

COVID-19 vaccination: Is it a matter of concern?

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Abstract

Background: COVID-19 vaccination is still a matter of concern among the public since its inception. Primary care physicians being in prime position can share accurate and ample information about COVID-19 vaccination so we estimated proportion and determinants of adverse events following immunization (AEFI) with Covishield vaccine, vaccination and reasons of non-vaccination. **Methods:** A cross-sectional study was conducted from January to April 2021. Data collection was done by using data capture tool Epicollect-5. Regression analysis was performed to evaluate the association of AEFI and vaccine acceptance with various demographic variables. **Results:** Of 520 subjects, 408 got vaccinated, and of these 125 (30.6%) developed AEFI. Females without AEFI had lower median age than females having AEFI. Only religion (aOR = 5.311; 95%CI: 1.216-23.1) was significantly associated with AEFI. Education (aOR = 0.399; 95%CI: 0.199-0.799), marital status (aOR = 0.459; 95%CI: 0.245-0.858), and religion (aOR = 3.874; 95%CI: 1.96-7.648) were significantly associated with vaccination. Most common local AEFIs were inflammation (46; 36.8%) followed by lump (10; 8%) at the site of injection. Most common systemic AEFI were fever (87; 69.6%), feeling unwell (65; 52%), generalized weakness/ fatigue (30; 20%), tiredness (26; 20.8%), flu-like symptoms (12; 9.6%), dizziness (10; 8%), headache (8; 6.4%) and gastrointestinal events active reporting of AEFI, public release of safety, and efficacy data. Primary care physicians can play a pivotal role by targeted awareness campaigns and trust-building activities to alleviate fear and anxiety related to vaccine.

Keywords: Adverse event following vaccination, COVID-19, India, nonacceptance, pandemic, vaccine hesitancy

Introduction

The origin of the outbreak of coronavirus disease 2019 (COVID-19) was initially detected in Wuhan, China in December 2019 and it spread rapidly around the globe. On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a worldwide pandemic, which created catastrophic changes and unprecedented challenges to global public healthcare system leading to more than 267 million confirmed cases of COVID-19, including more than 5 million deaths, reported to WHO till date. COVID-19

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vaccination coverage exceeds 8 billion globally and 132.93 crore nationally.^[1-3]

As the COVID-19 pandemic continued, we eagerly awaited the arrival of safe and effective vaccine. Vaccines showing early signs of promise and effectiveness, including two Indian-made vaccines (ChAdOx1 CoV-19 VACCINE: Covishield and Covaxin) that were granted emergency-use authorization.^[4-10]

COVID-19 vaccination is still a matter of concern among public since inception of vaccination drive, though it can be one of the most successful public health measures and achievements to protect us from changing the natural history of COVID-19 disease as witnessed in past 2 years, it is perceived as unsafe and unnecessary by a growing number of individuals. Lack of confidence and vaccine hesitancy is considered a threat to the success of vaccination

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programs and are believed to be responsible for low vaccination coverage.^[11-14] A sizeable amount of literature demonstrates that primary care physicians can play a crucial and vital role to decrease vaccine hesitancy, build public trust and confidence to promote COVID-19 vaccine uptake, and act as a resource person to ensure about the proper use of COVID-19 appropriate behavior.^[15-19]

Hence, the present study was conducted to estimate various "adverse events following COVID-19 vaccination" with Covishield vaccine, proportion of vaccination, reasons of nonvaccination, and their determinants to help the government in designing targeted awareness campaigns, public release of safety, and efficacy data of vaccine.

Methodology

Study subjects

This cross-sectional study was conducted among all employees including medical and paramedical personnel (doctors, nurses, and laboratory technicians), hospital administration, and others (clerks, sweeper, electrician, carpenter, attendants, etc.) working at a tertiary healthcare center at Rama Medical College Hospital and Research Centre, Kanpur from January to April 2021. All subjects above 18 years of age and willing to voluntarily participate were included in the study. Those who were unwilling, nonresponders, and absent on the day of the interview, left, or transferred from the institution were excluded. After taking verbal consent regarding voluntary participation, telephonic interview was conducted to gather information from all subjects.

Study tool

A semistructured, interviewer-administered questionnaire based on updated information about the COVID-19 vaccine (Covishield) ascertained by the "fact sheet for vaccine" provided by the Serum Institute of India Pvt. Ltd. was prepared.^[20] The questionnaire comprised the sociodemographic characteristics, AEFI after the first dose of vaccine, information regarding reasons of not being vaccinated, and vaccine hesitancy. Validity of the questionnaire was checked by feedback from selected experts. Based on their review, inappropriate and unrelated questions were either modified or removed. A pilot study was conducted among 30 subjects. The data of the pilot study were included in final analysis after applying necessary modifications. It was intended to approach as many subjects as possible to gather the maximum possible data to enhance the study's validity and generalizability.

Sample size

Total of 750 subjects were enlisted, of those 117 (15.60%) subjects could not be contacted, 86 (11.47%) were nonresponders, 23 (3.07%) were transferred out/left the institution, and four (0.53%) were uncooperative. Finally, 520 (69.33%) subjects were interviewed telephonically and included in the analysis.

Data collection and statistical analysis

Data collection was done from a day after the first dose of the COVID-19 vaccine (day 1) till, subjects were asked questions

about short-term, solicited, local, and systemic reactions. Data collection was done by Epi-collect-5 (data capture tool) then Microsoft excel sheet was extracted and validated.^[21] Data were checked for consistency and completeness before entry. A clean database was generated and analyzed in SPSS-20.0. Distribution of the study population according to their sociodemographic profile was presented by frequency and percentage (%). Binary logistic regression analysis was conducted to test for plausible determinants of adverse events and vaccine acceptance. All P values < 0.05 with 95% confidence intervals (CIs) were considered significant. Linearity of continuous variable was assessed via the Box-Tidwell procedure with Bonferroni correction. Independent variables were not multicollinear as assessed by the correlation matrix. There was no significant outlier (only one case) or highly influential point as per case-wise diagnostic hence it was included in the analysis.

Ethics statement

Ethical approval was obtained from the Institutional Ethics Committee (Reference No. IEC/RMC/est./Dean/2021/12033). The subjects were explained about the nature of the study and verbal consent was taken. Anonymity and confidentiality of the given information were maintained. Health education and adequate counseling were provided.

Results

Sociodemographic profile

Overall, 520 subjects (mean age; 29.02 ± 8.71 years) were included in the final analysis with (271; 52.1%) females. Four-fifth were residing in urban areas. A total of 291 (56%) were unmarried, 193 (37.1%) were living alone, 322 (61.9%) were healthcare personnel, and 446 (85.8%) were educated above graduate or professional.

Determinants of adverse events following COVID-19 vaccination

Among all vaccinee (n = 408), 125 (30.6%) developed adverse events following COVID-19 vaccination. Overall, female subjects had lower median age than males. Female subjects without AEFI had lower median age than females having AEFI [Figure 1].

Binary logistic regression model was statistically significant by Hosmer and Lemeshow test and correctly classified 69.4%of cases. Increasing age was associated with an increased likelihood of adverse effects. Vaccinees educated above graduate, married, and living with family had 1.27-, 1.24-, and 1.55-times higher odds of adverse effect than those who were educated below graduate, unmarried, and living alone. All determinants were nonsignificantly associated with AEFI except religion (aOR = 5.311; [95%CI: 1.216–23.1]) [Table 1].

Solicited local AEFI, reported was inflammation (pain, swelling, redness, etc.) (46; 36.8%) followed by lump (10; 8%) at the injection site. Most common systemic adverse events observed

Sociodemographic variable	AEFI Present (<i>n</i> =125), (<i>n</i> %)	В	Unadjusted OR [95% CI]	Adjusted OR [95% CI]	P^{\ddagger}
Age		0.004	1.004 (0.980-1.029)	1.029 (0.991-1.068)	0.133
Sex					
Male	57 (30.5)	-0.025	reference	-	-
Female	68 (30.8)		0.987 (0.647-1.505)	0.976 (0.592-1.609)	0.923
Education					
Below Graduate	18 (37.5)	0.246	reference	-	-
Graduate/Professional	107 (29.7)		1.419 (0.758-2.655)	1.279 (0.585-2.796)	0.537
Marital status					
Married	53 (32.3)	0.217	reference	-	-
Unmarried	72 (29.5)		1.14 (0.744-1.749)	1.242 (0.66-2.337)	0.502
Family					
Living with family	85 (33.9)	0.441	reference	-	-
Living alone	40 (25.5)		1.498 (0.961-2.335)	1.554 (0.919-2.629)	0.100
Religion					
Hindu	123 (32)	1.670	reference	-	-
Other	2 (8.3)		5.184 (1.20-22.396)	5.311 (1.216-23.1)	0.026
Residence					
Urban	100 (30.2)	0.101	reference	-	-
Rural	25 (32.5)		0.900 (0.529-1.532)	0.734 (0.618-1.978)	0.734
Occupation					
Healthcare personnel*	74 (28.7)	-0.049	reference	-	-
Other [†]	51 (34.0)		0.781 (0.507-1.203)	0.952 (0.546-1.659)	0.862

*(Doctors and nursing staff), †(Management staff, Clerk, Sweeper, Guard, Electrician, Warden, Mess worker, etc.), ‡(P<0.05 [significant]), OR: odds ratio

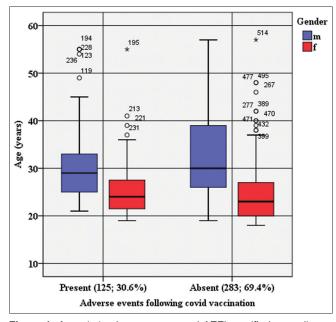


Figure 1: Association between age and AEFI stratified according to gender

was fever (87; 69.6%), feeling unwell (65; 52%), generalized weakness/fatigue (30; 20%), tiredness (26; 20.8%), flu-like symptoms (12; 9.6%), dizziness (10; 8%), headache (8; 6.4%), and gastrointestinal events (7; 5.6%). Most of the adverse events were mild-to-moderate intensity, resolved on their own without any medical assistance except in the cases (seven) of flu-like symptoms. Most of them were reported within 24 h of vaccination.

Reasons of nonvaccination

Out of 112 subjects, 22 (19.64%) did not get vaccinated because of contraindication, 14 (12.5%) were vaccine-hesitant, and 76 (67.84%) were attributed to other reasons like (45; 40%) being absent at session, being in night shift, busy, and family opposition. Most common reason for vaccine hesitancy (n = 14) was concern about safety and efficacy (9; 64.2%) followed by the perception of "let nature to take its own course" (4; 28.6%) and "COVID-19 is not dangerous to their health" (1; 1%).

Determinants of vaccination

Binary logistic regression model was statistically significant by Hosmer and Lemeshow test and correctly classified 78.5% of cases. Education (aOR = 0.399; 95%CI: 0.199–0.799), marital status (aOR = 0.459; 95%CI: 0.245–0.858), and religion (aOR = 3.874; 95%CI: 1.96–7.648) were significantly associated with vaccination. Those who belong to the Hindu religion and living alone had 3.87- and 1.07-times higher Odds of getting vaccinated than followers of other religions and those living with family, respectively [Table 2].

Discussion

The present study investigated various aspects associated with vaccination at the tertiary healthcare center, designated for the treatment of COVID-19 patients. Nearly 30% of the subjects had experienced AEFI. Incidence of AEFI reported in our study is more than reported in phase 1/2 clinical trial of this vaccine and study conducted among Armed Forces Medical Services healthcare workers (HCWs) deployed in northern India.^[10,22]

Table 2: Regression analysis of determinants of vaccination								
Sociodemographic variable	Vaccination yes (n=408), (n, %)	В	Unadjusted OR [95% CI]	Adjusted OR [95% CI]	P^{\ddagger}			
Age		-0.014	1.022 (0.999-1.046)	0.986 (0.953-1.02)	0.443			
Sex								
Male	187 (75.1)	-0.395	reference	-	-			
Female	221 (81.5)		0.682 (0.448-1.039)	0.674 (0.407-1.114)	0.124			
Education								
Below Graduate	48 (64.9)	-0.920	reference	-	-			
Graduate/Professional	360 (80.7)		0.441 (0.259-0.751)	0.399 (0.199-0.799)	0.010			
Marital status								
Married	164 (71.6)	-0.780	reference	-	-			
Unmarried	244 (83.8)		0.486 0.318-0.743)	0.459 (0.245-0.858)	0.015			
Family								
Living with family	251 (76.8)	0.064	reference	-	-			
Living alone	157 (81.3)		0.757 (0.486-1.180)	1.066 (0.608-1.870)	0.823			
Religion								
Hindu	384 (80.5)	1.354	reference	-	-			
Other	24 (55.8)		3.269 (1.718-6.218)	3.874 (1.96-7.648)	0.000			
Residence								
Urban	331 (78.6)	-0.233	reference	-	-			
Rural	77 (77.8)		1.051 (0.620-1.782)	0.792 (0.436-1.440)	0.445			
Occupation								
Healthcare personnel*	258 (80.1)	-0.223	reference	-	-			
Other [†]	150 (75.8)		1.290 (0.843-1.973)	0.800 (0.445-1.438)	0.456			

*(Doctors and nursing staff), *(Management staff, Clerk, Sweeper, Guard, Electrician, Warden, Mess worker, etc.), *(P<0.05 [significant]), OR: odds ratio

Although it is lesser than reported by Kamal *et al.*^[9] and Menni *et al.*,^[23] this variation could be because of different periods of follow-up.

Most of the adverse events were milder and resolved without any kind of medical supervision or management. No severe or serious AEFI was reported among the vaccinee. Most common adverse event observed was pain and lump at the injection site, fever, and generalized weakness. This supports the findings of the studies, wherein majority of recipients reported nonserious AEFI.^[9,10,24-26] Majority of adverse events were noted within the first 24–48 h of vaccination with a declining trend after this period simulating other studies.^[9] In our study, the incidence of AEFI was higher among females. These findings are consistent with the results of other studies.^[9,10,23,27,28]

Vaccine hesitancy is often complex and varies greatly across populations. The reason for vaccine hesitancy in this study was, let nature take its course, concerns about safety and efficacy, and do not think COVID-19 is dangerous to health. Other studies have also found that patients share comparable concerns regarding the safety profile, currently recognized and unforeseen side effects, and the development and approval process of COVID-19 vaccines.^[11,19,29,30]

Education, marital status, and religion were significantly associated with vaccine acceptance or hesitancy. A study done by Kwok *et al.*^[51] revealed that 63% were willing to be vaccinated and willingness was associated with younger age. Healthcare personnel primarily doctors had a positive attitude toward a COVID-19 vaccine as reported by Nzaji *et al.*^[32]

As patients are always comfortable to receive medical care from their local community physician, who can provide reliable and trustworthy information. They can ask the patients about their plan for getting vaccinated by empathizing with them about the beneficial effects of vaccination, sharing their own experiences after vaccination, and communicating the risk of not getting vaccinated in the changing scenario of disease. Hence, primary healthcare physician can provide health education by informing them about the benefits of vaccination, allay anxiety and myths associated with the vaccines, and information about AEFI, which will be mild and will resolve on its own, to increase the uptake of vaccine, and reduce hesitancy.^[32-34]

The institution where vaccination is being conducted should have both active as well as passive surveillance systems with community participation to monitor AEFI and further be reported to district health authorities for the purpose of necessitating any relevant intervention. Although local and systemic reactions are expected and are often mild and transient, they may have the most immediate influence on patients' perceptions of the vaccination experience and, in turn, can affect vaccination drive and coverage.

Key findings

Most of the AEFI were transient and milder, observed in the first 24 h predominantly with decreasing incidence in subsequent weeks after both the doses. No serious AEFI was observed. Findings of this study reveal that the vaccine is safe and well-tolerated with lower reactogenicity. There is paucity of similar published studies in the public domain. All the subjects received two doses of vaccines and we studied adverse events for 4 weeks from each dose. Hence, we could report all the possible AEFI precisely. We contacted the subjects thrice so that probability of dropout and underreporting can be reduced. The authenticity and accuracy of reporting the AEFI were better as the study was conducted exclusively in healthcare center workers who could be assessed easily and precisely report the adverse events to the researcher. Like about four to five subjects called back, to report AEFI or to enquire about the second dose schedule.

This cross-sectional study design cannot establish causal inferences. Moreover, the small sample size and the institutional setting are only representative of similar settings and could not be validated externally. Therefore, studies utilizing larger samples, more representative populations, and investigation on the possible "nonspecific effects" of vaccines and short- and long-term benefits could be performed with properly designed and long-lasting comparative studies or randomized controlled trials. Few adverse events could have been coincidental and not attributable to the vaccination directly.

Key message

Primary care physician should consider vaccinations as a major component of their practice. Vaccines for instance, not only protect the individual and their family, but the public's health at large. They can be the best source of information about disease, its changing scenario, and preventive measurements. They should teach other healthcare workers to practice and ensure COVID-19 appropriate behavior.

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Conflicts of interest

There are no conflicts of interest.

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