

Survey of side effects post 1st dose of COVID-19 vaccine and adherence of guidelines during vaccination procedure in a tertiary health care hospital in India

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Abstract

Introduction: Indian drug regulation authorities issued emergency approval to two vaccines and started the vaccine drive on 16th January 2021. Acceptance of COVID-19 vaccine is still an important aspect in the success of the vaccination drive in India. An important factor affecting the acceptance of Covid-19 vaccine is lack of sufficient data on its side effects. **Material & Methods:** This was a cross sectional survey which was conducted among the people getting 1st dose of Covid-19 vaccine. A questionnaire-based feedback form was distributed to all the people getting 1st dose of covid-19 vaccine through social networking sites like E-mail and WhatsApp. The questionnaire consisted of questions focusing on side effects within 30 minutes, 30 minutes to 24 hours and after 24 hours of vaccination. The questionnaire also consisted questions related to vaccination procedure and overall satisfaction level about COVID-19 vaccination. **Results:** Out of total participants 522, 52.5% (275) were male and 47.3% (247) were females. It was noted that over 53.1 % did not encounter any side effects, while 20.4 % had tenderness, pain and warmth and 18.9 % had chills and felt feverish. Also, it was found on analysis that 187 respondents (35%) did not have experience any symptom after 24 hours of vaccination. **Conclusion:** The research work was done to analyse the side effects after 1st dose Covid-19 vaccine among the population of India at a tertiary care hospital. In this study it was found that after 1st dose vaccine side effects were mild and were settled within 1 to 2 days. Fever and pain at the site of injection were two most of the common symptoms seen within 24 hours. Lot of people are anxious of getting vaccination done due to fear of getting serious side effects, but as per the findings of these study side effects were not serious. Vaccination centre was able to follow the standard guidelines as per the protocol made by the government, which is an important step in transmission of infection, proper storage of vaccine and also help in observation of any side effect during first 30 minutes post vaccination. This study will help in awareness among the general population regarding the commonly found side effects post Covid-19 Vaccine and help in the increasing the acceptance of the COVID-19 vaccine.

Keywords: Side effects, Covid-19 vaccine, Vaccination centre.

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Introduction

Coronavirus disease 2019 (Covid-19), have spread to millions of people and has put a lot of burden on the healthcare system and affected the economy worldwide. To combat this disease multiple vaccine candidates have been developed [1,2]. To control covid-19 pandemic a vaccine need to be safe with least side effects, need to be given to a large population and also it should also prevent against severe acute respiratory syndrome coronavirus 2 infection [3]. Production and distribution of safe and efficacious vaccine to everyone is the priority of all the nations worldwide [2]. Government of India had started the vaccination programme from 16 Jan 2021 onwards and gave emergency clearance to few vaccines in the initial stage of vaccination drive in India [4,5].

Surveillance of safety and adverse effects following vaccination will help in developing the benefit risk profile of the vaccine [6]. So, this study was planned to collect the data from people getting COVID 19 vaccine and describing any side effects after receiving 1st dose of vaccine and their experience during vaccination procedure. Therefore, awareness among general public regarding probable side effects seen post vaccination can be generated and it will also help to educate the public and health care personals regarding standard protocols which should be followed during vaccination procedure and can highlight various mistakes during vaccination procedure and dispel misinformation and reduce vaccine hesitancy among general public.

Material and Methods

Study design

This cross-sectional survey was conducted amongst the people getting vaccination in a level 3 COVID-19 hospital in Western Uttar Pradesh. A feedback form was designed which contained questions related to post vaccination symptoms, vaccination procedure and overall satisfaction level about COVID-19 vaccination. Few questions with descriptive options were also present to the section of symptom profile. So that, a versatile data of post vaccination symptoms can be collected. The feedback form was sent to those who were vaccinated

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in TMMC& RC, Moradabad. Respondents were informed that their participation was voluntary. The data obtained in the study were exclusively obtained through google form and was further converted into Excel sheet for data analysis. This information was collected from first dose of COVID-19 vaccine till 15 February 2021.

Statistical Analysis

All the data were exported from Google forms app to Microsoft excel and then was analysed. All quantitative variables are presented as percentages, means and all qualitative variables in frequency and percentages. For the comparison of categorical variables chi square test were used. All the quantitative variables were presented as frequency and percentages.

Result

Total 522 respondents filled the google form. The respondents in the survey included doctors, staff nurses, paramedical staff, students and admin staff. It was analysed that 52.5% (275) were male and 47.3% (247) were females. Among those who were surveyed, out of them medical & dental students were 79.5% (415), Physicians 17.24% (90), paramedical staff 2.10 % (11), administrative staff 0.5 % (3) and others 0.5 % (3). All the respondents were in the range of age from 19 to 46 years.

It was noted that over 53.1 % did not encounter any side effects. While 20.4 % had tenderness, pain and warmth, 18.9 % had chills and felt feverish, including a small group who complained of swelling, lump and redness at the injection site. After first dose of vaccination most prevalent symptoms were tiredness, headache, fever & diarrhoea.

During first 30 minutes post vaccination among all respondents, 82% (429) did not experience any symptom, 4% developed fever, 3.6% developed headache, 1.7% developed body ache, 1.3% developed nausea and vomiting within 30 minutes after vaccination. (Figure 1)

On analysis of the symptoms after vaccination from 30 minute to 24 hours, it was found that total 10.5% (55) respondents were having no symptoms while 42.5% people experienced symptoms like fever, 33% (171) patients experienced pain at site of injection, 14.3% (75) headache, 12.5% (65%) patients developed body ache and around 3% developed nausea/vomiting.

Also, it was found on analysis that 187 respondents (35%) did not have experience any symptom after 24 hours of vaccination. But there were 338 respondents (65%), experienced mild symptoms like fever, pain at site of injection, headache, body ache, nausea/ vomiting & generalized myalgias as well dizziness.

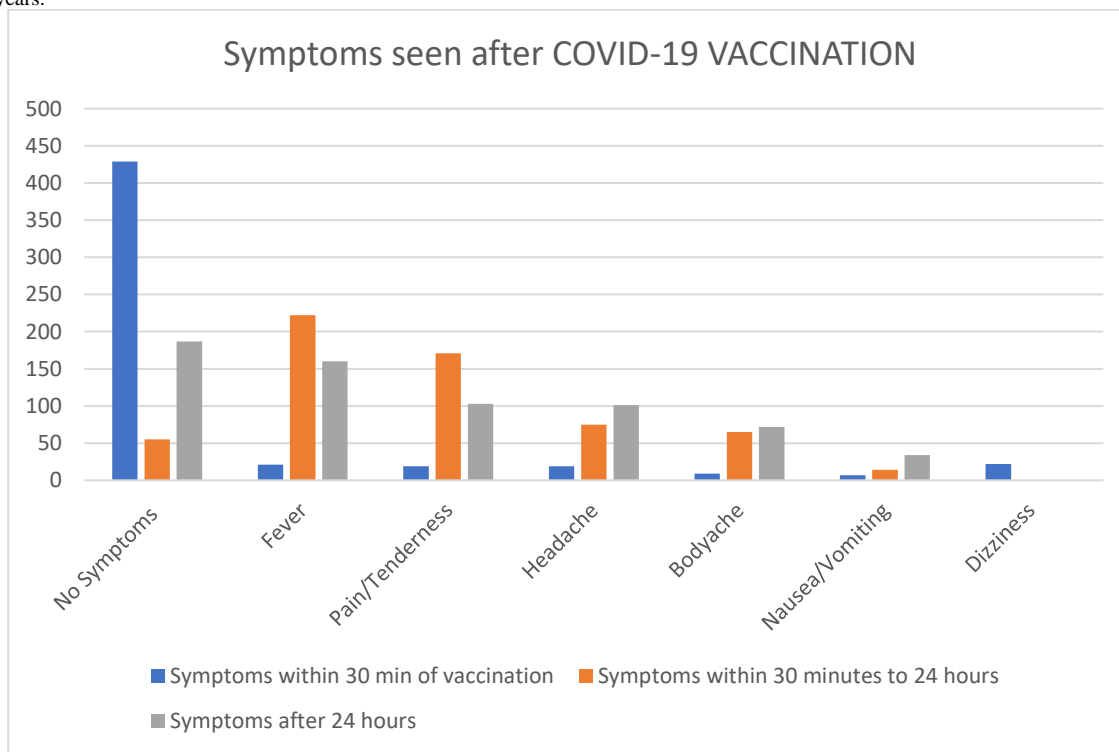


Fig 1: Symptoms after COVID-19 symptoms

Out of total 522 respondents, only 330 (63.2%) took medicine for symptomatic relief after vaccination while 192 (36.7%) didn't take any after vaccination. All of them had either pain killers/ paracetamol. On analysis, it was found that more females had symptoms as compared to males especially from 30 min to 24 hours post COVID-19 vaccination period (Table 1).

Table 1: Symptoms post vaccination from 30 min to 24 hrs

	Females	Males
Total respondents	247(47.3%)	275(52.6%)
Symptoms present	233	234
Symptoms absent	14	41

In this study, data was also collected regarding the experience during the process of vaccination at the vaccination centre. (Table 2)

Table 2: Experience during vaccination procedure

	Yes	No	May be
Any medication for symptomatic relief	330 (63.2%)	192 (36.7%)	
Whether Social distancing was maintained.	423 (81%)	99 (19%)	
Monitoring of body temperature done or not.	339 (65%)	183 (35%)	
Did you have to wait for your turn to get vaccination.	398 (76.3%)	124 (23.7%)	
Whether procedure was well explained before vaccination	394 (75.5%)	128 (24.5%)	
Whether proper hand sanitization was done	407 (77.9%)	42 (8%)	73 (13.9%)
Whether disposal of syringe done after use or not	477 (91%)	16 (3%)	29 (5.5%)
Did you wait for 30 min in observation room after vaccination	516 (98.8%)	6 (1.2%)	

In the end all the respondents were also asked to rate the overall their experience of COVID-19 vaccination on a scale ranging from 1 to 5. And it was found that more than 2/3rd majority of the respondents (377) were very happy with the process of vaccination (scored 4 or 5 on likert scale). However very few respondents (37) were not satisfied as they recorded their response 1 & 2 on the rating scale.

Discussion

All the respondents who participated in the study provided the side effect pattern soon after their vaccination. Majority of the patients presented with commonly found symptoms following vaccination. Fever was the most common symptom within 24 hours of vaccination and was followed by pain at the injection site. Respondents took only pain killers and antipyretic drugs after their vaccination. There was no serious symptom in post vaccination period. It was also seen that Women were having more symptoms than males, this could be due to better immune response and formation of more antibodies in response to vaccine among females.

In a study done in Czech Republic monitoring the side effects following Pfizer Vaccine, pain at the site of injection was the most common side effect and was seen in 94% of the patients which was followed by fatigue and headache post vaccination. The vaccine which was given to our study population group was Covishield. The difference in the side effects can be due to the different type of vaccine, injection technique, temperature of vaccine and injection velocity [7,8]. Adverse events of special interest which can be serious or not serious should be reported and are important to the investigator and to the manufacturer of the vaccine also. Fear of something unknown can lead hesitancy of getting vaccinated. By describing the expected side effect, through this study we can provide guidance to those fearing the new Covid 19 vaccine. This would also highlight the fact that post-vaccination symptoms were predictable and mild in nature. The COVID-19 pandemic is a global crisis and monitoring the side effects of vaccine is an important feature to ensure the potential of COVID-19 vaccine. It is also important to follow the safety protocol guidelines at the vaccination centre to ensure safety of everyone during vaccination.

Limitations

The limitation of our study was that the sample size of was small and only one centre was included in the study. Another limitation was that we saw side effects of only one vaccine and there was no comparison with other vaccines available in the market.

Conclusion

At the end of our study, we concluded that the side effects caused after COVID 19 vaccination (Covishield) were mild and didn't cause

any serious adverse reaction to any of our study participant and were settled in a couple of days. Vaccination safety Protocols were followed at the vaccination Counter and is important for everyone to be aware of the standard guideline issued by the government. This study will help in awareness among the general population regarding the commonly found side effects post Covid-19 Vaccine and help in the increasing the acceptance of the COVID-19 vaccine.

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