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Adverse Events Following COVID 19 Vaccine Shot

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ABSTRACT

Background: Coronavirus disease 2019 (COVID-19) is a rampant disease caused by severe acute respiratory syndrome coronavirus 2. The initial case was diagnosed in China, in late 2019. Since then, the disease had spread globally, leading to the current pandemic situation. Signs and symptoms of coronavirus disease are unpredictable, but includes mild to moderate fever, coughing, weakness, dyspnoea, and decreased sensation of smell and taste. Swift development of an efficient vaccine is needed to control and prevent the coronavirus disease 2019.

Objective: To assess the incidence of adverse events following the Covid 19 vaccine shot.

Methods: It is a descriptive study conducted among the health care students (nursing and paramedical) who took the first dose of the Covishield vaccine. This study aimed to assess the incidence of adverse events following the Covid 19 vaccine shot. A total of 150 students were selected by using the convenience sampling technique. The adverse events checklist was prepared to collect data from health care students by structured interview technique.

Results: The findings of the study show that 57 % had very common adverse events such as pain, itching, tiredness, headache, nausea, muscle ache 16% had common adverse events such as joint pain, lump at the injection site, vomiting, flu-like symptoms, 4% had uncommon adverse events loss of appetite, abdominal pain, excessive sweating.

Conclusion: Even though few newly developed vaccines demonstrate the efficacy up to 95%, multi-disciplinary level rigorous studies are required to determine the safety of vaccine which includes minimizing the adverse events following the vaccination shot.

Key Words: Adverse events, Coronavirus, Health care students, Pandemic, Vaccine

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a rampant disease caused by severe acute respiratory syndrome coronavirus 2. The initial case was diagnosed in China, in late 2019. Since then, the disease had spread globally, leading to the current pandemic situation. Signs and symptoms of coronavirus disease are unpredictable, but includes mild to moderate fever, coughing, weakness, dyspnoea, and decreased sensation of smell and taste.[1-4] Mostly the person infected with coronavirus develops mild to moderate symptoms such fever and cough, and less than 15% develop severe symptoms such as severe dyspnoea, Hypoxemia pneumonia, and less than 5% has critical symptoms such as respiratory failure and multiple organ dysfunction. The disease signs and symptoms commence from 1 to 14 days after exposure to the deadly virus.[5-8] Currently, there is no specific antiviral drug therapy available to treat ever spreading coronavirus disease, so we must use the existing treatment modalities for this pandemic disease. On the other hand, a preventive measure which includes physical distancing (6 feet), quarantining, aeration of indoor spaces, covering coughs and sneezes with the handkerchief, washing hands frequently, wearing a face mask can reduce transmission of infection. The vaccines also play a vital role in the prevention of Coronavirus disease.[9-12]

A COVID-19 vaccine is expected to provide protection against severe acute respiratory syndrome coronavirus 2, the virus causing coronavirus disease 2019. Before the COVID-19 pandemic, there was an established body of knowledge about the structure and function of coronaviruses causing diseases which enabled accelerated development

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of various vaccine technologies during early 2020.[13-16] For rapid development of an efficient vaccine against the severe acute respiratory syndrome coronavirus-2, the cause of the coronavirus disease 2019 (COVID-19) pandemic, and multidisciplinary level rigorous studies are required to determine the safety of vaccine which includes minimising the adverse events following the vaccination shot. In Phase III trials, several COVID-19 vaccines have shown efficacy as high as 95% in the prevention of symptomatic COVID-19 infections.[17-20]

Even though this newly developed vaccine has an efficacy of up to 95% in the prevention of coronavirus virus disease, many adverse events are reported globally. Logunov et al. conducted a study on the safety and efficacy of vector-based heterologous prime-boost COVID-19 vaccine by non-randomised trial consist of 76 participants between the age group 18 to 60 years. In this study, the most common adverse events reported were pain at the injection site 58%, fever 50%, headache 42%, and muscle and joint pain 24%. Most adverse events were mild to moderate and no serious adverse events were detected.[21] Ella et al. conducted a study on safety and efficacy of inactivated COVID-19 vaccine by randomised trial consist of 375 participants between the age group 18 to 55 years and reported that most common adverse events were pain at the injection site 5%, fever 50%, headache 3 %, nausea and vomiting 2% muscle and joint pain 24%. Most adverse events were mild 69 %, moderate 31% and no serious adverse events were detected.[22]

MATERIALS AND METHODS

A descriptive study was conducted among the health care students (nursing and paramedical) who took the first dose of the Covishield vaccine between January – February 2021. The study aimed to assess the incidence of adverse events following the Covid 19 vaccine shot. A total of 150 students were selected by using the convenience sampling technique. The tool has five sections which include demographic variables and an adverse events checklist. The demographic variables consist of Age, Gender, History of Allergy, History of respiratory problems, symptoms before vaccination, vaccination has taken in the past 6 months, participants ever tested for positive COVID 19, Family members ever tested positive for COVID 19, Motivation for vaccination. The adverse events Checklist consists of 3 sections which include very common adverse events, common adverse events, uncommon adverse events. Each section is further subdivided into two subparts namely the onset of symptoms of adverse events and duration of symptoms. The visual analogue pain scale was used to assess the level of pain at the injection site, a Modified 5D itch scale was used to assess the severity of itching at the injection site, the modified verbal rating scale was used to assess the level of swelling at the injection site, the infrared thermometer was used to assess the body temperature. The tool was validated by 5 medical experts in the field of pharmacology. The content validity index was found to be S-CVI/Ave = 0.9 and the reliability of the tool was calculated using Cronbach's alpha it was found to be 0.8. Before data collection, informed consent was obtained from the participants and the purpose of the study was explained to them. In the 30 minutes structured interview, the adverse events checklist was used to collect data and it is rated as Yes for the presence of adverse events and No for the absence of adverse events. Data analysis was done by using descriptive and inferential statistics using SPSS 20.

RESULTS

Table 1 shows the distribution of demographic variables among health care students. Out of 150 students, 90 (60%) were in the age group of 18-20 years. Regarding gender, 105 (70%) were female. Regarding allergy 142 (95 %) had no history of allergy. Regarding respiratory problems, 135 (90%) had no history of respiratory problems. In symptoms before 127 (85) had no symptoms before vaccination. Regarding motivation for vaccination 38 (26%) were motivated by vaccine awareness program. No students tested positive for COVID-19 before vaccination.

Table 1: Frequency and Percentage distribution of Demographic variables among health care students (N=150)

S. No	Demographic Variables		Frequency	Percentage
1.	Age in years	18-20	90	60
		20-22	38	25
		22-24	12	8
		24-26	10	7
2.	Gender	Male	45	30
		Female	105	70
3.	History of any allergies	Yes	8	5
		No	142	95

Table 1: ***(Continued)***

S. No	Demographic Variables		Frequency	Percentage
4.	History of respiratory problems	Yes	15	10
		No	135	90
5.	Symptoms before Vaccination	Yes	23	15
		No	127	85
6.	The vaccine has taken in the past 6 months	Yes	9	6
		No	141	94
7.	Ever tested positive for COVID 19	Yes	0	0
		No	150	100
8.	Family members tested positive for COVID 19	Yes	10	7
		No	140	93
9.	Motivation for COVID 19 Vaccination	Self-motivated	45	30
		Vaccine Awareness program	38	26
		Social media	15	10
		World leaders getting vaccinated	21	14
		Motivated by family members	17	11
		Motivated by teachers	14	9

Table 2 shows the frequency and percentage distribution of very common adverse events after vaccination among health care students. Out of 150 students, 98 (65%) had pain, redness, warmth, swelling, itching at the injection site, 102 (68%) felt unwell after vaccination, 90 (60%) had the symptoms of tiredness after vaccination, 87 (58%) had a headache after vaccination. 72 (48%) had muscle pain after vaccination.

Table 2: Frequency and percentage distribution of very common adverse events after the first dose of vaccination among health care students (N=150)

S. No	Very Common Adverse events	Yes		If Yes onset of Symptoms on						Duration of Symptoms				No	
				Day 0		Day 1		Day 2		In Hrs		In Days			
		f	%	f	%	f	%	f	%	f	%	f	%	f	%
1.	Tenderness, pain, warmth, redness, itching, swelling, or bruising at the injection site	98	65	15	15	38	39	45	46	10	10	88	90	52	35
2.	Unwell after the vaccination	102	68	30	29	49	49	23	22	81	79	21	21	48	32
3.	Tiredness (fatigue) after vaccination	90	60	30	34	45	50	15	16	75	83	15	17	60	40
4.	Chills or feverish after vaccination	83	55	30	36	42	51	11	13	10	12	73	88	67	45
5.	Headache after vaccination	87	58	15	17	52	60	20	23	25	29	62	71	63	42
6.	Feeling of nausea after vaccination	78	52	45	58	27	35	6	7	55	71	23	29	72	48
7.	Having muscle ache	72	48	52	73	15	21	5	6	21	29	51	71	78	52

Table 3 shows the frequency and percentage distribution of common adverse events after vaccination among health students. Out of 150 students, 30 (20%) had joint pain, 18 (12%) had a lump at the injection site, 21 (14%) had the symptoms of vomiting, 27 (18%) had flu-like symptoms.

Table 3: Frequency and percentage distribution of common adverse events after the first dose of vaccination among health care students (N=150)

S. No	Common Adverse Events	Yes		If Yes onset of Symptoms on						Duration of Symptoms				No	
				Day 0		Day 1		Day 2		In Hrs		In Days			
		f	%	f	%	f	%	f	%	f	%	f	%	f	%
1.	Having Joint pain	30	20	18	60	8	27	4	13	5	17	25	83	120	80
2.	Lump at the injection site	18	12	10	56	6	33	2	11	4	22	14	78	132	88
3.	Vomiting episode after vaccination	21	14	15	71	2	10	4	19	6	29	15	71	129	86
4.	Flu-like symptoms, such as high temperature, sore throat, runny nose, cough, and chills	27	18	19	70	3	11	5	19	8	30	19	70	123	82

Table 4 shows frequency and percentage distribution of uncommon adverse events after vaccination among health care students. Out of 150 students, 5 (3%) had a feeling of dizziness, 3 (2%) had a loss of appetite, 6 (4%) had abdominal pain, 2 (1%) had excessive sweating.

Table 4: Frequency and percentage distribution of uncommon adverse events after the first dose of vaccination among health care Students (N=150)

S. No	Adverse events	Yes		If Yes onset of Symptoms on						Duration of Symptoms				No	
				Day 0		Day 1		Day 2		In Hrs		In Days			
		f	%	f	%	f	%	f	%	f	%	f	%	f	%
1.	Feeling dizziness after vaccination	5	3	4	80	1	20	0	0	3	60	2	40	145	97
2.	Loss of appetite after vaccination	3	2	1	33	2	67	0	0	1	33	2	67	147	98
3.	Abdominal pain after vaccination	6	4	0	0	4	67	2	33	4	67	2	33	144	96
4.	Excessive sweating after vaccination	2	1	1	50	1	50	0	0	2	100	0	0	148	99

Table 5 shows that there was no significant association of gender, history of allergy and history of respiratory problems with the body temperature among health care students.

Table 5: Association between selected demographic variables with body temperature among health care students (N=150)

Demographic Variables	f	Mean	SD	Sum of Square		Mean Square		ANOVA Test
				Between Group	Within Group	Between Group	Within Group	
Gender a. Male b. Female	 45 105	 98.74 98.76	 0.637 0.665	0.011	63.989	0.011	0.432	F=0.026 Df= 1,148 P =0.871 Not Significant
History of Allergy a. Yes b. No	 8 142	 98.95 98.74	 0.776 0.649	0.305	63.69	0.305	0.430	F=0.709 Df= 1,148 P=0.401 Not Significant
History of Respiratory problems a. Yes b. No	 15 135	 98.73 98.76	 0.631 0.662	0.012	63.988	0.012	0.432	F=0.027 Df= 1,148 P=0.869 Not Significant

DISCUSSION

This study was conducted to assess the incidence of adverse events following the Covid 19 vaccine shot among health care students. The findings of the study show that 57 % had very common adverse events, 16% had common adverse events, 4 % had uncommon adverse events. This was supported by Polack et al. in the study on the safety and efficacy of the BNT162b2 mRNA Covid-19 Vaccine. It is a randomised clinical trial with a sample of 43,548. Participants are randomly assigned in a ratio of 1:1 to the experimental group and the control group. The experimental group and control group received two doses of BNT162b2 vaccine and placebo 21 days apart respectively. The results the indicated that BNT162b2 vaccine was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6). The participants were developed adverse events such as short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low.[23] The study concluded that a two-dose regimen of BNT162b2 gave 95% protection against Covid-19. The present study is also consistent with a study conducted by Zhu et al. aimed to assess the immunogenicity property of recombinant adenovirus type 5 vectored COVID-19 vaccine.

It is a randomised clinical trial consist of 195 samples. Adults aged between 18 and 60 years were registered and allotted to any one of three dose groups (Low, Medium, High) divided based on the concentration of viral particles to receive an intramuscular injection of vaccine. Adverse events were studied one-week post-vaccination. The results of the study indicated that at least one adverse reaction within the first 7 days of post-vaccination was reported in 83% of participants in the low dose group, 83% participants in the medium-dose group, and 75% participants in the higher dose group. The commonly reported adverse reaction was injection site pain in 54% of recipients, and the most reported systematic adverse reactions were fever 46%, fatigue 44%, headache 39%, and muscle pain 17%. Most adverse reactions that were reported in all groups were mild or moderate level of severity. The study concluded that the adenovirus type 5 vector vaccine needs further investigation.[24]

CONCLUSION

Even though few newly developed vaccines demonstrate efficacy up to 95%, multi-disciplinary level rigorous studies are required to determine the safety of the vaccine which includes minimizing the adverse events following the vaccination shot.

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ETHICAL CLEARANCE: The principal investigator obtained informed written consent from the samples before commencing the study. The study was conducted according to the World Medical Association Declaration of Helsinki ethical principles for Medical Research Involving Human Subjects.[25]

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AUTHORS' CONTRIBUTIONS

Lathamangeswari C - Conception and drafting of the work, analysis and interpretation of data, critical revision, Manuscript writing and accountability for the work.

Pandurangan H – Collection and interpretation of data, critical revision, finalizing the Manuscript and accountability for the work.

Ramaiah P- Literature review, interpretation of data, critical revision, finalizing the Manuscript and accountability for the work.

Muthukrishnan A -Design of the work, analysis and interpretation of data, critical revision, Manuscript writing and accountability for the work.

CONFLICT OF INTEREST: The authors declare no conflict of interest

REFERENCES

1. WHO. Novel Coronavirus – China. 2021. https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/
2. Symptoms of Coronavirus. CDC.2021. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
3. Prevention of Coronavirus Disease(COVID-19). CDC.2021. https://web.archive.org/web/20200311163637/https://www.cdc.gov/coronavirus/2019-ncov/about/prevention.html
4. Quarantine for coronavirus. Australian Government Department of Health.2021. https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/how-to-protect-yourself-and-others-from-coronavirus-covid-19/quarantine-for-coronavirus-covid-19#what-is-a-close-contact
5. Buitrago-Garcia D, Egli-Gany D, Counotte MJ, Hossmann S, Emeri H, Ipekci AM, et al. Occurrence and transmission potential of asymptomatic and presymptomatic SARSCoV-2 infec-

tions: A living systematic review and meta-analysis. Plos Med. 2020;17:e1003346.
6. Oran DP, Topol EJ. The Proportion of SARS-CoV-2 Infections That Are Asymptomatic. Ann Intern Med. 2021;174(5):655-662.
7. Chen N, Zhou M, Dong X, Qu J, Han Y. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. Lancet. 2020;395(10223):507–513.
8. Lauer SA, Grantz KH, Bi Q, Jones FK, Meredith HR. The incubation period of coronavirus disease 2019 (CoVID-19) from publicly reported confirmed cases: Estimation and application. Ann Intern Med. 2020;172(9):577–582.
9. Li Q, Guan X, Wu P, Wang X, Tong Y. Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus–Infected Pneumonia. N Engl J Med. 2020;382(13):1199–1207.
10. Guan W, Ni Z, Hu Y, Liang W, He J. Clinical Characteristics of Coronavirus Disease 2019 in China. N Engl J Med. 2020382(18):1708–1720.
11. Steinbrecht W, Kubistin D, Plass-Dülmer C, Davies J, Gathen P von der, et al. COVID-19 Crisis Reduces Free Tropospheric Ozone across the Northern Hemisphere. Geophys Res Lett. 2021; 48(5): https://doi.org/10.1029/2020GL091987
12. In Hunt for Covid-19 Origin, Patient Zero Points to Second Wuhan Market - WSJ 2021. https://www.wsj.com/articles/in-hunt-for-covid-19-origin-patient-zero-points-to-second-wuhan-market-11614335404
13. Mullard A. How COVID vaccines are being divvied up around the world. Nat 2020. https://www.nature.com/articles/d41586-020-03370-6
14. China can hit 500-mln-dose annual capacity of CanSinoBIO COVID-19 vaccine this year-state media.2021. https://ca.sports.yahoo.com/news/china-hit-500-mln-dose-103509138.html
15. Coronavirus (COVID-19) Vaccinations - Statistics and Research - Our World in Data 2021. https://ourworldindata.org/covid-vaccinations
16. Covid-19 vaccine: who are countries prioritising for first doses?. Coronavirus. The Guard. 2021. https://www.theguardian.com/world/2020/nov/18/covid-19-vaccine-who-are-countries-prioritising-for-first-doses
17. What to Do If You Are Sick with 2019-nCoV CDC. 2021. https://web.archive.org/web/20200214153016/https://www.cdc.gov/coronavirus/2019-ncov/about/steps-when-sick.html
18. Deckert A, Anders S, de Allegri M, Nguyen HT, McMahon S, et al. Effectiveness and cost-effectiveness of four different strategies for SARS-CoV-2 surveillance in the general population (CoV-Surv Study): a structured summary of a study protocol for a cluster-randomised, two-factorial controlled trial. 2021;22.
19. Nussbaumer-Streit B, Mayr V, Dobrescu AI, Chapman A, Klerings I, et al. Quarantine alone or in combination with other public health measures to control COVID-19. Joh WileS Ltd; 2020. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013574/full
20. Lau SKP, Luk HKH, Wong ACP, Li KSM, He Z, et al. Possible Bat Origin of Severe Acute Respiratory Syndrome Coronavirus 2. Emerg Infect Dis. 2021;26(7):1542–1547.
21. Ella R, Reddy S, Jordan H, Sarangi V, Prasad S, et al. Safety and immunogenicity clinical trial of an inactivated SARS-CoV-2 vaccine, BBV152 (a phase 2, double-blind, randomised controlled trial) and the persistence of immune responses from a phase 1 follow-up report. medRxiv. 2020.12.21.20248643. https://doi.org/10.1101/2020.12.21.20248643
22. Logunov DY, Dolzhikova I V., Zubkova O V., TukhvatullinAI, Dzharullaeva AS, et al. Safety and immunogenicity of a rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. Lancet. 2020;396(10255):887–897.
23. Zhu FC, Li YH, Guan XH, Hou LH, Li XJ, et al. Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial. Lancet. 2020;395(10240):1845–1854.
24. Polack FP, Thomas SJ, Kitchin N, Absalon J, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383(27):2603–2615.
25. Association world medical. WMA Declaration of Helsinki -Ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-2194