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# EVALUATION OF ADVERSE EFFECTS OF COVID-19 VACCINATION IN A DENTAL INSTITUTION – A CROSS-SECTIONAL STUDY

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## ABSTRACT

**Introduction:-** Covishield vaccine (Brand name-COVISHIELD™) is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

**Objectives:-** The study was conducted to evaluate adverse events that occurred after COVISHIELD™ vaccination.

**Methods:-**

A cross-sectional, questionnaire based survey was conducted at K.D. Dental College and Hospital, Mathura to compare adverse effects that occurred after COVISHIELD vaccination. This survey was conducted among 121 participants who were the faculties, students and non-teaching staffs who were 18 years and above and who were vaccinated with COVISHIELD vaccines. A self prepared questionnaire was made that composed of questions regarding demographic details, about comorbidities and about the symptoms that were present after 1st and 2nd doses and the distribution of symptoms as per onset and duration of 1st and 2nd doses respectively.

**Results: -**Among 121 participants, 3 participants had past COVID-19 positive history and 17 participants had comorbidities. Among those who were vaccinated with both 1st and 2nd doses of COVISHIELD vaccine, 96 participants showed symptoms after 1st dose of COVISHIELD vaccine. However, 36 participants had showed symptoms after 2nd dose of COVISHIELD vaccine. Symptoms that occurred after 1st and 2nd dose of vaccination disappeared within 2 days.

**Conclusion:-**The present study showed that there was significant reduction in occurrence of symptoms among participants after 2nd dose of COVISHIELD vaccine as compared to1st dose.

**Keywords: SARS-CoV-2, COVID-19, comorbidities, covishield vaccine**

## INTRODUCTION

A year has passed since the first case of novel coronavirus infections was detected in China's Wuhan province. During the initial period of the disease, the efforts were concentrated on preventing and slowing down transmission. But the COVID-19 pandemic continues to cause considerable mortality, placing a substantial burden on health-care systems around the world and having profound social and economic consequences due to the measures implemented to control the SARS-CoV-2 virus **[1]**.

The coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) has posed a serious threat to public health. SARS-CoV-2 belongs to the Betacoronavirus of the family Coronaviridae, and commonly induces respiratory symptoms, such as fever, unproductive cough, myalgia, and fatigue. To better understand the virus, numerous studies have been performed, and strategies have been established with the aim to prevent further spread of COVID-19, and to develop efficient and safe drugs and vaccines **[2]**.

Although not mandatory, India with its estimated population of 1380 million (as of 2020) had planned to administer the vaccine to all its citizens who were willing to take it.India, which had a robust vaccine development program, not only plans for domestic manufacture of COVID-19 vaccine but also for its distribution in countries that cannot afford to buy expensive vaccines from the Western world. The emphasis on manufacturing vaccine was on the quality control, quality production, and cost control to make them affordable to even the poorest nations in the world **[3]**.

The government of India had constituted the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) to provide guidance on all aspects of COVID-19 vaccine administration in India. According to National Expert Group on Vaccine Administration for COVID-19

(NEGVAC), the COVID-19 vaccine has been offered first to healthcare workers, frontline workers, and to persons above 50 years of age (with first preference for those above 60), followed by persons younger than 50 years of age with associated comorbidities.

Serum Institute of India (SII), Pune, had signed agreements with a few manufacturers such as Oxford-AstraZeneca, Codagenix, and Novavax. It is now producing at a large scale, the Oxford- AstraZeneca Adenovirus vector-based vaccine AZD1222 (which goes under the name "Covishield" in India) and the company produced 100 million doses per month after January 2021. SII will ramp up its capacity further to produce 2 billion doses per year. Covishield was produced under the "at-risk manufacturing and stockpiling license" from the Drugs Controller General of India (DCGI), and the Indian Council for Medical Research (ICMR). The ICMR funded the clinical trials of the Covishield vaccine developed with the master stock from Oxford-AstraZeneca **[3]**.

Covishield vaccine (Brand name-COVISHIELD$^{TM}$) is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Following administration, the genetic material of part of corona virus is expressed which stimulates an immune response **[4]**.

COVISHIELD$^{TM}$ regimen consistsof two doses of 0.5 ml each. There is no difference between the 1st and 2nd dose. Each dose has the same content of viral particles. The Indian government has recommended that the time interval between the 1st and 2nd dose should be between 12-16 weeks. As per the guidelines of The Ministry of Health and Family Welfare (MOHWF), can take the 2nd dose of the COVID-19 vaccine 3 months after recovery from COVID-19 symptoms **[5]**.

Some side effects or post vaccination symptoms had been reported with COVISHIELD$^{TM}$ vaccine such as tenderness, pain, warmth, or itching where the injection was given, generally feeling unwell, feeling tired (fatigue), chills or feeling feverish, headache, feeling sick (nausea), joint pain or muscle ache. Less common symptoms (may affect more than 1 in 10 people) like swelling or redness where the injection was given, fever, being sick (vomiting) or diarrhoea, pain in legs or arms, flu-like symptoms, such as high temperature sore throat, runny nose, cough and chills may also present. Uncommon or rarest symptoms (may affect up to 1 in 100 people) like sleepiness or feeling dizzy, abdominal pain, enlarged lymph nodes, excessive sweating, itchy skin, rash or hives. Major blood clotting (venous and/or

arterial thrombosis) in combination with low platelet count (thrombocytopenia) have been observed very rarely (with a frequency less than 1 in 100,000 vaccinated individuals) **[6-8]**.

So this survey was done to compare symptoms that occurred after COVISHIELD$^{TM}$ vaccination for 1$^{st}$ dose and 2$^{nd}$ dose respectively taking in consideration the presence of any comorbidity, record of past COVID-19 positive and demographic details among subjects studying and working in K.D. Dental College and Hospital, Mathura.

**MATERIALS AND METHOD**

A cross-sectional, questionnaire based survey was carried out among 121 participants in the month of April, 2021. at K.D. Dental College and Hospital, Mathura using convenient sampling who were 18 years and above and who were vaccinated with COVISHIELD$^{TM}$ vaccines. The Institutional Ethical Committee approval was obtained for the survey. Informed consent was obtained from each participant before starting of survey. A self prepared questionnaire was made that composed of 9 questions comprising demographic details, about comorbidities about history of COVID positive in past, about the symptoms that were present after 1$^{st}$ and 2$^{nd}$ doses and the distribution of symptoms as per onset and duration of 1$^{st}$ and 2$^{nd}$ doses respectively.

The data collected from participants was arranged in Microsoft excel sheet 2010. Data was recorded, tabulated, and statistically analysed using SPSS version. Chi square test and paired t-test analyses were performed to compare symptoms that occurred after 1st and 2$^{nd}$ doses of COVISHIELD$^{TM}$ and the demographic characteristics of the participants. The level of significance was set at $\leq 0.05$.

**RESULTS**

The study carried out among 121 participants where most of the participants i.e. 86(71.1%) were in between 19-29 years. The study population comprised of 54(44.6%) males against 67(55.4%) females. The other demographic features of the study population were alos described **(Table 1)**.

Comorbid conditions were present in 14% (n=121) of the study population. 2.5% (n=121) participants had COVID-19 positive history in past **(Table 2)**.

The predominant symptom reported was headache which was present in 78.5(n=121%) participants followed by headache which was present in 75.2% (n=121) participants. Other symptoms that were reported by the study participants were also described **(Table 3)**. The predominant symptom reported after 2$^{nd}$ dose of COVISHIELD vaccine was myalgia and fatigue which was present in 22.3% (n=121) participants followed by

headache which was present in 11.6% (n=121) participants. Other symptoms that were reported by the study participants were also described **(Table 4)**.

In most of the participants i.e. 33.1% (n=121), time duration for which symptoms of fever lasted was in between 24-48 hours after vaccination of 1st dose; in most of the participants i.e. 32.2% (n=121), time duration for which symptoms of malaise lasted was in between 24-48 hours after vaccination of 1st dose whereas in most of the participants i.e.25.6% (n=121), time duration for which symptoms of headache lasted was in between 24-48 hours **(Table-5)**.

In most of the participants i.e. 2.5% (n=121), time duration for which symptoms of fever lasted was in between 6-12 hours after vaccination of 2nd dose; in most of the participants i.e. 5.8% (n=121), time duration for which symptoms of malaise lasted was in between 2-6 hours after vaccination of 1st dose whereas in most of the participants i.e.5.8% (n=121), time duration for which symptoms of headache lasted was in between 2-6 hours **(Table 6)**.

Results were found to be statistically significant while comparing symptoms of myalgia, dizziness, fever, headache, flu like symptoms and loose stools after 1st and 2nd dose post vaccination **(Table 7)**.

**Table 1: Sociodemographic characteristics of the participants**

| Variables | Frequency (n=121) | Percentage (100%) |
|---|---|---|
| **Age group ( in years)** | | |
| **19-29** | **86** | **71.1** |
| **30-39** | **22** | **18.2** |
| **40 and above** | **13** | **10.7** |
| **Gender** | | |
| **Male** | **54** | **44.6** |
| **Female** | **67** | **55.4** |
| **Place of work** | | |
| **Faculty** | **20** | **16.5** |
| **Student** | **95** | **78.5** |
| **Non teaching staff** | **6** | **5.0** |

**Table 2: Medical condition of the participants**

| Variables | Frequency (n=121) | Percentage (100%) |
|---|---|---|
| **Past COVID-19 history** | | |
| **Yes** | **3** | **2.5** |
| **No** | **118** | **97.5** |
| **Comorbidity** | | |
| **Autoimmune disesase** | **4** | **3.3** |
| **Hypothyriodism** | **11** | **9.1** |
| **Hyperthyroidism** | **1** | **0.8** |
| **Other** | **1** | **0.8** |
| **None** | **104** | **86.0** |

**Table 3: Gender wise distribution of participants according to symptoms after 1st dose of COVISHIELD™ vaccine**

| Symptoms | Male | Female | Total (n=121) | Chi-square value | p-value |
|---|---|---|---|---|---|
| Myalgia and fatigue | 42(77.8%) | 46(68.7%) | 88(72.7%) | 1.254 | 0.180 |
| Dizziness | 24(44.4%) | 23(34.3%) | 47(38.8%) | 1.288 | 0.256 |
| Fever | 41(75.9%) | 50(79.6%) | 91(75.2%) | 0.813 | 0.666 |
| Headache | 41(75.9%) | 54(80.6%) | 95(78.5%) | 0.387 | 0.534 |
| Flu like symptoms | 3(5.6%) | 11(16.4%) | 14(11.6%) | 0.344 | 0.062 |
| Loose stools | 3(5.6%) | 2(3%) | 5(4.1%) | 0.449 | 0.480 |
| Nausea | 2(3.7%) | 4(6%) | 6(5%) | 0.865 | 0.649 |
| Vomiting | 1(1.9%) | 2(3%) | 3(2.5%) | 0.833 | 0.659 |
| Acne/pustules | 0 | 0 | 0(0%) | 121 | - |
| Allergy | 0 | 0 | 0(0%) | 121 | - |
| Stomachache | 0 | 1(1.5%) | 1(0.8%) | 0.813 | 0.367 |

**p≤0.05*(significant), Chi-square test.**

**Table 4:- Gender wise distribution of participants of symptoms after 2nd dose of COVISHIELD™ vaccine**

| Symptoms | Male | Female | Total (n=121) | Chi square Test | P value |
|---|---|---|---|---|---|
| Myalgia and fatigue | 10(18.5%) | 17(25.4%) | 27 (22.3%) | 0.810 | 0.368 |
| Dizziness | 0 | 2(3%) | 2 (1.7%) | 1.639 | 0.200 |
| Fever | 1(1.9%) | 5(7.5%) | 6 (5.0%) | 1.937 | 0.164 |
| Headache | 7(13%) | 7(10.4%) | 14 (11.6%) | 0.185 | 0.667 |
| Flu like symptoms | 0 | 1(1.5%) | 1 (0.8%) | 0.813 | 0.367 |
| Loose stools | 0 | 0 | 0 (0%) | 121 | - |
| Nausea | 0 | 1(1.5%) | 1 (0.8%) | 0.813 | 0.367 |
| Vomiting | 0 | 0 | 0 (0%) | 121 | - |
| Acne/pustules | 0 | 0 | 0 (0%) | 121 | - |
| Allergy | 0 | 0 | 0 (0%) | 121 | - |
| Stomachache | 0 | 0 | 0 (0%) | 121 | - |

**p≤0.05* (significant), Chi-square test**

**Table 5: Gender wise distribution of participants according to time duration for which symptoms lasted after 1st dose of COVISHIELD™ vaccine**

| Duration of Symptoms | Gender | | Total | Chi-square value | P-Value |
|---|---|---|---|---|---|
| | Male | Female | | | |
| **Fever** | | | | | |
| <2hrs | 3(5.6%) | 5(7.5%) | 8 (6.6%) | 3.348 | 0.647 |
| 2-6hrs | 10(18.5%) | 11(16.4%) | 21 (17.4%) | | |
| 6-12hrs | 11(20.4%) | 11(16.4%) | 22 (18.2%) | | |
| 12-24hrs | 11(20.4%) | 16(23.9%) | 27 (22.3%) | | |
| 24-48hrs | 18(33.2%) | 22(32.8%) | 40 (33.1%) | | |
| >48hrs | 1(1.9%) | 2(3%) | 3 (2.5%) | | |
| None | 0 | 0 | 0 (0%) | | |
| Total | 100% | 100% | 100% | | |
| **Malaise** | | | | | |
| <2hrs | 0 | 7(10.4%) | 7 (5.8%) | 3.348 | 0.647 |
| 2-6hrs | 10(18.5%) | 11(16.4%) | 21 (17.4%) | | |
| 6-12hrs | 10(18.5%) | 8(12%) | 18 (14.9%) | | |
| 12-24hrs | 12(22.2%) | 21(31.3%) | 33 (27.3%) | | |
| 24-48hrs | 21(38.9%) | 18(26.9%) | 39 (32.2%) | | |
| >48hrs | 1(1.9%) | 2(3%) | 3 (2.5%) | | |
| None | 0 | 0 | 0 (0%) | | |
| Total | 54(100%) | 67(100%) | 121(100%) | | |
| **Headache** | | | | | |
| <2hrs | 4(7.4%) | 6(9%) | 10 (8.3%) | 3.348 | 0.647 |
| 2-6hrs | 12(22.2%) | 13(19.4%) | 25 (20.7%) | | |
| 6-12hrs | 11(20.4%) | 13(19.4%) | 24 (19.8%) | | |
| 12-24hrs | 10(18.5%) | 18(26.9%) | 28 (23.1%) | | |
| 24-48hrs | 16(29.6%) | 15(22.3%) | 31 (25.6%) | | |
| >48hrs | 1(1.9%) | 2(3%) | 3 (2.5%) | | |
| None | 0 | 0 | | | |
| Total | 54(100%) | 67(100%) | 121(100%) | | |

**p≤0.05*(significant), Chi-square test**

**Table 6: Gender wise distribution of participants according to time duration for which symptoms lasted after 2nd dose of COVISHIELD™ vaccine**

| Duration of Symptoms | Gender | | Total | Chi-square value | P-Value |
|---|---|---|---|---|---|
| | Male | Female | | | |
| **Fever** | | | | | |
| <2hrs | 0 | 1(1.5%) | 1 (0.8%) | 2.672 | 0.445 |
| 2-6hrs | 0 | 2(3%) | 2 (1.6%) | | |
| 6-12hrs | 1(1.9%) | 2(3%) | 3 (2.5%) | | |
| 12-24hrs | 0 | 0 | 0 (0%) | | |
| 24-48hrs | 0 | 0 | 0 (0%) | | |
| >48hrs | 0 | 0 | 0 (0%0 | | |
| None | 53(98.1%) | 62(92.5%) | 115 (95%) | | |
| Total | 54(100%) | 67(100%) | 121(100%) | | |
| **Malaise** | | | | | |
| <2hrs | 2(3.7%) | 2(3%) | 4 (3.3%) | 7.600 | 0.107 |
| 2-6hrs | 0 | 7(10.4%) | 7 (5.8%) | | |
| 6-12hrs | 2(3.7%) | 4(6%) | 6 (5.0%) | | |
| 12-24hrs | 1(1.9%) | 0 | 1 (0.8%) | | |
| 24-48hrs | 0 | 0 | 0 (0%) | | |
| >48hrs | 0 | 0 | 0 (0%) | | |
| None | 49(90.7%) | 54(80.6%) | 103 (85.1%) | | |
| Total | 54(100%) | 67(100%) | 121(100%) | | |
| **Headache** | | | | | |
| <2hrs | 2(3.7%) | 1(1.5%) | 3 (2.5%) | 4.179 | 0.382 |
| 2-6hrs | 4(7.4%) | 3(4.5%) | 7 (5.8%) | | |
| 6-12hrs | 1(1.9%) | 5(7.5%) | 6 (5.0%) | | |
| 12-24hrs | 1(1.9%) | 0 | 1 (0.8%) | | |
| 24-48hrs | 0 | 0 | 0 (0%) | | |
| >48hrs | 0 | 0 | 0 (0%) | | |
| None | 46(85.1%) | 58(86.5%) | 104 (86%) | | |
| Total | 54(100%) | 67(100%) | 121(100%) | | |

**p≤0.05*(significant), Chi-square test**

**Table 7: Comparison of symptoms occurred after 1st and 2nd dose of COVISHIELD™ vaccine**

| Symptoms After 1st and 2nd dose | Mean± Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference | | t | df | Sig. (2-tailed |
|---|---|---|---|---|---|---|---|
| | | | Lower | Upper | | | |
| myalagia | 0.504±0.534 | 0.049 | 0.408 | 0.600 | 10.380 | 120 | 0.000* |
| dizziness | 0.744±1.037 | .094 | 0.557 | 0.930 | 7.889 | 120 | 0.000* |
| fever | 2.108±1.425 | .130 | 1.851 | 2.366 | 16.209 | 119 | 0.000* |
| headache | 2.678±1.959 | .178 | 2.325 | 3.030 | 15.037 | 120 | 0.000* |
| flu like symptoms | 0.537±1.683 | .153 | 0.234 | 0.840 | 3.510 | 120 | 0.001* |
| loose stool | 0.248±1.199 | .109 | 0.032 | 0.464 | 2.274 | 120 | 0.025* |
| nausea | 0.281±1.634 | .149 | -0.013 | 0.575 | 1.891 | 120 | 0.061 |
| vomiting | 0.190±1.199 | .109 | -0.026 | 0.406 | 1.743 | 120 | 0.084 |
| stomach | 0.091±1.00 | .091 | -0.089 | 0.271 | 1.000 | 120 | 0.319 |
| none | -8.430±5.509 | .501 | -9.421 | -7.438 | -16.833 | 120 | 0.000* |

**p≤0.05*(significant), Paired t-test.**

## DISCUSSIONS

COVISHIELD™ is the local version of Oxford-AstraZeneca COVID-19 vaccine. Serum Institute of India, which is the largest vaccine manufacturer by volume, tied up with AstraZeneca to produce 1 billion doses of its COVID-19 vaccine **[9-12]**.

In this study, we were looking for the side effects after the 1st and 2nd doses of COVISHIELD™ vaccine where we found out that most of the participants had symptoms from 1st dose and not all but

some people were found to have symptoms after second dose of COVISHIELD™ vaccine.

Female participants were comparatively higher in proportion compared to male participants which is in accordance to the studies conducted by Cristina Menni *et al* **[8]** and Merryn Voysey *et al*. On the contrary, the study conducted by Fernando P. Polack *et al*, Nawal Al Kaabi *et al* and Sourya Sourabh Mohakuda *et al* revealed that most of the participants were male.

Few of the participants had comorbidities which is in accordance to the study conducted by Sourya Sourabh Mohakuda *et al*.

In our study, more than two-third of the participants had shown symptoms post-vaccination of 1st dose of COVISHIELD vaccine. Fever was the most common symptom post vaccination of 1st dose followed by headache and then followed by myalgia and fatigue which was commensurated with the study published by Sourya Sourabh Mohakuda *et al*. where they had noticed myalgia as the most common symptoms after vaccination of 1st dose followed by fever and headache. The time duration for which symptoms like fever, malaise and headache lasted was in between 24-48 hours in most of the participants after 1st dose of vaccination. In very few of the participants, the time duration for which symptoms like fever, malaise and headache lasted was more than 48 hours after 1st dose of vaccination which was commensurated with the study published by Sourya Sourabh Mohakuda et.al. where they had noticed no such symptoms lasted for more than 48 hours in any individual.

Very few of the participants had shown symptoms post-vaccination of 1st dose of COVISHIELD vaccine. Myalgia and fatigue were the most common symptoms post vaccination of 2nd dose followed by headache and then followed fever. On the contrary, no such studies were conducted that revealed time duration of symptoms after 2nd dose of vaccination.The time duration for which symptoms like fever, malaise and headache lasted was in between 6-12 hours in most of the participants after 2nd dose of vaccination. No such symptoms lasted for more than 48 hours in any individual.

There were few limitations in our study. Firstly, the sample size of the study was small. So, the study cannot be generalized. Secondly, since it was a questionnaire based study, no checkup had been done to detect comorbidities of the partcipants. Comorbidities had been specified by asking verbally to the participants. Thirdly, the study was conducted for a short term adverse effects of 1st and 2nd dose of COVISHIELD™ vaccine.

Further studies are therefore recommended by taking larger samples. Also follow up studies are to be conducted for a long term side effects of COVID-19 vaccine.

**CONCLUSION**

COVID-19 vaccine has numerous positive effects including disease prevention. But there are some side effects felt after the 1st and 2nd dose of COVISHIELD™ vaccine which mostly include myalgia, fatigue, headache, fever, dizziness, flu like symptoms and loose stools. Short-term adverse effects of both vaccines were moderate in frequency, mild in severity, and short-lived in this study. No serious adverse effects had been reported after vaccination of 1st and 2nd dose which would undoubtedly help individuals in their decision to get vaccinized. Adverse effects are more frequently reported in younger individuals and women. The duration of symptoms did not last for more than 2 days in both 1st dose and 2nd dose of COVISHIELD™ vaccine that might indicate better tolerability in this geographical area. Our data could be used to inform people on the likelihood of side-effects on the basis of their age, gender and the type of vaccine being administered.

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**CONFLICT OF INTEREST**

Authors declare that there are no conflicts of interest.

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