



A STUDY OF POST VACCINATION ADVERSE REACTION IN INDIVIDUALS VACCINATED AGAINST COVID-19 VACCINES AT TERTIARY CARE HOSPITAL.

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ABSTRACT **INTRODUCTION:** Government of India is taking all necessary steps to face the challenge posed by the growing pandemic of COVID-19. Vaccination against covid-19 is one of the most important strategies in prevention of covid-19, its complication and morbidity and mortality due to it. To minimize SARS-CoV-2 infection, at-risk populations must be targeted in efforts to boost vaccine effectiveness and infection control measures. Some people still become infected with SARS-CoV-2 after vaccination but in some people COVID-19 vaccines show excellent efficacy in clinical trials. This study aimed to identify post-vaccination SARS-CoV-2 infection and describe the characteristics of post-vaccination illness. Objectives: 1) To study the demographic characteristics in beneficiaries who were vaccinated with covid-19 vaccine at tertiary care hospital. 2) To study the post vaccination complications in vaccine receivers. **Material and METHOD:** The present Cross-sectional descriptive study is conducted at a tertiary care hospital in individuals who were vaccinated with covid-19 vaccine by using Pre designed and pre tested questionnaire by telephonic survey. Statistical analysis: Mean, Percentages are calculated. **RESULT:** In present study, there were 56% male and 43% female. Covishield vaccine was taken by 79.1% and Covaxine by 20.9%. After 1st dose of vaccination (Covishield or Covaxine) common symptoms seen were fever (33.3%), chills (3.3%), pain at vaccine site (6.2%), swelling at vaccine site (3.1%), body pain (20.4%), joint pain (12.5%), headache (9.9%) and fatigue (8.4%). All clinical symptoms were mild to moderate. Similar symptoms were seen after 2nd dose of covid-19 vaccination. **CONCLUSION:** study suggest that, the covid-19 vaccine available in India are safe and they can reduce the chances of vaccinated person becoming seriously ill.

KEYWORDS : Covid-19, Vaccination, Covishield, covaxin, Adverse reaction

INTRODUCTION:

Vaccination against SARS-CoV-2 is a leading strategy to change the course of the COVID-19 pandemic worldwide. The UK was the first country to authorize a vaccine against SARS-CoV-2. Vaccination (compared with no vaccination) was associated with reduced odds of hospitalization or having more than five symptoms in the first week of illness following the first or second dose, and long-duration (≥ 28 days) symptoms following the second dose [1]. Even though safe and effective vaccines are now being administered but vaccination programs still face significant obstacles. One study on flu vaccine suggested that 35.8% of adults refuse to take flu vaccines Same thing is seen in case of covid-19 vaccination [2].

The vaccinations provide good protection but they do not offer full immunity and it likely reduce transmission of the virus to others, the extent of this remains uncertain. A sizable number of people around the world express hesitancy towards taking COVID-19 vaccines. This is defined as "delay in acceptance or refusal of vaccines despite availability of vaccination services. The number of factors such as religion, gender, political ideology and trust in medical and scientific institutions have been shown to be associated with vaccine hesitancy in general population [3].

It is estimated that a novel COVID-19 vaccine will need to be accepted by at least 55% of the population to provide herd immunity, with estimates reaching as high as 85% depending on country and infection rate [4].

The COVID-19 vaccines can cause mild adverse effects after the first or second dose, including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills, and joint pain, and can also rarely cause anaphylactic shock. These clinical symptoms were mild to moderate after the first dose of vaccine. However, after the second dose of vaccine the clinical symptoms were moderate to severe. Moreover, facial swelling and Bell's palsy has also been reported [5]. Thrombocytopenia and rare thromboembolic events after the ChAdOx1 nCoV-19 (Oxford Astra Zeneca) vaccine have been reported in Denmark, Norway, Germany, Austria, and the United Kingdom [6]. With this background we have planned to study the post vaccination adverse reaction in individuals vaccinated against covid-19 vaccine with Covishield and Covaxin at Tertiary Care Hospital.

MATERIAL AND METHOD:

This is a cross-sectional descriptive study carried out in a tertiary care hospital in western Maharashtra. The data for the present study was collected from vaccination center who received two doses of vaccine (fully vaccinated) with covid-19 vaccine between February 2021 and April 2021. As per the record, total beneficiaries were 3338. From this, every fifth beneficiary was selected as study subject. Thus 667 study subjects were selected by systematic random sampling. Out of 667 study subjects, 543 responded to call whereas 124 did not. These 124 subjects were excluded from the study. Pretested questionnaire was used to obtain information about socio-demographic variables like age, sex, type of family and adverse reaction after 1st dose, and 2nd dose of covid-19 vaccine, covid-19 infection after 2nd dose of covid-19 vaccine. The survey was carried out by telephonic mode. The data was collected after 1 month of 2nd dose of covid-19 vaccination. At this vaccination center both covishield and Covaxin were used. Collected data was analysed using Microsoft office excel 2007. Ethical approval and permission were taken from institutional Ethics Committee.

RESULT:

Table 1: Demographic characteristics in study subject (- 543)

| Parameters | Respondents | Frequency | Percentage |
|---|--------------|-----------|------------|
| Age (in years) | 18- 30 | 194 | 35.7 |
| | 31-45 | 103 | 18.9 |
| | 46-60 | 127 | 23.5 |
| | >60 | 119 | 21.9 |
| Sex | Male | 308 | 56.7 |
| | Female | 235 | 43.3 |
| Type of family | Nuclear | 367 | 67.6 |
| | Joint | 131 | 14.1 |
| | 3 Generation | 45 | 8.3 |
| Residency | Urban | 364 | 67.1 |
| | Rural | 179 | 32.9 |
| Type of Vaccine | Covishield | 429 | 79.1 |
| | Covaxine | 114 | 20.9 |
| Covid-19 infection after 2 nd dose | Yes | 92 | 16.9 |
| | No | 451 | 83.1 |

In the present study there were 35.7% vaccinees in the age group of 18 to 30 years and 18.9% in the age group of 31 to 45 years, 23.4% in 46 to 60 and 21.9% in above 60 years of age group. There were 56.7% males and 43.3% females. 67.6% belonged to nuclear family, 14.1% to joint

family and 8% to three generation family. Covishield vaccine was taken by 79.1% and Covaxin was taken by 20.9%. Covid-19 infection after 2nd occurred in 16.9 % vaccine receivers.

Table 2: Study subjects and complains after 1st and 2nd of vaccine (n-543)

| complaints | After 1 st dose | | After 2 nd dose | |
|---------------|----------------------------|------------|----------------------------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| No complaint | 195 | 35.9 | 205 | 37.7 |
| One complaint | 98 | 18.0 | 117 | 21.6 |
| ≥2 complaints | 250 | 46.1 | 221 | 40.7 |
| Total | 543 | 100 | 543 | 100 |

Table 2 shows that, 35.9 % and 37.7 % study subject did not report any complaints after 1st dose and 2nd dose respectively. at least one complaint was reported by 18.0 % and 21.6respondants after 1st and 2nd dose respectively. two or more complaints were reported by 46.1% and 40.7% respondents after 1st and 2nd dose respectively.

Table 3: Distribution of study subjects according to complains after 1st and 2nd dose (Combined Covishield and Covaxin) (n-543)

| Complaints | After 1 st dose | | After 2 nd dose | |
|------------------|----------------------------|------------|----------------------------|------------|
| | Frequency | Percentage | Frequency | Percentage |
| Fever | 181 | 33.3 | 133 | 24.4 |
| Chills | 18 | 3.3 | 8 | 1.4 |
| Vomiting | 11 | 2.0 | 2 | 0.3 |
| Nausea | 11 | 2.1 | 10 | 1.8 |
| Fatigue | 46 | 8.4 | 68 | 12.5 |
| Pain at site | 34 | 6.2 | 44 | 8.11 |
| Redness at site | 8 | 1.4 | 4 | 0.7 |
| Swelling at site | 17 | 3.1 | 21 | 3.8 |
| Headache | 54 | 9.9 | 67 | 12.3 |
| Muscle pain | 25 | 4.6 | 10 | 1.8 |
| Body pain | 111 | 20.4 | 98 | 18.1 |
| Itching | 7 | 1.2 | 8 | 1.4 |
| Joint pain | 68 | 12.5 | 32 | 5.8 |
| Cough | 12 | 2.2 | 17 | 3.1 |
| Palpitation | 3 | 0.5 | 0 | 0 |
| Polymenorrhea | 1 | 0.1 | 0 | 0 |
| breathlessness | 5 | 0.9 | 3 | 0.5 |

The above table depicts that, fever (33.3%) and body pain (20.4%), and joint pain (12.5%) were the common symptoms in study subject after 1st dose while fever (24.4%), body pain (18.1%), headache (12.3%) and fatigue (12.5%) were the most common symptom after 2nd dose (Table 3)

Table 4: Complain after receiving Covishield and Covaxin in study subject (n-543)

| vaccine | No. of complaints | After 1 st dose | | After 2 nd dose | |
|------------|-------------------|----------------------------|------------|----------------------------|------------|
| | | Frequency | Percentage | Frequency | Percentage |
| Covishield | Nil | 161 | 37.5 | 179 | 41.7 |
| | 1 | 92 | 21.4 | 97 | 22.6 |
| | ≥2 | 176 | 41.1 | 153 | 35.7 |
| Covaxin | Nil | 34 | 29.8 | 26 | 22.8 |
| | 1 | 18 | 15.8 | 41 | 36.0 |
| | ≥2 | 62 | 54.4 | 47 | 41.2 |

Out of 543 vaccinees, 429 subjects received Covishield vaccine while 114 received Covaxin. In covishield vaccine receivers, 37.5 % and 41.7% respondents did not report any complaint after 1st dose and 2nd dose of Covishield vaccination respectively, while 21.45% and 22.6% reported one complaint and 41.1% and 35.7% reported two or more complaints after 1st and 2nd dose of covishield vaccine respectively.

In covaxin receivers, 29.8%.5 and 22.8% respondents did not report any complaint after 1st dose and 2nd dose of Covaxin respectively, while 15.8% and 36% reported one complaint and 54.4% and 41.2% reported two or more complaints after 1st and 2nd dose of covishield vaccine respectively.

DISCUSSION:

There are several safe and effective vaccines that prevent in people of any age group from getting seriously ill from covid -19. Though this is

true every vaccine some or other adverse reactions. At the time of study, two approved vaccines i.e. covishield and covaxin were made available after thorough testing. These vaccines have certain differences in their properties and actions on the body

In our study, after the first dose most common symptom were fever (33.3%), body pain (20.4%), joint pain (12.5%), headache (9.9%), but some minor symptoms were also seen like nausea, pain at site, fatigue, chills, swelling at site. Very uncommon symptom like palpitation, breathlessness, cough itching vomiting were seen but in low percentage. While after 2 dose fever (24.4%), body pain (18.1%), fatigue (12.5) were common symptom but in low percentage. In similar study, conducted by J. Sadoff, M. Le Gars et al. Interim Results of a Phase 1–2a Trial of Ad26.COVS.2 Covid-19 vaccine, they found that after the administration 1 and 2 dose of covid-19 vaccine the most common adverse events were fatigue, headache, myalgia, and injection-site pain and fever are seen [7].

The COVID 19 vaccine used in India are safe and effective but may have minor side effects like fever, pain, etc. at the injection site as seen in the present study. These effects can happen in any vaccine.

In present study, 35.9% and 37.7% respondents did not report any complaints after 1st dose and 2nd dose respectively. While 64.1% and 62.3% respondents reported one or more complaints after receiving some 1st dose and 2nd dose respectively. Though more than 60% respondents reported complaints after vaccination, but these are very mild and can be treated at home.

S.A. MEO et al. presented that Pfizer and Moderna vaccine in some cases shows serious adverse effects, and in rare cases, have produced severe allergic reactions, including anaphylaxis [4]. Unlike these findings in present study no serious complaints occurred in the vaccinees receiving Covishield or covaxin.

Julia Hippisley-Cox et al. presented increased relative incidences of thrombocytopenia, venous thromboembolism in ChAdOx1 nCoV-19 vaccination and arterial thromboembolism with BNT162b2 mRNA vaccination [6]. These complications are not seen in covishield and covaxin in our study. In contrast, in our study Both Covishield and Covaxin vaccines are safe and effective.

In our study covid-19 infection occurred in 16.9% subjects who had taken two doses of either covishield or covaxin, but the percentage was very low and the infection was mild and did not required hospitalization.

CONCLUSION:

Elderly people, children, pregnant mother and people with comorbidity are more vulnerable to covid infection, so to vaccinate this group in first priority is most important steps. Full course of covid-19 Vaccines, Covishield and Covaxin were safe and effective to minimize complication of covid infection but still we do not know yet whether it will stop passing the covid virus to others. Till then, we all should follow the guidelines given by the government to protect yourself and your family

Recommendation:

Full course of covid-19 Vaccination is the only hop to protect from covid infection, in addition to wearing proper face mask, practicing social distancing and hand sanitizing practices.

Similar study needs to be conducted with large sample size covering all the vaccine available in our state for their safety and effectiveness

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