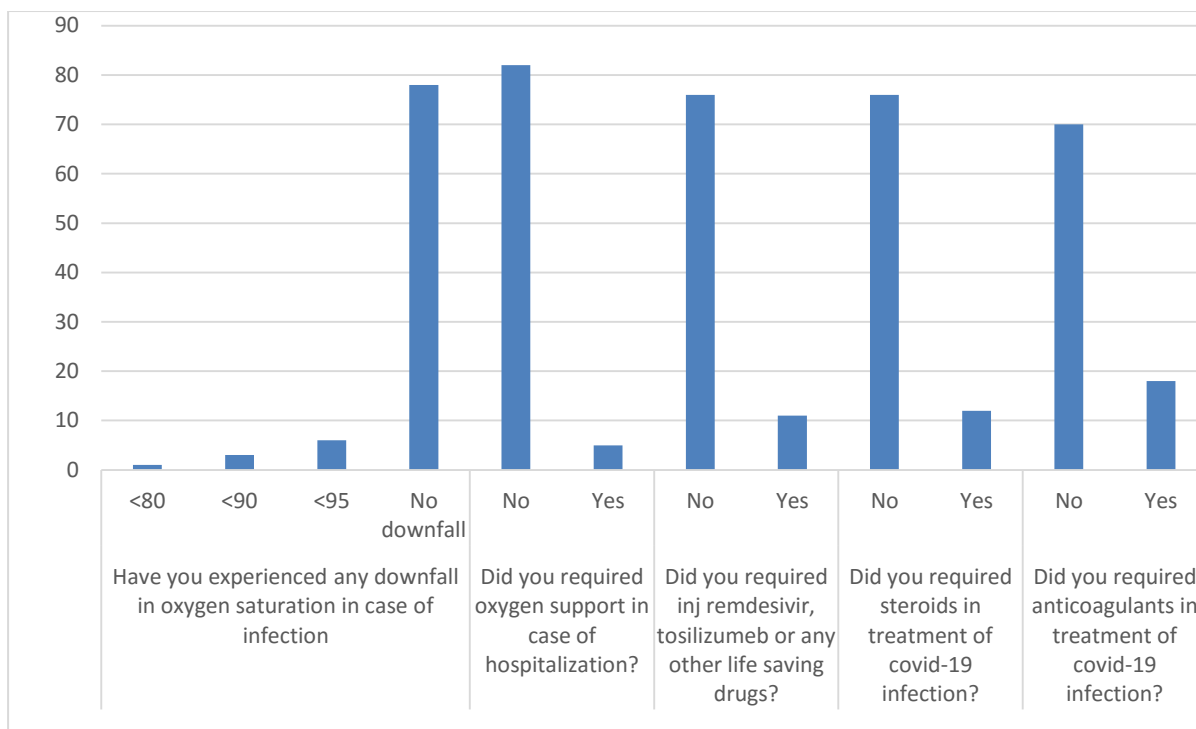
Table 3: Symptoms after first dose of covid-19 vaccine.

	Fever After First Dose	Weakness after first dose	Headache and Body Ache after first dose	Malaise after first dose	Tachycardia after first dose
No	421	449	456	698	732
Yes	336	308	301	59	25
Total	757	757	757	757	757

Table 4: Symptoms after second dose of covid-19 vaccine.

	Fever After Second Dose	Weakness after Second dose	Headache and Body Ache after Second dose	Malaise after Second dose	Tachycardia after Second dose
No	722	663	692	745	740
Yes	35	94	65	12	17
Total	757	757	757	757	757

Charter 1: Treatment modalities after covid-19 infection.



Out of total 757 responses 92.2% received both the doses of vaccines. This includes 651 people administered Covishield and 47 administered Covaxin. The remaining 7.8% of people did not receive the second dose. 11.3% of people experienced decrease in their oxygen level and 94.3% experienced the need of oxygen during the disease course.

Post vaccination a majority of the healthcare worker falling under the age of 30 were found to more symptomatic compared to the rest of the age groups (Table 1). Females were found to be predominantly more symptomatic compared to the males irrespective of their age (Table 2).

The need of administering steroids was found in 13.6% people and other drugs 12.6%. 20.5% people were prescribed anticoagulants (Charter 1).

All over the level of acceptance of the vaccine was high and majority of the people did acknowledge the vaccine benefits.

Our healthcare workers who responded to the survey stated few to none symptoms after vaccination where fever headache body ache being the most common symptoms. None of the people were found to develop any serious post vaccination symptom or complication. (Table 3 and

Table 4).

Majority of vaccine recipients did not contract the disease and they found the vaccine to be effective and beneficial in order to cease the spread of the disease. The people who were infected by the virus even after vaccination showed a mild disease progression leading to no serious aftermath effect. Our findings can be co-related to the results of the various published studies and trials.

A total of 757 people responded to the questionnaire given to them, which lasted for eight months from the month of September 2020 to April 2021. Among those who responded, 59.5% were healthcare workers including doctors, nurses, technicians followed by general population (40.5%). Amongst the vaccine recipients 37.8% were male and 62.2% female. From the survey responders 698 people (92.2%) were administered Covishield (manufactured by Serum Institute, India) vaccine and 59 (7.8%) people were given Covaxin vaccine (manufactured by Bharat Biotech, India).

According to those receiving two standard doses of Astra oxford ChAdOx1 nCoV-19, after the prime vaccination local reactions were reported in 43 (88%) of 49 participants in the 18-55 years group, 22 (73%) of 30 in the 56-69 years group, and 30 (61%) of 49 in the 70 years and older group, and systemic reactions in 42 (86%) participants in the 18-55 years group, 23 (77%) in the 56-69 years group, and 32 (65%) in the 70 years and older group. As of now various other vaccines have been approved for by the government, one often being Sputnik V, Moderna, Zycov-D, J&J. In terms of efficacy, both Covishield and Covaxin were highly effective in the overall population.^{10,12}

There was a small pool of subjects due to which mass response to the vaccine cannot be formulated. The symptoms being highly subjective can also lead to overestimation of the symptoms. The follow up responses were taken into account within two months of vaccination, leading to little or no knowledge regarding post two months.

3. CONCLUSION

Two third of the population did experience at least one symptoms post vaccination. Fever, headache and body ache being the most common symptom. The symptoms were more common with the females as compared to the males. No serious events were noted. Only 11.6% of the vaccinated people contracted the disease leading to positive outcome from the vaccine making us believe in the vaccine efficacy. The severity of the infection was mild in people getting infected even after vaccination which again leads us to the positive side of vaccination.

Consent

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

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.

REFERENCES

1. Baden LR, El Sahly HM, Essink B, Kotloff K, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med*. 2021 Feb 4;384(5):403-416.
2. Banerji A, Wickner PG, Saff R, Stone CA Jr, et al. mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach. *J Allergy Clin Immunol Pract*. 2020 Dec 31:S2213-2198(20)31411-2.
3. CDC. COVID-19 Death Data and Resources, National Center for Health Statistics, Atlanta, GA: US Department of Health and Human Services, CDC; 2021.
4. CDC. COVID-19 vaccination: clinical considerations. Interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States. Atlanta, GA: US Department of Health and Human Services, CDC; 2020.
5. Chen YT, Shao SC, Hsu CK, Wu IW, Hung MJ, Chen YC. Incidence of acute kidney injury in COVID-19 infection: a systematic review and meta-analysis. *Crit Care*. 2020 Jun 16;24(1):346. doi: 10.1186/s13054-020-03009-y.
6. Ganyani T, Kremer C, Chen D, Torneri A, Faes C, Wallinga J, Hens N. Estimating the generation interval for coronavirus disease (COVID-19) based on symptom onset data, March 2020. *Euro Surveill*. 2020 Apr;25(17):2000257. doi: 10.2807/1560-7917.ES.2020.25.17.2000257.

7. Zarocostas J. How to fight an infodemic. *Lancet*. 2020;395:676.
8. Hua J, Shaw S. Corona virus (COVID-19) “infodemic” and emerging issues through a data lens: the case of China. *Int J Environ Res Public Health*. 2020;17(7):2309.
9. Paakkari L, Okan O. COVID-19: health literacy is an underestimated problem. *Lancet Public Health*. 2020 April 14;5(5):e249–e250.
10. India rolls out the world’s largest COVID-19 vaccination drive, January 16, 2021. Retrieved from: <https://www.who.int/india/news/feature-stories/detail/india-rolls-out-the-world-s-largest-covid-19-vaccination-drive>.
11. Sharma M. Story of the biggest vaccination drive in the world so far. *Journal of Pharmacovigilance and Drug Research*. 2021;2(2):1
12. Wise J. Covid-19: New data on Oxford AstraZeneca vaccine backs 12 week dosing interval. *BMJ* 2021;372:n326 | doi: 10.1136/bmj.n326.

UNDER PEER REVIEW