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Research Article

Safety Surveillance of COVID-19 Vaccine in Tertiary Care Hospital among Target Population: An Observational Study

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Abstract

Vaccines are a critical new tool in the battle against COVID-19. Development of safe and effective vaccines are necessary to combat the pandemic. The aim of the study is to provide public awareness to improve vaccination rate and prevent vaccination hesitancy by studying the knowledge, attitude and perception about COVID-19 vaccines, the occurrence of side effects after the administration of COVID-19 vaccine and its management. The participants who fulfilled the inclusion criteria were provided the previously structured and approved data collection form. The knowledge, attitude and perception towards COVID-19 vaccination was then determined by allocating a score for each response. The collected data was statistically interpreted using SPSS software and R software. The incidence of side effects following administration of 2 doses of COVID-19 vaccine and its management was analyzed. The knowledge regarding COVID-19 vaccinations was low among more than half of the total study population. Female gender showed a higher knowledge score compared to males. Nearly half of the study population (42.5%) was found to have a high attitude score. Age as a variable was found to be of significant association with attitude. It was concluded from our study that the majority of the participants were aware about the COVID-19 vaccines available in India. This study also points out that a majority of the participants experienced fear and hesitancy prior to getting vaccinated. Only a minority of the respondents were of the belief that vaccination would prevent the spread of COVID -19 infection.

Keywords: COVID - 19, knowledge, attitudes, perceptions, vaccine, side effect

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious viral illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). These are RNA viruses that undergo genetic evolution over time, resulting in mutant variants that may have different characteristics than its ancestral strains. The COVID-19 infection primarily affects the lungs and has emerged as a deadly disease that has washed out millions of human beings from the earth in the past two years of time. Even though it is predominantly a respiratory illness it can affect other organs as well. People affected with COVID-19 infection have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms appear within two days to two weeks after exposure to the virus and include fever, shortness of breath, body ache, fatigue, gastrointestinal manifestations like nausea, vomiting, diarrhoea, loss of smell and taste, etc.¹

Traditional drug discovery approaches are time-consuming, and trial-and-error methods are often ineffective. The development of a new drug takes on average one to two decades, due to the safety and efficacy requirements. The approach of repurposing the existing drugs based on similarity of disease mechanisms seems to be highly promising. Moreover, repurposed drugs have the advantage of less development costs and time because of their previously

available pharmacokinetic, toxicology, and safety data. Recently, the spotlight has been on developing vaccines against the coronavirus. A vaccine is a biological preparation made from weakened or killed microorganism, its toxins or its surface proteins. The general stages of the development cycle of a vaccine are exploratory stage, pre-clinical stage, clinical development, regulatory review and approval, manufacturing and quality control.²

Clinical development is a three-phase process. During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded and vaccines are given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety. Many vaccines undergo Phase IV formal, ongoing studies after the vaccine is approved and licensed.³

In August 2020, more than 350 COVID-19 therapeutic drugs (mostly repurposed) were investigated, more than 75% of them entered in human clinical trials, and more than 150 repurposed. Vaccines are under study with about 25% of them on the various phases of human trials. The Pfizer/BioNtech Comirnaty vaccine was listed for WHO Emergency Use Listing (EUL) on December 31, 2020. The SII/Covishield and AstraZeneca/AZD1222 vaccines (developed by

AstraZeneca/Oxford and manufactured by the State Institute of India and SK Bio respectively) were given EUL on February 16, 2021. The Janssen/Ad26.COV 2.S developed by Johnson & Johnson, was listed for EUL on March 12, 2021. The Moderna COVID-19 vaccine (mRNA 1273) was listed for EUL on April 30, 2021 and the Sinopharm COVID-19 vaccine was listed for EUL on May 7, 2021. The Sinopharm vaccine is produced by Beijing Bio-Institute of Biological Products Co Ltd, subsidiary of China National Biotec Group (CNBG). The Sinovac-CoronaVac was listed for EUL on June 1, 2021.^[4] Vaccine ingredients differ by manufacturer. All of the Covid-19 vaccines are free from metals such as iron, nickel, cobalt, lithium and rare earth alloys. They are also free from manufactured products such as microelectronics, electrodes, carbon nanotubes or nanowire semiconductors. Covishield vaccine [ChAdOx1 nCoV- 19 Coronavirus Vaccine (Recombinant)] is one of the vaccines currently approved for use in India. It is approved for restricted use in emergency conditions in individuals of 18 years and above. The vaccination course consists of two separate doses of 0.5 ml each given intramuscularly to the deltoid muscle. The second dose is administered between 4 to 6 weeks after the first dose.

Some studies justify the administration of the second dose up to 12 weeks after the first dose. From ongoing clinical trials, the vaccine is shown to provide individuals with protective immune responses after the completion of two doses. The Covishield vaccine is composed of L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate (EDTA) and water for injection. Exclusion criteria for vaccination include people who have any severe allergic reaction to any ingredients of this vaccine or people who have experienced any severe allergic reaction to the first dose of the Covishield vaccine. Prior to receiving the dose of vaccine, individuals are advised to inform the healthcare providers about their medical conditions including any anaphylaxis to drugs or food, bleeding disorders, immunocompromised status or on drugs that affect the immune system, if the individual is pregnant, lactating or planning to conceive or if the individual is having a fever. The healthcare provider must also be informed about the prior dose of Covid vaccine if any. If the second dose is missed or the time schedule is skipped, then it must be informed to the healthcare provider for decision making as it is necessary to complete the vaccination by taking both the doses. It is advised to stay at the vaccination centre for about 15 minutes after getting the shot to detect and manage any unusual reaction that may occur following vaccination^{2,3}

Even after completing both the doses of Covid vaccination, precautions must be taken as there are chances of getting the Covid 19 infection and there are no established studies that reported the complete prevention of Covid 19 disease after Covid vaccination.⁵ Necessary actions must be taken to prevent the spread that include:

- Keeping a distance of at least 1-2 meters from others
- Wearing a mask always, especially in crowded, closed and poorly ventilated settings
- Following proper handwashing techniques
- Covering cough or sneeze with bent elbow

If a person gets affected by Covid 19 even after the administration of the first dose of Covid vaccine, the second dose can be given eight to twelve weeks after the incidence of the infection. The body produces antibodies after infection similar to the post vaccination condition. Individuals treated for COVID-19 with monoclonal antibodies or convalescent plasma, should wait 90 days before getting a COVID-19

vaccine. People with COVID-19 who have symptoms should wait to be vaccinated until they have recovered from their illness and have met the criteria for discontinuing isolation; those without symptoms should also wait until they meet the criteria before getting vaccinated. As per Centres for Disease Control and Prevention, quarantine procedures are recommended to individuals without complete vaccination, who have had a close contact with the infected person particularly within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period. People who have completed the dose of Covid vaccination are advised to quarantine only if they are experiencing any symptoms. Quarantine procedures include fourteen days of isolation after the last contact with the infected person. Proper monitoring is required for fever, cough, shortness and other symptoms of Covid 19 disease. It is also advised to avoid contact with people who are at higher risk of contracting the infection. Evidence suggests that people get better protection by being fully vaccinated compared with having had COVID-19. Studies showed that unvaccinated people who already had COVID-19 are more than 2 times as likely than fully vaccinated people to get COVID-19 again. Side effects and adverse events often accompany vaccination. Certain rare adverse events have been reported with the administration of the J&J/Janssen COVID-19 Vaccine. It was a rare condition called thrombosis with thrombocytopenia (TTS) which is a serious condition with blood clots and low platelet counts. As of September 15, 2021, more than 14.7 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. 47 confirmed reports of people who were identified by CDC and FDA who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. CDC and FDA are monitoring reports of Guillain-Barre Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 Vaccine. It is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and might lead to paralysis. Most people fully recover from GBS, but some have permanent nerve damage. After more than 14.7 million J&J/Janssen COVID-19 Vaccine doses administered, there have been around 201 preliminary reports of GBS identified in VAERS as of September 15, 2021. These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older. VAERS has also received 1,491 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have confirmed 890 reports of myocarditis or pericarditis. Based on the reports of the serious, unexpected and severe adverse events that have occurred following vaccination of Covid 19, proper measures must be taken to detect, manage and prevent the adverse events of vaccination. Post marketing studies are therefore a crucial step in the safety surveillance of COVID 19 vaccinations.⁵

MATERIALS AND METHODS

An observational study was conducted among 341 students of various batches of Bachelor of Dental Surgery (BDS), Bachelor of Science in Nursing (BSc Nursing), and Diploma in Operation Theatre and Anaesthesia Technology (DOTAT) courses in NIMS Medicity, Neyyattinkara, Trivandrum, a tertiary care hospital. The study was conducted for a period of six months. The subjects were selected based on inclusion and exclusion criteria. Inclusion criteria included subjects who have undergone vaccination with 2 doses of Covishield and subjects willing to participate. Exclusion criteria included subjects who are not vaccinated or who have undergone vaccination with only the first dose of Covishield or with other Covid-19 vaccines and subjects not willing to participate. The study

variables that were taken into consideration were socio-demographic factors (age, gender), educational status (BDS, BSc Nursing, DOTAT) and response to vaccination. The necessary permission and clearance for the study was obtained from the Institutional Research Committee of NIMS Medicity, Neyyattinkara, Trivandrum. The objectives, participant selection criteria and requirements of the study were explained verbally to the study population, after which the participants who fulfilled the inclusion criteria were provided the previously structured and approved data collection form. From each participant, general socio demographic details were collected. Further 15 questions to assess the knowledge, attitude and perception of the participant towards the vaccination, and 9 questions on the vaccine related side effects were also administered. The knowledge, attitude and perception towards COVID-19 vaccination was then determined by allocating a score for each response. The collected data was statistically interpreted using SPSS software version 13.0 and R software version 4.0.3. The incidence of side effects following administration of 2 doses of COVID-19 vaccine and its management was analysed.

RESULTS AND DISCUSSION

A total of 341 students enrolled in the study, out of which 189 students (55.4%), 137 students (40.2%), and 15 students (4.4%) pursued BDS, BSc Nursing and DOTAT courses respectively. Female participants formed a majority of the study population, accounting to a total number of 307 (90 %) and males 34 (10%), with ages ranging from a minimum of 18 years to a maximum of 30 years and a mean age of 21.26 years. Among 341 respondents, 271 (79.5%) participants encountered side effects after the first dose and 70 (20.5%) participants encountered no side effects after the first dose of Covishield vaccination.

Headache is the most common side effect experienced by the majority of the respondents (n = 191), accounting for 70.48% of the participants, followed by joint and muscle pain, feeling tired, chills, feeling unwell, etc. A minority also experienced

itching, skin rash, abdominal pain, and decreased appetite. Other side effects experienced by participants are insomnia, increased sleep, shivering, and vomiting. Among 341 respondents, 87 (25.5%) participants encountered the side effects while a majority of 254 (74.5%) participants encountered no side effects after the second dose of Covishield vaccination. Tiredness was the most encountered side effect, accounting 49.43% for 43 participants. Joint pain, muscle ache, pain warmth and tenderness at the injection site and headache were also prevalent in most people. Other side effects that were encountered were insomnia and increased sleep.

Among 271 participants, 157 participants managed side effects by self-medication, 130 with home remedies and 18 underwent hospital consultation. Headache, tiredness, joint pain and muscle pain are the main side effects that were managed at home, with home remedies and self medications. Side effects like fever, chills, flu like symptoms, nausea, etc were also managed at home.

Descriptive Statistics for Different Variables

The median age of the participants is 21 years with a minimum age of 18 years and maximum age of 30 years. Based on the median age, the participants are categorized into 2 groups, one with participants of age greater than or equal to 21 and the other with participants of age greater than 21. To assess the knowledge of the participants on COVID - 19 vaccination, the 4 variables related to knowledge were added to get the total knowledge score. The median knowledge score was then found out and the value is 4. The total knowledge score less than or equal to 4 is considered as less knowledge and more than 4 is considered as good knowledge. The attitude is assessed by adding the attitude score variables. 5 variables related to attitude were added up to get the total attitude score. The median attitude score is 6. An attitude score less than or equal to 6 is considered a low attitude and more than 6 is considered a good attitude score. The negative variable scoring is reversed to find out the total score (table 1).

Table 1. Descriptive statistics for different variables

	Mean	Median	Standard Deviation
Age	21.26	21	1.80
Attitude Score	5.84	6	1.74
Knowledge Score	3.75	4	0.96

Univariate Analysis of Age against Knowledge

Out of 261 participants with the knowledge score = or < 4, 67% (n=174) belonged to the category of age = or < 21 and 33% (n = 87) were of age >21 years. Out of 80 participants with knowledge score >4, 57% (n = 46) individuals were aged <=21 years and 43% (n = aged >21 years. The association of this variable was analysed by using the Chi square test and was found to have a Chi square value of 2.248. The association was not found to be statistically significant (p=0.13).

Univariate Analysis of Age against Attitude

Out of 196 participants with attitude score = or < 6, 139 members (70.9%) were aged < or = 21 and 57 (29.1%) were males. Out of 145 respondents with an attitude score >6, 81 participants (55.9%) were aged < or = 21 and 64 (44.1%) were aged > 21 years. The association of this variable is tested by Chi square test and found that the association is statistically significant. Chi square value is 8.53 and p value is 0.004 (table 2).

Table 2. Univariate analysis of age against attitude

Table 2. Univariate analysis of age against attitude					
Age in years	Attitude				Total
	= or < 6		> 6		
	Number of participants	Percentage (%) of participants	Number of participants	Percentage (%) of participants	
Age = or <21	139	70.9%	81	55.9%	307 (90.0%)
Age >21	57	29.1%	64	44.1%	34 (10.0%)
Total	196	100 %	261	100%	341

Univariate Analysis of Age against Perception

Out of 207 participants with a perception score of 0, 139 (67%) belonged to age = or < 21 and 68 (33%) aged >21 years. Out of 134 individuals having perception score 1, 81 (60%) respondents were aged = or < 21 years and 53 (40%) aged >21 years. The association of this variable is tested by the Chi square test and found that the association is not statistically significant. The Chi square value is 1.59 and the p value is 0.206.

Univariate Analysis of Gender against Knowledge

Out of 261 participants with a total knowledge score of = or < 4, 228 respondents (87%) were females and 33 respondents (13%) were males. Out of 80 participants of knowledge score >4, 79 participants (99%) were females and 1 participant (1%) was male. The association of these variables was tested by Chi square test and found that the association is statistically significant. Chi Square value is 8.86 and significant value $p=0.001$ (table 3).

Table 3. Univariate analysis of gender against knowledge

Table 3. Univariate analysis of gender against knowledge					
GENDER	Knowledge				TOTAL
	= or < 4		> 4		
	Number of participants	Percentage (%) of participants	Number of participants	Percentage (%) of participants	
Female	228	87.4%	79	98.8%	307 (90.0%)
Male	33	12.6%	1	1.3%	34 (10.0%)
Total	261	100%	261	100%	341

Univariate Analysis of Gender against Attitude

Out of 196 participants with attitude score = or < 6, 171 members (87%) were females and 25 (13%) were males and out of 145 respondents with attitude score >6 136

participants (94%) were females and 9 (6%) were males. The association of this variable is tested by Chi square test and found that the association is statistically significant. Chi square value is 3.98 and significant value $p=0.046$ (table 4).

Table 4. Univariate analysis of gender against attitude

Table 4. Univariate analysis of gender against attitude					
GENDER	Attitude				TOTAL
	= or < 6		> 6		
	Number of participants	Percentage (%) of participants	Number of participants	Percentage (%) of participants	
Female	171	87.2%	136	93.8%	307 (90.0%)
Male	25	12.8%	9	6.2%	34 (10.0%)
Total	196	100 %	261	100%	341

Univariate Analysis of Gender against Perception

Out of 207 participants, participants with perception score 0 constituted 89% (n=184) of females and 11% (n =23) males and out of 134 individuals having perception score 1, 92% (n = 123) were females and 8% (n = 11) were males. The association of this variable was tested by Chi square test and found that the association is not statistically significant. Chi square value is 0.76 and significant value $p=0.382$.

Univariate Analysis of Course against Knowledge

Out of 261 participants, knowledge score = or < 4, 52% are from BDS, 6% from DOTAT and 42% from nursing. Out of 80 participants, knowledge scores >4 individuals 66% are from

BDS and 34% from nursing. The association of this variable is tested by Chi square test and found that the association is statistically significant. Chi Square value is 7.88 and significant value $p=0.019$.

Univariate Analysis of Course against Attitude

Out of 196 participants of attitude score = or < 6, 47% (n = 93) studied BDS, 4% (n = 8) studied DOTAT and 42% from nursing and out of 145 attitude score >6 individuals 66% from BDS, 5% from DOTAT and 29% from nursing. The association of this variable is tested by chi square test and found that the association is statistically significant. Chi square value is 13.28 and significant value $p=0.001$ (table 5)

Table 5. Univariate analysis of course against attitude

Table 5. Univariate analysis of course against attitude					
COURSE	Attitude				TOTAL
	= or < 6		> 6		
	Number of participants	Percentage (%) of participants	Number of participants	Percentage (%) of participants	
BDS	93	47.4%	96	66.2 %	189 (55.4%)
DOTAT	8	4.1 %	7	4.8 %	15(4.4%)
Nursing	95	48.5 %	42	29 %	137 (40.2%)
Total	196	100 %	145	100 %	341 (100%)

Univariate Analysis of Course against Perception

Out of 207 respondents of perception score 0, 55% (n = 114) studied BDS, 6% (n = 13) studied DOTAT and 39% (n = 80) studied nursing. Out of 134 individuals having perception score 1, 56% (n = 75) studied BDS, 1.5% (n = 2) from DOTAT and 42.5% (n = 57) from nursing. The association of this variable is tested by the Chi square test and found that the association is not statistically significant. Chi square value is 4.56 and p value is 0.102.

This study was conducted to assess the side effects and adverse effects following the administration of Covishield vaccination, among students in NIMS Medicity, Neyyattinkara, Thiruvananthapuram. This paper presents findings from the questionnaire-based survey conducted to assess the knowledge, attitudes and perceptions of the study population towards COVID-19 vaccinations, and to assess the occurrence and management of side effects after two doses of Covishield administration in the same population. The findings of vaccine related side effects do not reflect the general side effect profile for Covishield when taken into a large cross-sectional population because young individuals are more likely to experience serious side effects compared to elderly population. This is because of the efficiently functioning immune system in younger adults compared to the elderly people. The conclusions derived from the study of knowledge, attitude and perception will be crucial in developing COVID-19 vaccination related awareness and health education programs. This in turn will help in enhancing vaccination rate and reducing vaccine hesitancy.

The knowledge regarding COVID-19 vaccinations was low among more than half of the total study population. While considering age and gender as variables, gender was found to be significantly associated with knowledge greater than the mean score of 4. Female gender showed a higher knowledge score compared to males. But this association is limited by the distribution of male and female participants in the study population. A majority of the study participants were females (90%) and this might have influenced the association. The knowledge about COVID vaccination was not significant in terms of the participant's age. Nearly half of the study population (42.5%) was found to have a high attitude score. Age as variable was found to be of significant association with the attitude. The mean attitude score for youngsters is 5.6 and adult is 6.22. The mean difference is statistically significant, and shows that adults have more mean scores than youngsters. Gender as a variable also shows a nearly significant association with attitude (p = 0.076), but the association is within the limitations of sample size.

CONCLUSION

It was concluded from our study that the majority of the participants were aware about the COVID-19 vaccines available in India. The results also signify the role that social media and mass media play in providing and sharing health related information. Most of the people gained knowledge about the COVID 19 vaccines for the first time through mass media like TV and radio, followed by social media, internet, and newspapers. A small group of participants did not know about the safety and efficacy of the newly developed Covid- 19 vaccines and were hesitant to encourage their family, friends and relatives to get vaccinated. Majority respondents were of the opinion that healthcare workers should be given preference for vaccination shots. This study points out that a majority of the participants experienced fear and hesitancy prior to getting vaccinated. This might be due to the lack of availability of adequate information about the safety and efficacy of the newly developed vaccines, or because of misleading information that might have appeared in social

media. Only a minority of the respondents were of the belief that vaccination would prevent the spread of COVID 19 infection. The reports on various social media have also influenced a minority of the population and made them reconsider the choice to get vaccinated. Apart from this, the bad reaction to COVID 19 vaccination that has occurred to a known person has also made a majority of respondents reconsider the choice of getting vaccinated. The majority of the study population belonged to the female gender and this alters the association between gender and various parameters like attitude, perception and knowledge towards COVID- 19 vaccination. The distributions of participants in the study based on course were not equal. This influenced the study result.

Since the COVID 19 vaccines are being enrolled into public for human use after limited testing and trials, there is a lack of detailed knowledge about the complete safety profile of the vaccines. Continuous post marketing surveillance testing and monitoring is necessary to update the unknown and serious side effects or adverse effects that may follow vaccination. This in turn helps to select the vaccine that is most efficacious and safe. Vaccine related adverse events and health related complications that may require hospitalization of the recipients can thus be reduced. The provision of adequate education and interventions to enhance knowledge and attitude of the general population towards vaccination is necessary to improve vaccine acceptance rates and prevent vaccine hesitancy. The unreliable information and news that might be spread through mass media is another limiting factor that causes vaccine hesitancy. This can be tackled by providing reliable and authentic information and awareness programs for the public as a whole.

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