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Side effects after first and second doses of Covid-19 vaccine among health care providers in tertiary care hospital

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Abstract

Background: Acceptance of Covid-19 vaccination among the general population is one topic that has been discussed worldwide. Large number of doses of vaccine has been administered throughout the world, but, concerns about safety of Covid-19 vaccination still persists. There have been reports of adverse effects with Covid-19 vaccination which are mild and resolve spontaneously. This study was done to evaluate the side effects after first and second doses of Covid-19 vaccine among health care providers in tertiary care hospital.

Material and methods: This cross-sectional, questionnaire based study was done among health care workers after first and second dose of vaccine in Teerthanker Mahaveer Medical College & Research Center, Moradabad, India between January 2021 to July 2021. In this survey, post Covid-19 vaccination questionnaire was designed using Google Forms and was shared to vaccinated participants through social media and mail. Snowball sampling method was used for gathering a total of 485 responses. Informed consent was obtained from all research participants and the study was approved by the Institutional Review Board (IRB)

Results: The respondents were health care professionals which included Physician, Surgeons, and Other Health Care Workers. The most common adverse effects reported after both doses of vaccination were fever, chills and rigor, headache, myalgia, malaise and pain at site of injection. The results showed that 65% (n=338) of participants had mild symptoms like headache, fever, pain at injection site, malaise, myalgia, dizziness, nausea and vomiting after first dose of vaccination. In comparison 39% (n=190) of participants reported mild symptoms after the administration of second dose of vaccination. A total of 63% (n=330) and 41% (n=197) participants took medication for relief of symptoms during post-vaccination period after the first and second dose of vaccine with slight female preponderance.

Conclusion: The most prevalent adverse effects following vaccination were nausea and vomiting, headache, dizziness, fever, chills, fatigue, including pain, redness and swelling at the injection site with more female preponderance. The adverse effect encountered were higher in number after the first dose of vaccination.

Key words: vaccination, adverse effects, Covid-19, health care workers

Introduction

Nowadays, Covid-19 vaccine is being discussed wildly worldwide. Large number of doses of vaccine has been administered throughout the world [1]. But, some concerns about safety and adverse effects related to COVID-19 vaccination is still there [2]. However according to WHO, Covid-19 vaccines also can cause some side effects. Mostly these reactions to vaccine are mild and they went away on their own. The probability of any side effects following vaccination varies according to specific vaccine. Many initiatives were taken by the government, at different levels (central, state, etc). While vaccination is best and important option in this pandemic condition to boost

immunity and staying healthy. In various randomized clinical trials related to COVID-19 vaccines, It has been reported that some local adverse effects like pain, redness and swelling at injection and few systemic side effects like headache, dizziness, malaise, myalgia with rare but few severe adverse effects [3-6]. About 50% to 90% of participants experienced only mild side effects [3,4,6]. Emergence of data on adverse effects related to Covid-19 vaccine reported through various reporting systems e.g. government-sponsored reporting systems [7-11].

The objectives of this prospective study were to identify and compare various adverse effects (adverse drug reaction) encountered after receiving first and second dose of vaccination for COVID-19 among health care professionals. These results may help the population in gaining a confidence and better understanding of side effects after COVID-19 vaccination.

Material and methods

Study design

This observational, cross-sectional study was based on self-administered online survey, which was done using questions pertaining to the post vaccine experience after first and second dose of vaccine in a tertiary care hospital of Western Uttar Pradesh of India. In this survey, post Covid-19 vaccination feedback form was designed using Google Forms platform and questions were formatted in the binary fashion to the extent possible. In this questionnaire few questions were descriptive in which respondents can put their own experiences in addition to other options. There was also provision of "others" as an option to collect more descriptive and versatile data. Then this Google form was shared to vaccinated persons in Teerthanker Mahaveer Medical College & Research Center, Moradabad, India between January 2021 to July 2021 through what's app and mail. Snowball sampling method was used for gathering a total of 485 responses. All the respondents were informed regarding their voluntary participation. In this survey, only those were included who were 18 years and above. The data was thereafter transferred into Excel sheet for its analysis. Informed consent was obtained from all research participants and the study was approved by the Institutional Review Board (IRB). Questionnaire was formed in Goggle forms. Participants were asked to fill the questionnaire after first and second dose of vaccine. All the participants enrolled in the study received either Covaxin or Covishield. Questions were framed in such a way to collect the data of adverse effects. To answer those questions there were options like pain at injection site, headache, fever, chills and rigor, malaise, myalgia, dizziness, hypersensitivity reaction, any other, and none of the above. These response options were identified because similar symptoms had been reported earlier in different clinical studies. This questionnaire as Goggle Form link was shared with all the vaccinated participants. To prevent problem of missing data, it was mandatory to respond all questions to submit the form otherwise submission of this questionnaire would not be complete. For precipitation in this survey no incentive was given. The primary objective of the study was to evaluate and assess differences, as well as severity of symptoms after 1st and 2nd dose of COVID-19 vaccine and various symptoms appeared in different time interval among health care workers in Medical College.

Statistical analysis

The baseline characteristics of data transferred from goggle form to Microsoft Excel and were analyzed using Descriptive statistics. All quantitative variables were presented as mean and percentage, and the qualitative variables are presented as percentages and frequency. Chi-Square test was used for comparison of categorical data.

Results

After thorough literature search and various guidelines from the WHO and MoHFW on the various adverse reactions after COVID-19 vaccine this study was designed. The questionnaire was in English language. This questionnaire was shared two times, firstly after 1st dose of Covid-19 vaccine and secondly after 2nd dose of Covid-19 vaccine. However, Total 2 groups were formed, Group 1 – those participants who had received first dose of Covid-19 vaccine and group 2 – after receiving 2nd dose of Covid-19 vaccine. Total respondents who filled the google form were 522 after 1st dose (group1) and 485 after 2nd dose (group2) of Covid-19 vaccine. The respondents in the survey were health care professionals which included Physician, Surgeons, and Other Health Care Workers (Staff Nurses, Paramedical Staff, Students and Administration Staff). The analysis showed that in group 1 (after 1st dose) 52.5% (275) were male, 47.3% (247) were females and in group2 (after 2nd dose) 48.24% (234) were male, 51.75% (251) were females. Among those who were surveyed, In group 1 - students 79.5% (415), Doctors 17.24% (90), paramedical staff 2.10 % (11), administrative staff 0.5 % (3), others 0.5 % and in group 2- students 82.68% (401), Doctors 13.40% (65), paramedical staff 1.03% (5), administrative staff 0.41 % (2), others 2.47 %. Age of participants were from 19 to 65 years. After both doses (i.e. First and Second Dose) of vaccination most common side effects were fever, chills and rigor, headache, myalgia, malaise and pain at site of injection.

During first 30 minutes, in group 1- 82% (429) had no symptom, but there was fever 4%, headache 3.6%, body ache1.7%, and nausea and vomiting 1.3%. (Table 2) However in group 2 – 82% (401) did not experience any symptom, 0.8% developed nausea and vomiting 1.4% developed myalgia and malaise, 2.2% developed dizziness, 3.2 % developed pain at injection site, 2.47% developed headache and 3% developed fever (Table 1 and Figure 1). There was no difference in adverse effects based on gender distribution.

Table 1 Adverse effects in the first 30 minutes after vaccination (n (%))

Symptoms in first 30 min	After 1st dose	After 2nd dose
No	429(82%)	401(82.68%)
Nausea/ vomiting	7(1.34%)	4(0.82%)
Myalgia	9(1.7%)	7(1.44%)
Dizziness	22(4.2%)	11(2.26%)
Pain at injection site	19(3.6%)	16(3.29%)
Headache	19(3.63%)	12(2.47%)
Fever	21(4.01%)	15(3.09%)

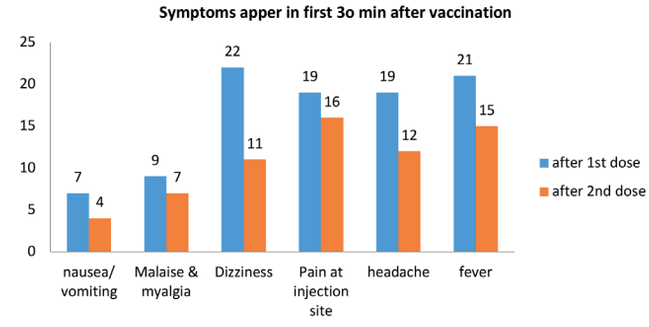

Figure 1 - Symptoms reported by patients in first 30 minutes' post vaccination

On data analysis of the side effects in post vaccination period that started from 30 minute after vaccination to 24 hours (1 day) after vaccination, in group 1, a total 10.5% (55) participants had not reported any symptoms but there was fever 42.5%, pain at injection site 33% (171), headache 14.3% (75), body ache 12.5%(65), nausea/vomiting 3%. However, in group 2 total 30.72% (149) respondents were having no symptoms while remaining respondents experienced symptoms like nausea/vomiting 18(3.7%), malaise and myalgia 130(26.80%), dizziness, pain at site of injection 179(36.90%), headache 86(17.73%), fever 130 (26.80%) and chills and rigor 47(9.69%) (Table 2 and Figure 2).

Table 2 Adverse effects from 30 minutes – 24 hours after vaccination (n (%))

Symptoms from 30 min - 24 hours	After 1st dose	After 2nd dose
No	55 (10.53)	149 (30.72%)
Nausea/ vomiting	14 (2.68%)	18 (3.71%)
Myalgia	69 (13.215)	130 (26.80)
Dizziness	0	0
Pain at injection site	171 (32.75%)	179 (36.90)
Headache	75 (14.36)	86 (17.73%)
Fever	222 (42.52%)	130 (26.80%)
Chills and rigor	57 (10.91%)	47 (9.69%)

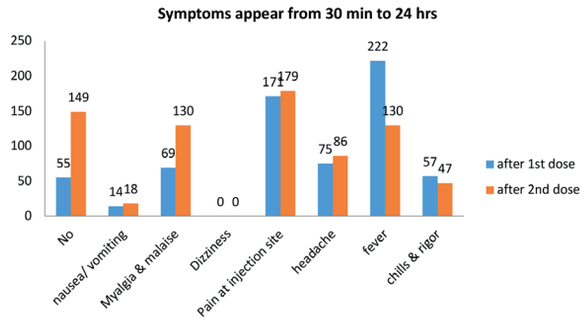

Figure 2 - Symptoms reported by patients after 30 minutes to 24 hours post vaccination

Also, on analysis of symptoms appear after 24 hours of vaccination, it was found that group 1 - 187(35%) respondents had no any symptom. But, there were 338 (65%) participants who reported mild symptoms like headache, fever, pain at injection site, malaise, myalgia, dizziness, nausea and vomiting. However, the analysis of participant showed that in group 2 - 295 respondents (60.82%) did not reported any symptom. But total 190 respondents (39.17%), reported few mild symptoms which are shown in Table 3 and Figure 3. There was no difference in adverse effects based on gender distribution.

Table 3 Adverse effects after 24 hours of vaccination (n (%))

Symptoms after 24 hours	After 1st dose	After 2nd dose
No	187 (35.82%)	295 (60.82%)
Nausea/ vomiting	34 (6.51%)	2 0.41%)
Myalgia	130 (24.90)	18 (3.71%)
Dizziness	0	6 (1.23%)
Pain at injection site	103 (19.73)	26 (5.36%)
Headache	101 (19.34%)	22 (4.53%)
Fever	160 (30.65%)	68 (14.02%)
Chills and rigor	60 (11.49%)	6 (1.23%)

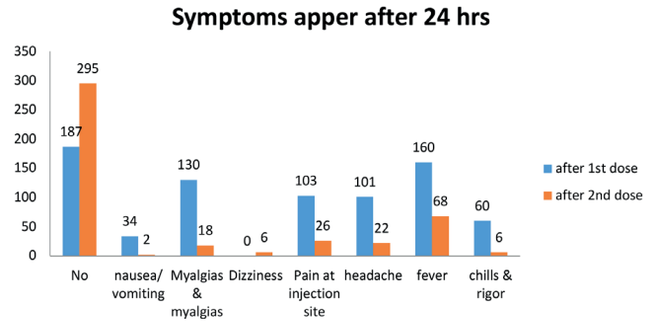

Figure 3 - Symptoms reported by patients after 24 hours post vaccination

In group 1 – a total of 330 (63.2%) participants took medication for relief of symptoms in vaccination period, whereas, 192 (36.7%) participants took no medication following first dose of Covid-19-19 vaccine. However, in group 2 - only 197 (40.61%) had medicine for relief of symptoms in post vaccination period while 288 (59.38%) did not have any kind of medication following vaccine administration. Most of the participants either took paracetamol as a drug for pain relief or NSAIDS. We also performed the data analysis of vaccination procedure, and it was found that more than 75% of respondents were vaccinated by maintaining social distance, explanation of vaccination procedure, hand sanitization and proper disposal of syringe at vaccination centre except monitoring of body temperature (Table 4).

Table 4 Analysis of vaccination procedure (n (%)

	After 1st dose	After 2nd dose
Maintenance of Social distancing	423 (81%)	335 (69.07%)
Recording of body temperature	339 (65%)	162(33.40%)
Any waiting period to get vaccination.	398 (76.3%)	372(76.70%)
Explanation of procedure before vaccination	394 (75.5%)	342 (70.51%)
Proper hand sanitization	407 (77.9%)	353(72.78%)
Proper disposal of syringe	477 (91%)	430(88.65%)
Rest of 30 min after vaccination in observation room	516 (98.8%)	412(84.94%)

In this study side effects were reported more in females, during the period post vaccination i.e. 30 minutes to 24 hours (1 day), in comparison to males (Table 1). There was no difference in adverse effects based on gender distribution.

All the participants also rated their encounter with the vaccination team for Covid-19-19 vaccination center. The rating scale adopted for this study had scores in the range of 1 to 5. Majority of the participants (> 2/3rd participants) (n=377) rated their experiences as very satisfied with the vaccination process (A score of ≥ 4 on 5 point Likert scale). A limited number of participants (n=37) rated their experience as not happy with their experience (A score of ≤ 2 on 5 point Likert rating scale).

Discussion

Data of symptoms was collected by giving questionnaire following the first and second dose of vaccination. Our study compared data of same vaccine to evaluate the severity and incidences of adverse reactions between the first and second doses to more accurately after each inoculation. Most of the respondents presented with the complaint of following symptoms following vaccination like malaise, myalgia, pain

at site of injection, dizziness and fever within 24 hours of vaccination. Results of this study are in consistent with studies conducted by Mennic et. al, and Haya Omeish et. al. that demonstrated following side effects after administration of vaccination for COVID-19, which included pain at the site of injection as reported by majority of patients, followed by flu-like symptoms and Gastrointestinal symptoms were more following first dose of COVID-19 vaccination [12,13]. It was also noticed in this study that as compared to males, females experienced more symptoms. This could be due to better immunity and higher formation of antibodies in response to vaccination among males than females. Other studies also showed similar results of gender dependent association with vaccine related side effects especially fatigue, headache, myalgia and chills after both the doses. [12-14].

In this study, symptoms like nausea/vomiting, malaise, myalgia, dizziness, pain at site of injection, headache, fever, chills and rigor were more frequent after first dose of vaccine as compared to second dose in first 30 min and after 24 hrs of vaccine except in 30 min -24 hrs, where nausea/vomiting, malaise, myalgia, pain at site of injection and headache was more frequently encountered after the administration of second dose in comparison to the first dose. But fever, chills and rigor was reported more often after the administration of first dose in comparison to the second dose in first 30 min, 30min- 24 hrs and even after 24 hrs. However, there was marginal difference in these symptoms after first and second dose. Results of this study were similar to studies done by Omeish et al. [13]. On comparison of data of adverse effects (Adverse drug reaction) following first dose of vaccination as compared to the second dose, studies conducted on the administration of vaccine developed by BNT162b2Mrna, Pfizer and AstraZeneca reported more frequent local and systemic adverse effects were more after receiving second dose as compared to first dose [15]. In contrast, data of this study was not in alignments with results observed in these studies, as adverse effects were more frequent following administration of the first dose as compared to the second dose, with the exception for enlargement of lymph node, some sexual disturbance and chills. In their study pain at injection site and fever was the most common symptom in 30 min to 24 hrs after first and second dose of vaccine. This observation was similar to another cross-sectional study which showed that other local site adverse effects were far too lass as compared to participants complaining of pain at the site of injection which was reported in 88.04% of participants [13,16].

Gastrointestinal symptoms, especially nausea, was reported more after first dose as compared to second dose in first 30 min as well as after 24 hrs of vaccination. But it was found that incidences of nausea were reported more after second dose as compared to the first dose in 30 min to 24 hrs after vaccination. These results are partly in consistent with other studies as well as the reports of WHO of AstraZeneca vaccine.

In our study on analysis it was found that headache was more common after 24 hrs of first dose of vaccination in comparison to the second dose of vaccine [17-19]. However there was marginal difference in headache in first 30 min and 30 min -24 hrs after first and second dose of vaccine. These results are in consistent with other study that showed that about half of all the participants who were administered vaccine of either AstraZeneca or Pfizer vaccines ad complaint of headache [16,18,21]. Study done by Kadali et.al. which considered the manifestation of neurological symptom showed that they were rarely encountered in participants following vaccination is consistent with results of our study where dizziness was the only neurological symptom. No single serious symptom was reported by any of the respondent in post vaccination period. Our study revealed that most of the side effects were only mild and do not require any hospitalization and the adverse effects encountered by the participants subsided few days following vaccination. The similar results were shown in other study also where side effects were in the category of mild to moderate in severity and were resolved within days following vaccination. However, this survey was done within a span of few days following vaccination. Hence, delayed side effects were not reported.

Limitations

There are certain limitation of this study, firstly in this study all the participants were from the same center as well as the size of the sample. Another limitation was that all the respondents received only Covishield so there was no comparative data of adverse effects after the administration to two set of vaccines.

Conclusion

The frequent adverse effect for Covishield vaccination were nausea/vomiting, dizziness, headache, fever, chills, fatigue. The other adverse effects encountered included pain at the site of injection along with redness and swelling with Covishield vaccine. The adverse effects were reporter frequently by females as compared to males. To summarize the adverse effects reported were well-tolerated, but, long-term study is required to investigate for long-term side effects and safety profiles of the vaccine. It was also concluded through this study that the majorly side effects after second dose were less as compared to the vaccine by first dose of Covid-19 (Covishield). However all side effects were mild. There was no serious adverse reaction after administration of Covid-19 vaccine in study participant. All the vaccination safety protocol issued by the government was followed at the vaccination centre.

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