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Original Research Article

Survey on individual experiences after first dose of COVID-19 vaccination amongst Indian oral health care personnel

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ABSTRACT

Introduction: Apprehension pertaining to adverse events associated with vaccine can create hesitancy in population which undermines their confidence in vaccination programmes. Clarity regarding what could be expected post-vaccination through reliable scientific data helps in allaying the apprehension. Our research aims at gauging the adverse experiences of oral health care professionals following first dose of immunization against COVID-19 with ChAdOx1 nCoV-19 (COVISHIELD™) and BBV152 (COVAXIN®).

Materials and Methods: Data was collected by means of e-questionnaire circulated through online media such as social media platforms to oral health care professionals in India. Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data has been depicted. Comparison of frequencies of categories of variables with groups was done using chi square test.

Results: Pain at site of injection (n=243) was the most frequently reported AEFI, followed by fever (n=225), headache (n=185), body ache (n=156) and fatigue (n=146). Majority of the AEFIs were perceived to be of mild (58.22%) to moderate (31.50%) severity by the respondents and resolved within first two days of immunization.

Conclusion: AEFIs are almost inevitable when population on a nation-wide scale is involved in the vaccination scheme Availability of scientific data pertaining to AEFIs that could be expected post-vaccination such as our findings could provide clarity to general population about the issue, thereby purging any apprehension developed due to myths circulation through various modes of media.

1. Introduction

The effects of a pandemic are not only related to its physical impact, but also extend to including mental health problems such as pathological anxiety, depression and post-traumatic stress disorder induced by higher levels of stress and fear.[1] What makes the COVID-19 pandemic even more dreadful is the uncertainties surrounding the nature of disease as well as its ever-evolving epidemiological status. This is pertinently applicable for the COVID-19 pandemic as a person of any gender or sociodemographic status can get infected while only speculations are available surrounding its actual nature while the disease is propagating at an alarming rate.[2] It has been estimated that about 67% of the population must develop immunity against the causative SARS-CoV-2 virus in order to curtail the spread effectively.[3] Development of vaccine against the virus was most eagerly awaited by people throughout all the countries. At present, purified

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inactivated whole-virion vaccine manufactured under the name COVAXIN® by Bharat Biotech, and vector-based vaccine, COVISHIELD™ by Serum Institute of India are being administered to health care workers and general population on age-based priority.[4] However, owing to the limited production of vaccine, it cannot be made instantaneously available to the entire population. Keeping in mind this restriction, it was recommended by CDC's Advisory Committee on Immunization Practices (ACIP) that health care personnel should be included in this first group to avail the facility of vaccination as they are at the frontier in combatting the pandemic.[5]

Certain reactions such as redness or pain at the site of injection site, fever, headache, fatigue may follow administration of any vaccine. These are collectively termed as adverse events following immunization (AEFIs) and can also be synonymously called as adverse experiences.[6] AEFIs are defined as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine". Observation of these would only be natural in those vaccinated against COVID-19 as well. However, conveyance of unpleasant experiences in an exaggerated manner which may get amplified through spread of rumors or myths further add to the pre-existing fear generated as a result of the pandemic.[7] Consequently, there develops a reluctance amongst population to accept the vaccination program.[8] In order to mitigate the general hesitation to opt for vaccination, it is essential to provide accurate and reliable data pertaining to the post-vaccination experiences of individuals through scientific studies.[9] Demonstration of realistic information in this form would allay any existing fears associated with uncertainties revolving the nature of vaccine. The vaccination programs would gain confidence of the apprehensive individuals and subsequently motivate the masses in acquiring the most valuable means for tackling the pandemic.

The present survey aims to gauge the severity and duration of adverse events experienced post-vaccination against COVID-19 by oral health care personnel of India, inclusive of dental students, academicians and practitioners. Our objective is to provide data pertaining to post-vaccination experience to those who have not opted for vaccination out of fear for side effects. The research also carries the objective to appraise them that certain side effects can be expected post-vaccination to some extent but allaying apprehension is very much necessary to combat the pandemic.

2. Materials and Methods

A cross-sectional study was conducted by means of a questionnaire-based survey across a period of two months from March to May 2021. The team comprised of experts in dentistry and oral pathology (SS, TC, MS, YA), public health expert in epidemiological and data analytics (KY). The study protocol was reviewed and approved by institutional ethical committee. A four-sectioned questionnaire was constructed that comprised of consent statement, individual information and history of COVID-19 or medical conditions, details related to vaccination status and post-vaccination experiences.

Upon consenting to fill the survey, the demographic information of the respondents was recorded along with history of COVID-19 infection or any other existing condition. The respondents then had to indicate whether they had been vaccinated with first dost of vaccine against COVID-19. A negative answer ended the survey while others were then asked to specify whether they had been vaccinated with COVAXIN®, COVISHIELD™ or any other vaccine. Similarly in the following section, the respondents had to indicate whether they experienced any adverse effect post immunization and a negative answer would again end the survey. Respondents who experienced adverse events were then asked to specify time of onset of events since immunization, their severity (mild, moderate, severe) and duration. The grading was in line with a previous research protocol of phase-I trial for immunogenicity and safety of SARS-CoV-2 vaccine, BBV152 (COVAXIN®).[10]

Dental practitioners or academicians residing in any state of India, having BDS or higher educational qualification as well as students pursuing BDS course in any dental institute of India were considered as eligible for the study. Those not consenting to fill the survey or opting out of the survey process were excluded from the study. Sample size was determined using a single proportion formula as below:

$$n = \frac{1.96^2 p(1-p)(DEFF)}{d^2}$$

Where p = Estimate of the expected proportion, d = Desired level of absolute precision

Assuming the current event rate to be at least 50%., keeping 5% confidence limit, for p = 0.05

$$n = \frac{1.96\ x\ 1.96\ \ (0.50\ x\ [1\ -\ 0.50)}{0.05\ x\ 0.05}$$

n = 384

It was estimated that at least 385 respondents should complete the survey.

The research protocol was approved by institutional ethical review board. The questionnaire was pilot-tested on 20 respondents and reliability of questions was tested using Cronbach's alpha analysis. A Cronbach's alpha value of 0.895 indicated a good internal consistency and validity. Few corrections as necessitated after test for face validity were made.

The final questionnaire was created using Google Forms and the link was forwarded to dental students, academicians

and clinicians by means of online social media platforms and messenger applications.[11] A final sample size of n=451 respondents was achieved by purposive sampling method (Figure 1). The data obtained from respondents was entered into a MS Office Excel Sheet (v 2010, Microsoft Redmond Campus, Redmond, Washington, United States).

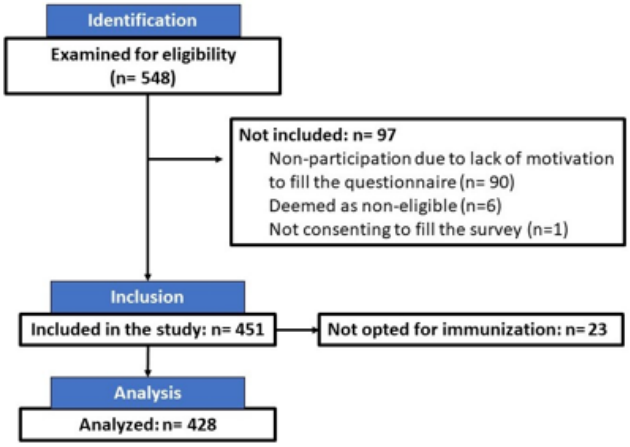

Fig. 1: Process of inclusion of respondents in the survey process for final analysis

Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorical data, Mean & SD for numerical data have been depicted. Comparison of frequencies of categories of variables with groups was done using chi square test. For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus, giving a power to the study as 80%.

3. Results

The study population comprised of 295 female and 156 male respondents of which majority were students and academicians from dental institutes of India (74.7%) while others were clinicians. 70% of the respondents resided in the state of Maharashtra, while the remainder were from various areas across India, predominantly, Delhi and Kerala. The age of respondents ranged from 18 to 67 years with a mean of 26.91 years (S.D. = +9.253). 9.1% (n=41) of the respondents had been previously diagnosed with COVID-19. Majority of respondents (93.6%) had been immunized with first dose against COVID-19 of which 59.43% (n=252) of the respondents had received COVISHIELD™ while remainder had received COVAXIN®.

When considering all the adverse experiences irrespective of their severity or duration, 61.2% (n=276) had AEFI in some form. There was a statistically highly significant difference seen for the frequencies between the groups ($p<0.01$) with higher frequency of respondents immunized with COVISHIELD™ experiencing AEFIs. The onset of AEFIs occurred on the same day of vaccination for highest number of respondents (34.4%) followed by onset of AEFIs on the next day/after 24 hours for 23.3% respondents (n=105). When considering onset of AEFIs, a statistically highly significant difference seen for the frequencies between the groups ($p<0.01$) with higher frequency of individuals immunized with COVISHIELD™ experiencing AEFIs on the same day of immunization. A small number of respondents had onset of symptoms immediately or after 48 hours of vaccination (n=5 each, respectively).

Pain at site of injection (n=243) was the most frequently reported AEFI, followed by fever (n=225), headache (n=185), body ache (n=156) and fatigue (n=146). Majority of the AEFIs were perceived to be of mild (58.22%) to moderate (31.50%) severity by the respondents. The frequency of respondents experiencing mild pain at site of injection and mild fever was significantly higher ($p<0.01$), in those immunized with COVAXIN® (n=78, 81 respectively) as compared to COVISHIELD™ (n=56, 56 respectively). Distribution of AEFIs reported according to their severity is comprehensively illustrated in Figure 2. The AEFIs lasted for varying durations ranging from 1-2 days to more than a week as depicted in Figure 3.

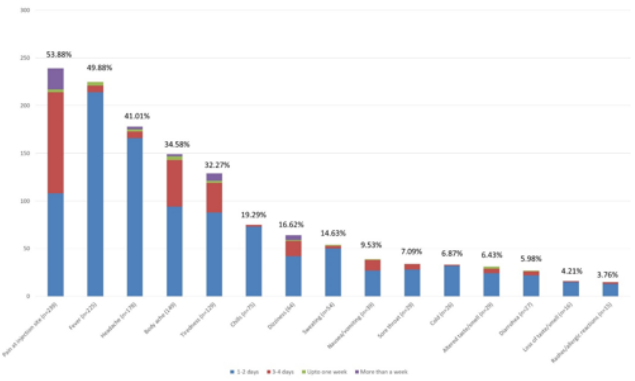

Fig. 2: Distribution of responses with respect to severity of AEFIs perceived by the respondents

Besides the listed AEFIs, others such as transient syncope, loss of gait, muscle spasm and pain in lower limbs were discerned by few respondents (n=1 each, respectively).

4. Discussion

Depending on their level of threat to health, AEFIs are primarily divided into three categories– minor, severe and serious.[12] Minor AEFIs are most commonly reported and comprise of minor reactions such as pain at injection site, mild fever, fatigue, etc. that are generally most common and self-limiting. Severe AEFIs are exaggerated versions

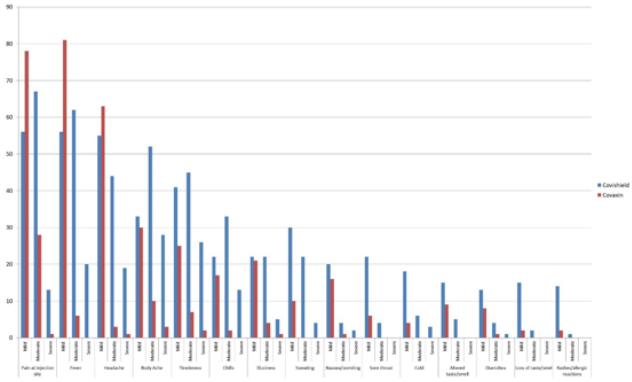

Fig. 3: Distribution of responses with respect to duration of AEFIs

of minor reactions that usually do not cause long term problems such as high-grade fever or sepsis. Severe AEFIs are conditions that lead to hospitalization, disability or even death. Majority of AEFIs tend to occur as a result of body immunity or physiological defense mechanisms rather than an allergic reaction. Studies to identify AEFIs associated with common vaccines such as MMR, DTP and BCG have served to guide immunization programmes previously.[13]

The peculiar nature of COVID-19 pandemic warranted hasty development of vaccines across the globe. Consequently, these have been approved by national regulatory authorities of various countries through the globe for emergency use, bypassing the norms of standard clinical trials for safety and effectivity testing. Data from pre-clinical research pertaining to ChAdOx1 nCoV-19 (COVISHIELD™) and BBV152 (COVAXIN®) vaccines have elucidated expected outcomes and AEFIs from their use.[14–16] Our results were in accordance with findings of previous clinical trials that most of the observed adverse events are of mild to moderate severity that resolved within two days post-immunization.[17,18]

Also, pain at the site of injection was the most commonly reported adverse even in previous clinical trials, followed by headache, fatigue/tiredness and fever.[19,20] Headache, in particular, was found to be more prevalent in individuals vaccinated with BBV152 vaccine which is in corroboration with our finding that there was a statistically highly significant frequency ($p<0.01$) of individuals experiencing headaches that almost unexceptionally lasted for 1-2 days post-immunization with COVAXIN®. Whereas, fatigue or tiredness lasting for 1-4 days post-vaccination was observed in greater number of individuals vaccinated with COVISHIELD™ as compared to COVAXIN®.

Allergic reactions were the least frequent adverse events observed (3.76%), all of which were perceived to be of mild to moderate severity by the respondents. The ability of vaccines is to evoke sufficient humoral as well as cell-mediated immune responses is one of their most desired characteristics. Commonly, adjuvants to amplify the immune response or certain components such as preservatives or proteins are conjugated with vaccines to improve corresponding properties.[21,22] These adjuvants that tend to induce allergic responses rather than the active ingredient of vaccine. The novel mechanism of action of vaccines against COVID-19 such as mRNA vaccines has been suggested as a possible reason for higher risk of allergic reaction.[22] Majority of individuals experiencing allergic reactions were noted in those immunized with COVISHIELD™, which is a vectored vaccine supports the suggested hypothesis.

Even so, the lack of large-scale studies related to AEFIs associated with COVID-19 vaccines coupled with hype created by mass media tend to undermine the confidence of general population in vaccination strategies.[23] The resultant 'vaccine hesitancy' has posed serious problems in past as well wherein it was included amongst top ten threats to human health by WHO.[24] The problem is further aggravated in developing or low-to-medium income countries such as India. National immunization centers hold the responsibility to administer vaccines as well as gather data on AEFIs associated with them. The limited number of health care workers as well as facilities cripples the ability to actively follow-up on AEFIs, subsequently leading to suboptimal surveillance. For this purpose, data from local research such as the present study, emphasizing on collecting such data are crucial as they could be pooled together to extrapolate nationwide scenario.[25]

Our study presents itself with certain limitations wherein the data was elucidated from those able to respond to the survey and could have possibly skipped those hospitalized or experiencing serious AEFIs. Also, it was based on subjective responses from the population rather than actual clinical assessment. Although the age range of respondents was relatively wide, it did not cover pediatric and geriatric populations, which may particularly be prone to certain adverse events. Therefore, the results may not be generalizable to populations belonging to these age groups. Even so, the findings of our research could educate general population as to what could be expected post-vaccination. Scientific information from reliable sources would also serve to allay apprehension and hesitancy related to vaccination by providing better clarity.

5. Conclusion

AEFIs are almost inevitable when population on a nation-wide scale is involved in the vaccination scheme. Majority of AEFIs were perceived to be of mild to moderate severity by the respondents and resolved within first two days of immunization. Availability of scientific data pertaining to AEFIs that could be expected post-vaccination such as our findings could provide clarity to general population about the issue, thereby purging any apprehension developed due to myths circulation through various modes of media.

6. Source of Funding

None.

7. Conflict of Interest

None.

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