To Study Adverse Effect following Immunization (AEFI) and COVID-19 Infection amongst COVID-19 Vaccine Beneficiaries

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Abstract
COVID-19 vaccines have been rolled out recently in several parts of the world. Little is known about the post-vaccination experience outside of clinical trial conditions. The aim of this study was to investigate the adverse effects and infection rate of vaccinated people in a community scenario. It will help to educate the public, dispel misinformation and reduce vaccine hesitancy.

Aim and Objectives: Assessing total beneficiaries of COVID-19 vaccination and finding among them COVID-19 infection and AEFI after vaccination.

Subject and Methods: Cross sectional Study at COVID-19 Vaccination centre at DCH in Mumbai, since 1st February2021–31st July 2021, Data was collected by calling telephonically the registered beneficiaries in Vaccination Centre, data was collected and analysed in MS-excel sheet and SPSS using CHI-square test. Results: 49.68% of the beneficiaries were from the age group of 45-60 years followed by >60 years age group (34.70%), 97.08% beneficiaries were from Mumbai. 3593(43.59%) had taken both the doses of COVID-19 vaccine while 4650(56.41%) had taken only first dose of COVID -19 vaccine. 36(0.44%) had contracted COVID-19 infection after vaccination. 88.71% had no AEFI after taking vaccine. 1.65% had mild AEFI 9.63% had moderate AEFI.

Conclusion: Very few had contracted COVID-19 infection after vaccination. Out of all AEFI maximum were mild to moderate.

Introduction
The vaccination program has commenced in many countries worldwide, which is marked as a significant milestone in curbing the spread of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causal agent of the corona virus disease 2019 (COVID-19) pandemic.1 Individuals who have been vaccinated are less inclined to be severely infected than those who have not received vaccines.2 These vaccines, which have received emergency authorisation from different regulatory bodies around the world, such as the Food and Drug Administration in the USA, have different mechanisms of delivery of antigens. Researchers have revealed that different vaccines have varied levels of efficacy, i.e., between 60% and 95%.3

Studying the clinical profile of those who got infected after receiving one or two doses of vaccine will give a clear indication as to the level of protection that a first dose and a second dose offered. If the first dose was enough to prevent serious disease and hospitalisation, then it should help the authorities decide whether covering as many people as possible with at least a single dose vaccine is the appropriate strategy for the State, it is pointed out.4

COVID-19 vaccines have been rolled out recently in several parts of the world. Although the protective efficacy is frequently discussed, little is known about the real-world post-vaccination experience outside of clinical trial conditions.2

The aim of this study was to investigate the adverse effects and infection rate of vaccinated people in a community scenario.

Knowledge about what to expect after vaccination will help educate the public, dispel misinformation and reduce vaccine hesitancy.

Aim and Objectives
1. To assess total beneficiaries of COVID-19 vaccination
2. To find COVID-19 infection after vaccination
   - To compare 1st and 2nd dose COVID-19 vaccine beneficiaries for Covid-19 infection
   - To study severity of infection after vaccination in beneficiaries with co-morbidities
3. To study AEFI after vaccination.

Subject and Methods
1. Study Design: Cross sectional study design
2. Study Setting: COVID-19 Vaccination centre at DCH in Mumbai, India run by MCGM
3. Study Duration: All patients with COVID-19 vaccination registered in centre since 1st February2021–31st July 2021
4. Sample Size: Universal sample size
5. Inclusion Criteria: Those who had taken at least first dose and second dose of COVID-19 Vaccination
7. BIAS: Information bias
Data Collection: Data was collected by calling the registered beneficiaries in Vaccination Centre

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### Results

As of 20th September 2021, we had vaccinated Covishield doses 2, 21,570 (1st - 1,56,353 and 2nd - 65,217) and Covaxin doses 21,727 (1st - 10,670 and 2nd - 11,057) in the age group of 18-45 years. Among 13 those required hospitalization were 4 and rest others required home treated (i.e. O2 required). And among 13 those became positive after taking COVID-19 vaccine. 1.65% had mild (redness, itching, and swelling on injection site) and 49.68% of the beneficiaries were from Mumbai and 2.92% were from out of Mumbai who had come to the centre for COVID-19 Vaccination. Among which 57.58% were male and 42.42% were female. The result was statistically not significant with Chi-square value is 0.0584 and p-value = 0.80896.

### Discussion

Vaccines for SARS-COV-2 became available in December 2020. The development of an effective vaccine over a relatively short period of time required the coordinated efforts of multiple scientists, pharmaceutical companies, and government organizations.3

The Government of India (GOI) launched a nationwide vaccination drive in a phased manner based on 16th January 2021 for health care workers...
Initially and subsequently extending to frontline workers, and the higher-risk population at designated sites in two doses 28 days apart.\(^6\)

We have studied, the response of people towards vaccination campaign and in our study, we have considered all the citizens who were registered or got vaccinated at our centre during the time interval of 26 January till July 2021. All the beneficiaries were contacted telephonically and were asked to respond to pre-filled questionnaires’ regarding their experience and feedback of vaccination at our centre. They were specifically asked for any side effect or adverse reaction to vaccination or any event of Covid symptoms or Covid positive status post vaccination. Total 8243 beneficiaries were registered for this study. Data was analysed on the basis of Age, gender, AEFI, Covid positive status, co-morbidities. Amongst the sample, 49.68% of the beneficiaries were from the age group of 45-60 years followed by >60 years age group (34.70%). Only 15.62% of the beneficiaries were from the age group of 18-45 years. Among which 57.58% were male and 42.42% were female; also 97.08% beneficiaries were from Mumbai and 2.92% were from out of Mumbai.

In our study, 3593(43.59%) had taken both the doses of COVID-19 vaccine while 4650(56.41%) had taken only first dose of COVID-19 vaccine.

During vaccination, 88.71% beneficiaries had developed no adverse reaction to vaccination, only 1.65% had mild (redness, itching, and swelling on injection site) AEFI 9.63% had moderate (swelling, pain, redness at injection site) AEFI 9.63% had moderate AEFI 9.63% had severe AEFI (raise in BP, fever), no beneficiary developed any severe adverse reaction to vaccination.

The post vaccination Covid positive rate in our study group is only 0.44% which is significantly less amongst all vaccinated beneficiaries. As per Survey of symptoms following COVID-19 vaccination in India by Jayadevan R etal.\(^2\) a total of 5396 people responded to the survey over a one-week period from 29 January to 4 February. Overall, 65.9% of respondents reported at least one post-vaccination symptom. Tiredness (45%), myalgia (44%), fever (34%), headache (28%), local pain at injection site (27%), joint pain (12%), nausea (8%) and diarrhoea (3%) were the most prevalent symptoms. The chance of having symptoms decreased with advancing age. The frequency of symptoms was 81% (3rd decade or 20-29 years), 80% (4th decade or 30-39 years), 68% (5th decade), 58% (6th decade), 45% (7th decade), 34% (8th decade) and 7% (9th decade, 80-90 years). Post-vaccination symptoms were more likely to be reported by women (74.7%) compared to men (58.6%) (p< 0.001). Among those who reported symptoms, 79% noticed them within the first 12 hours. 472 out of 5396 (8.7%) reported past history of COVID-19. Their symptom profile was not different to those who did not have a past history. In 90% cases, the symptoms were either milder than expected or meeting the expectation of the vaccine recipient. No serious events were reported. Symptoms were more common among younger individuals.

As per Abohelwaa M, Elmassry M, Abdelmalek J, et al all residents and fellows reported side effects after vaccination, including pain at the injection site (77; 100%), local redness (9; 11.6%), local swelling (13; 16.8%), fever (25; 32.5%), fatigue (25; 32.5%), chills (34; 44.1%), headache (38; 49.4%), but no anaphylaxis or palpitations. No one reported severe incapacitating side effects.\(^7\)

A total of 195 people, i.e., 11.8%, suffered from COVID-19 confirmed by the test, while 83.3% (1385) did not suffer from it, and 72 people refrained from selecting the answer. However, based on the circumstances and symptoms, 18.5% (299) of people developed COVID-19, unconfirmed by the test, and 72.5% (1173) of people did not suspect COVID-19, but the asymptomatic transition of COVID-19 cannot be ruled out. When asked about the course of COVID-19, the answers were obtained that 74 people had an asymptomatic course, 325 people mild, 69 people moderate, and 1185 people did not suffer from COVID-19. A total of 468 suffered from COVID-19, which does not coincide with the responses to the previous question, i.e., people with a confirmed COVID-19 test result and confirmed based on symptoms and circumstances, i.e., 488 people. Assuming that 468 people suffered from COVID-19, it can be stated that as many as 28.3% of the respondents suffered from COVID-19.

According to Abohelwaa M, Elmassry M, Abdelmalek J, Payne D et al one survey respondent tested positive for COVID-19, 8 days following the first vaccine dose and no respondents tested positive following the second dose of vaccine.\(^7\)

According to J. Muthukrishnan, VasuVardhan V et al.\(^8\) COVISHIELD has shown to reduce infections by 80-94%. In present study only 36(0.44%) had contracted COVID-19 infection after vaccination while others were unaffected.

**Conclusion**

1. Maximum beneficiaries were from the age group of 45-60 years followed by >60 years age group and then from the age group of 18-45 years.

2. Most of the beneficiaries were from Mumbai.

3. 43.59% had taken both the doses of COVID-19 vaccine while 56.41% had taken only first dose of COVID-19 vaccines. The result is statistically significant.

4. Very few had contracted COVID-19 infection after vaccination while others were unaffected.

As per the result both doses of COVID-19 vaccine reduces the risk of hospitalization.

According to result the risk is more in those having co-morbidities although the result is not significant.

5. Out of all AEFI maximum were mild to moderate.

**References**


