International Journal of Community Medicine and Public Health
Priya A et al. Int J Community Med Public Health. 2022 May;9(5):2255-2259
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040
DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20221249

Original Research Article

Call based enquiry for COVID-19 vaccine (Covishield) adverse events in a tertiary care government hospital in India

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Received: 27 March 2022
Revised: 21 April 2022
Accepted: 22 April 2022

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ABSTRACT

Background: Vaccination is one of the crucial intervention to fight against the ongoing COVID-19 pandemic. The ongoing vaccination drive aims for achieving national vaccination coverage. Due to the expedited roll out of COVID-19 vaccine, there has been a fear and concern regarding its safety. The present study aims to enquire actively about the adverse events after COVID-19 vaccination and disseminate this information to the public to promote vaccine acceptance.
Methods: A call based active enquiry was done to know the frequency and severity of various adverse events among the recipients of COVID-19 vaccine's Covishield (SII-ChAdOx1 nCoV-19) first dose. Call based enquiry was done for local as well as systemic adverse events on day 1, 3 and 7 of vaccination.
Results: Out of the total of 1201 who responded to calls on all three days, 766 (63.7%) of them had at least one of the adverse event. There were only 4 (0.33) recipients who had severe/serious events. The most frequent systemic and local AEFI reported was body ache/ malaise and pain at injection site in 309 (25.7%) and 664 (55.3%) participants respectively. Most of the AEFI's improved over a week with only 17 (1.4%) participants reporting persistence of any adverse event on day 7 of vaccination.
Conclusion: Our study can provide scoping base for development of a proper surveillance program to monitor the AEFI by 'active' query and use of a call-based system especially for novel vaccines.

Keywords: Coronavirus disease 2019, Vaccine (Covishield), Adverse event, Telehealth

INTRODUCTION

The world was taken up by the novel coronavirus disease (COVID-19) pandemic progressively since its spread from China in December 2019 which affected the global socioeconomic political scene.[1] Coronavirus disease 2019 (COVID-19) has rapidly spread in India and there has been 30,316,897 confirmed cases and 397,637 deaths as of June 29, 2021.[2] Vaccines came as a hope to control the wrath of the ongoing pandemic. The immediate need was to expedite the trials and launch the vaccines for public use and henceforth emergency use authorization had to be provided to COVID 19 vaccines.

The COVID-19 vaccination program was initiated on 16th January, 2021 in accordance with the Govt of India initiative for COVID-19 vaccination. The ongoing vaccination drive aims for achieving national vaccination coverage. Due to the expedited roll out of COVID-19 vaccine, there has been a fear and concern regarding its safety. The need was felt to address the concern of the public trust for novel vaccines and avoid vaccine

hesitancy. The present study aims to enquire actively about the adverse events after COVID-19 vaccination and disseminate this information to the public to promote vaccine acceptance. An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.[3]

METHODS

Study period and design

The study was done between January 2021 to March, 2021. It was a cross sectional call based descriptive enquiry for adverse events among the vaccine recipients in the first phase of vaccination drive at a tertiary care government hospital, Rajarshi Dashrath autonomous state medical college (RDASMC), in Ayodhya, Uttar Pradesh, India. RDASMC Ayodhya is a 300 bedded COVID 19 hospital with 20 beds in ICU. To investigate for adverse events following COVID 19 vaccination, a call-based enquiry was done on day 1, day 3 and day 7 after getting the vaccine shot (Day 0). Covishield (SII-ChAdOx1 nCoV-19) being manufactured by Serum Institute of India, Pune by using the Oxford/Astra Zeneca Adenovirus vector-based vaccine AZD1222 strain master stock, was used on all the vaccination days in the study period.

Sample size

To cover maximum recipients and for greater power of the study, a convenience sample with all the recipients getting the vaccine shot in the study period were recruited. The study population comprised of all the participants whose name was there in pool for vaccination in the first phase of vaccination drive at our hospital.

Inclusion and exclusion criteria

Vaccine recipients who gave written informed consent to participate were included in the study. The recipients who had any contraindication for vaccine administration were excluded from the study.

Data collection

Ethical clearance was obtained from the institutional ethics committee of Rajashri Dashrath autonomous state medical college, Ayodhya, India prior to the conduct of study. At the time of vaccination, the subjects were made to wait in the observation room for 30min. Informed written consent to participate in the study was taken during waiting time on the vaccination site after explaining the aim and purpose of the study. Consent form was followed by a questionnaire enquiring regarding the socio demographic, vaccine and COVID-19 infection related details of the vaccine recipient. The call was made to enquire about the adverse event on day 1, day 3 and day 7 of vaccination (Day 0 being the day on which vaccine dose was received). The participants were encouraged to report any adverse event experienced by them on the days when the calls were not done by the team. If the subjects did not respond to the call at the first time, they were contacted again twice on the same day before labelling them as non-responders.

Tools for the study

A semi opens ended questionnaire consisting of demographic details, past COVID-19 infection and vaccine related attributes was used. This questionnaire was filled while the participants were waiting in the observation room and who had consented to participate in the study. The data collected over the call consisted of the 10 adverse events with their severity and duration as experienced by the subjects after the vaccine shot. Over the call the participants were encouraged to report any adverse event other than those that were listed.

Outcome of the study

Primary outcome: To explore the frequency of the adverse events experienced by the vaccine recipients and association, if any, with other documented attributes. Time lines for these data were day 1, 3 and 7 after vaccination.

Secondary outcome: To generate evidence of any rare side effects, if any, of the vaccine among the recipients.

The reported side effects were grouped as per the national guidelines as minor, severe and serious AEFI.[4] Those recipients who needed medical care/observation were referred to the hospital's telemedicine and AEFI team of doctors for necessary care and intervention.

Ethical considerations

The study did not include any method that went beyond "less than minimal" risk to subject or their acquaintances. A written informed consent was obtained from subjects prior to their inclusion in the study. The confidentiality of responses were assured. The study was approved by the institute ethical committee constituted for this purpose.

Statistical analysis

The data collected in the questionnaire and over the call were maintained in the MS excel sheets and SPSS version 20.0 (IBM Corp, NY, USA) was used for further analysis. Appropriate simple descriptive tabulations and tests of significance like Pearson's Chi-square[2] test were used. Statistical significance was set at $p<0.05$.

RESULTS

Out of the total of 1306 beneficiaries whose name was there in the pool, 1276 HCWs were vaccinated in the study period. Out of the total of 1258 recipients who consented to participate in the study, 1201 (95.4%)

responded to the calls on all 3 days. The mean age of the study group was 34.1 years (Range-18 to 70). Males were 861 (71.7%) and females were 340 (28.3%) in our study. A total of 869 (72.4%) vaccine recipients were aware about the name of the vaccine which was being administered to them and its side effects and rest 332 (27.6%) said they were not sure about it. Willingness to be vaccinated by self was present in 986 (82.1%) of the recipients while 215 (17.9%) were motivated by others to get vaccinated. A total of 146 (12.2%) recipients were COVID 19 infected prior to vaccination.

Out of the total of 1201 who were included in the study, 766 (63.7%) had at least any one AEFI. Recipients who reported more than one AEFI was 253 (21.1%). The incidence of AEFI is described day wise in Table 1-3 for days 1, 3 and 7 respectively. The most frequent systemic and local AEFI reported was body ache/malaise and pain at injection site in 309 (25.7%) and 664 (55.3%) participants respectively. Severe/serious AEFI comprised a total of 3 (0.2%) systemic adverse events and 1 local events (0.08%) on day 1. There were a total of 4 (0.33%) peculiar adverse events which is grouped under "others". It comprised of 1 serious event of Thyrotoxicosis post vaccination in a 47-year-old female who was a known case of hypothyroidism. The other 3 events were that of loss of taste (ageusia) in 2 participants and loss of smell(anosmia) in 1 participant.

On day 1, 766 participants (63.7%) had at least any one adverse event which came down to 288 (23.9%) participants on day 3. The adverse events subsided over a week with only 17 (1.4%) participants reporting persistence of any adverse event on Day 7. A significant difference was observed between those who were younger than 45 years and the ones who were of 45 years or greater in age in systemic adverse events of diarrhea, body ache/malaise and local adverse events (pain, redness and swelling) as described in Table 4 and Figure 1.

Table 1: Incidence of AEFI: (Day 1).

Variables	Frequency (%)	Minor (%)	Severe/ serious
Systemic AEFI			
Fever	284 (23.6)	284 (23.6)	-
Body ache/ malaise	309 (25.7)	309 (25.7)	-
Diarrhoea	31 (2.6)	30 (2.5)	1 (0.08)
Dizziness	126 (10.5)	126 (10.5)	-
Chills	253 (21.1)	253 (21.1)	-
Headache	285 (23.7)	285 (23.7)	-
Nausea/ vomiting	126 (10.5)	125 (10.4)	1 (0.08)
Others[##]	4 (0.33)	3 (0.2)	1 (0.08)
Local AEFI			
Pain	664 (55.3)	664 (55.3)	
Redness	43 (3.6)	43 (3.6)	-
Swelling	64 (5.3)	63 (5.2)	1 (0.08)

[##]Ageusia (loss of taste)-2, anosmia-1, thyroid storm-1.

Table 2: Incidence of AEFI: (Day 3).

Variables	Frequency (%)	Minor (%)	Severe/ serious
Systemic AEFI			
Fever	78 (6.5)	78 (6.5)	-
Body ache/ malaise	118 (9.8)	118 (9.8)	-
Diarrhoea	-	-	-
Dizziness	-	-	-
Chills	-	-	-
Headache	48 (3.9)	48 (4.0)	-
Nausea/ vomiting	19 (1.6)	19 (1.6)	-
Others[##]	4 (0.3)	3 (0.2)	1 (0.08)
Local AEFI			
Pain	208 (17.3)	208 (17.3)	-
Redness	11 (0.9)	11 (0.9)	-
Swelling	9 (0.7)	9 (0.7)	-

Ageusia (loss of taste)-2; anosmia (loss of smell)-1, thyroid storm-1.

Table 3: Incidence of AEFI: (Day 7).

Variables	Frequency (%)	Minor (%)	Serious/ severe
Systemic AEFI			
Fever	5 (0.4)	5 (0.4)	-
Body ache/ malaise	13 (1.1)	13 (1.1)	-
Diarrhoea	-	-	-
Dizziness	-	-	-
Chills	-	-	-
Headache	9 (0.7)	9 (0.7)	-
Nausea/ vomiting	2 (0.2)	2 (0.2)	-
Others [##]	4 (0.3)	3 (0.2)	1 (0.08)
Local AEFI			
Pain	11 (0.9)	11 (0.9)	-
Redness	-	-	-
Swelling	2 (0.2)	2 (0.2)	-

[##]Ageusia (loss of taste)-2, anosmia (loss of smell)-1, thyroid storm-1.

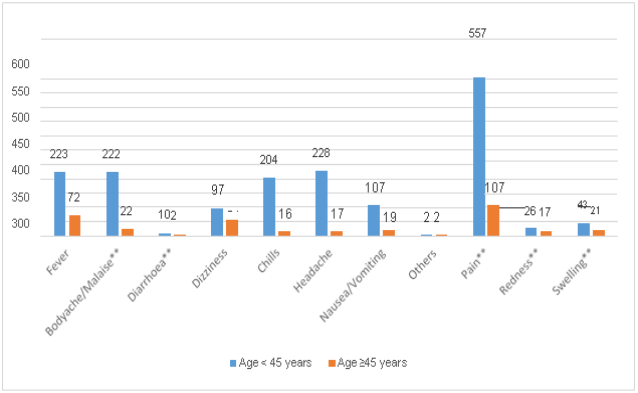

Figure 1: Systemic and local adverse event as per age (p<0.05).**

Table 4: Adverse events stratified according to age.

Variables	Age (<45 years), (n=957) (%)	Age ≥ 45 years), (n=244) (%)	P value
Systemic AEFI			
Fever	223 (23.3)	61 (25.0)	0.58
Bodyache/ malaise	222 (23.2)	87 (35.7)	<0.01**
Diarrhoea	10 (1.0)	21 (8.6)	<0.01**
Dizziness	97 (10.1)	29 (11.9)	0.43
Chills	204 (21.3)	49 (20.1)	0.67
Headache	228 (23.8)	57 (23.4)	0.87
Nausea/ vomiting	107 (11.2)	19 (7.8)	0.12
Others	2 (0.2)	2 (0.8)	0.18$
Local AEFI			
Pain	557 (58.2)	107 (43.9)	<0.01**
Redness	26 (2.7)	17 (7)	<0.01**
Swelling	43 (4.5)	21 (8.6)	<0.01**

** Significant p<0.05; **$** Fisher exact test.

DISCUSSION

The most frequent systemic and local AEFI reported in our study was body ache/malaise and pain at injection site in 309 (25.7%) and 664 (55.3%) participants respectively. The frequency of AEFI in our study was less compared to a study done in Korea which reported 95.4% and 95.1% of systemic and local AEFI respectively.[5] This difference may be explained by the fact that it was a voluntary reporting by the recipients and probably the ones who did not experience any AEFI did not respond on the web-based link which was shared to them. ChAdOx1 nCoV-19 has an acceptable safety profile and has been found to be efficacious against symptomatic COVID-19 in the interim analysis of ongoing clinical trials.[6]

Most of the AEFI resolved by day 3 after vaccination and in only 17 (1.4%) recipients AEFI persisted on day 7 of the study. Most of the AEFI was in the minor category which is quite expected and accepted by the beneficiaries. This finding can be used to promote vaccine acceptance among the public. In our study only 4 (0.33%) AEFI were severe (3) or serious (1) in magnitude. The AEFI that was serious (thyrotoxicosis) and required inpatient admission was of concern and may direct towards future policy recommendations of including thyrotoxicosis/severe hyperthyroidism in contraindicated group to receive the ChAdOx1 nCoV-19 SII vaccine. Further studies need to be done to evaluate its safety and efficacy in autoimmune disorders of thyroid.

The systemic events of diarrhea and body ache /malaise was reported more by those who were more than 45 years of age (p<0.01). This finding is in contrast to the interim analysis which said that reactogenicity of the vaccine decreased with age.[6] This could be explained by the fact that very few of our study subjects were more than 60 years of age. Further study needs to be done to find out any age group wise association of adverse events with considerable number of elderly being recruited in the study. This could help in proper monitoring and also counselling them for the expected adverse events.

Limitations

In our study there was a limitation that the adverse events reported were subjective and our study lacked the objective assessment of the events reported. Moreover, recall bias may have occurred for events occurring/fading between calls made on day 3 and day 7. Daily call would have been a better methodology but was avoided so that the participants are not poked up by the call every day.

CONCLUSION

Our study can provide scoping base for development of a proper surveillance program to monitor the AEFI by active query and use of call-based system. Web based/application based self-reporting is difficult in our setting with a significant population who don't have access to web or the ability to comprehend the web-based information. The call-based surveillance system can also be used for the vaccines that are already there in our country's immunization program and especially for novel vaccines for proper monitoring of the safety of the vaccines. The sharing of information about the safety of novel vaccines can help a lot to alleviate vaccine hesitancy.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Chandna VB, Patil SM, Shirahatti PS, Sujay S, Tejaswini M, Ranganatha LV et al. The current status and perspectives for the emerging pandemic: COVID-19. Int J Pharm Pharm Sci. 2020;12:1-10.
2. World Health Organization. WHO coronavirus (COVID-19) dashboard. 2021. Available at: https://covid19.who.int. Accessed on June 29, 2021.
3. World Health Organization. AEFI training module 3. Accessed from https://www.who.int/vaccine_safety. Accessed on June 29, 2021.
4. Revised AEFI guidelines. Govt of India. Ministry of health and family welfare. Accessed from https://main.mohfw.gov.in/. Accessed on June 29, 2021.
5. Jeon M, Kim J, Oh CE, Lee JY. Adverse Events Following Immunization Associated with Coronavirus Disease 2019 Vaccination Reported in the Mobile Vaccine Adverse Events Reporting System. J Korean Med Sci. 2021;36(17):e114.

6. Voysey M, Clemens SAC, Madhi SA. Safety and efficacy of the ChAdOx1nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet. 2021;397:99-111.

Cite this article as: Priya A, Gupta P, Kumar V, Srivastava SK, Yadav YK, Srivastava A. Call based enquiry for COVID-19 vaccine (Covishield) adverse events in a tertiary care government hospital in India. Int J Community Med Public Health 2022;9:2255-9.