Assessment of Adverse Events of Covishield Vaccine Among Vaccinated Employees of aTeritiary Health Care Setting

Mrs.Soni.P.S[1], Mrs. Vineeta Jose[2], Mrs. Thanseela.T[3],Dr. Susan Jose[4],

[1]*MSc Nursing, Professor, HOD, Department of Community Health Nursing,KIMS College of Nursing,*
[2]*M.Sc. Nursing, Assistant Professor, Department of Community Health Nursing, KIMS College of Nursing*
[3]*M.Sc. Nursing, Lecturer, Department of Community Health Nursing, KIMS College of Nursing*
[4]*Ph. D, M.Sc. Nursing, Principal and HOD, Department of Medical –Surgical Nursing, KIMS College of Nursing*
Corresponding author: Mrs. Soni.P.S, Professor, HOD, Department of Community Health Nursing, KIMS College of Nursing,Chempakamangalam, Korani P.O, Trivandrum-695104

Abstract:
The present study was conducted to assess the adverse events of Covishield vaccine among vaccinated employees in a tertiary care Setting, Thiruvananthapuram.The objectives of the study wereto assess the adverse events (immediate & delayed adverse events) of Covishield vaccine among vaccinated employees and to find out the association between the immediate and delayed adverse events of Covishield vaccine and selected socio-personal variables (age, Gender, Occupation, presence of comorbidities, presence of contraindications to Vaccine, History of Covid infection).An online descriptive survey design was used for the study. 709 vaccinated employees responded to the survey who satisfied the inclusion criteria during the data collection period in month of April -July-2021 and used a Convenient sampling Technique.A Survey Tool to assess the adverse events of Covishield vaccine among vaccinated employees was used for Data Collection. Immediate and delayed adverse events was surveyed from each participant.Link for Survey has been shared directly through What's App/ e-mail OR indirectly through HODs of the concerned Departments.The participant who has given Consent, were further proceeded with the access to data collection tool. This descriptive survey findings revealed majority of Vaccinated employees with Covishield Vaccination, 84% were not having any immediate adverse events within 30 minutes and about 33.9% not having any delayed Adverse Events from 30 minutes with in 1week after Vaccination.Of those who had immediate adverse events, predominant one identified was Pain at Vaccination Site and Headache (4.9%).Of those who had Delayed adverse events, predominant one identified was Fever (38.8%). All the symptoms were mild and lasted less than 1 week. None reported with any severe AEFI. There was statistically significant association between Immediate and Delayed adverse events of Covishield Vaccine with selected socio personal variables
Key Word: *Adverse events of Vaccine*

I. Background of the Study

The COVID had their ill effects on all dimensions of human life including physical, psychological, social, and financial aspects of health. According to then prevailing COVID-19 statistics in worldwide, nearly 114.8 million confirmed cases, 90.3 million cases were recovered and 2.54 million faced death.

In India 11.4 million confirmed cases whereas 10.8 million cases recovered and 182 thousand died from COVID-19. In Kerala, 1011 thousand total cases, 1092 thousand cases recovered, and 4250 death cases were reported whereas in Trivandrum 102483 confirmed cases, 99058 cases were recovered and 1024 faced death. The latest information in the path of battle with the corona virus was the invention of vaccine.

Kerala started with Vaccination Drive from 16th January 2021. Drive started with Covishield Vaccine for Health Care Workers and Frontline workers. Adverse events are common with any drug/ Vaccine.So, a survey on adverse events helps to take adequate measures in the vaccination setting as well as to get an awareness for all.

Need and Significance: In Kerala, only Covishield Vaccine was available and only Health Care Professionals were included in the Drive in the beginning of Vaccination Venture. KIMSHEALTH is one of the health care institutions which was actively involved in the vaccination drive as per the recommendations issued by the Government of India. A total of 200-300 persons gets vaccinated every day. Employees who participated in the Vaccination, few of them developed mild to moderate side-effects. Thus, the researchers felt the need to conduct a research survey on the adverse events of vaccine in vaccinated employees.

Statement of the problem
       A study to assess the Adverse Events of Covishield Vaccine Among Vaccinated Employees of a Teritiary Health Care Setting, Thiruvananthapuram.

Objectives
To assess the adverse events (immediate & delayed adverse events) of Covishield vaccine among vaccinated employees.
To find out the association between the immediate and delayed adverse events of Covishield vaccine and selected socio-personal variables.

II.   Materials and Methods:
Study Setting: Study was conducted in KIMSHEALTH, Trivandrum
Study Design: An online descriptive survey design was used.
Study Population: Population of the study included all vaccinated employees of KIMSHEALTH, Trivandrum

Inclusion criteria:
All employees who were willing to participate in the study.
Employees who were vaccinated with Covishield.
Employees who completed one week after receiving the vaccination.

Exclusion criteria:
Those who couldn't read and write English or Malayalam.
Employees who could not comply the online modes of data collection.
Surveyed Sample Size (N=709)
Sampling Technique: Convenient sampling Technique.

III.   Methodology:
       Link for Survey has been shared directly through What's App/ e-mail OR indirectly through HODs of the concerned Departments. The participants received the Google form link with an online informed consent and participant information sheet. The participant who has given Consent, were further proceeded with the access to data collection tool.

STUDY VARIABLES:
       Socio personal variables such as age, gender, occupation, comorbidities, history of any allergies or any other contraindications and History of Covid-19 infection were included.
       Study variables: Adverse events (immediate and Delayed events) of Covishield vaccine among vaccinated employees.

DATA COLLECTION TOOL
ONLINE SURVEY TOOL

Section A
Socio personal data to assess age, sex, occupation, comorbidities, history of any allergies or any other contraindications and history of Covid -19.
Section B
Tool to assess the adverse events of Covishield vaccine among vaccinated employees.
Mode of Data Collection:
Data was collected using Google forms with link sent through What's App/ e-mail

IV. Analysis

Descriptive and inferential statistical methods were used to analyse the data with statistical software SPSS.
Frequency and Percentage was used to compute the Immediate and delayed adverse events of Covishield vaccine

Chi-square test was used to assess the association between the (immediate and delayed) adverse events of Covishield vaccine with the selected socio-personal variables

SECTION-A-Frequency Distribution of Socio-Personal Variables

SL NO:	AGE GROUP	f	%
1	20-29	255	36
2	30-39	267	37.7
3	40-49	136	19.2
4	50-59	19	2.7
5	60-69	18	2.5
GENDER			
1	Male	241	34
2	Female	468	66
OCCUPATION			
1	Physician	116	16.4
2	Nurse	270	38.1
3	Paramedical	181	25.5
4	Administration	39	5.5
5	Supporting Service	103	14.5
COMORBIDITIES			
1	NO comorbidities	551	77.7
2	CVS Problems	10	1.4
3	Renal Problems	0	0
4	Hepatic Problems	1	0.001
5	Diabetes	31	4.4
6	Hypertension	47	6.63
7	Cancer	6	0.008
8	Thyroid Problems	79	11.1

9	Neuro Problems	5	0.007
10	Immuno compromised	1	0.001
CONTRAINDICATIONS			
1	No Contraindications	653	92
	Food Allergy	36	5.1
3	Drug allergy	16	2.3
4	Autoimmune Disease	6	0.008
5	Bleeding disorders	4	0.006
HISTORY OF COVID INFECTION			
1	Infected	175	24.7
2	Non-Infected	534	75.3

SECTION B 1. Frequency Distribution of Immediate Adverse Events of Covishield Vaccination   N=709

SL NO:	IMMEDIATE ADVERSE EVENTS	f	%
1	Nil	596	84
2	Pain at site	35	4.9

3	Fatigue	23	3.2
4	Chills	12	1.7
5	Head ache	35	4.9
6	Nausea	5	0.71
7	Joint pain	20	2.8
8	Fever	30	4.2
9	Vomiting	2	0.28
10	Flu-like s/s	6	0.85
11	Dizzy	13	1.83
12	Abdominal pain	2	0.28
13	Excessive sweating, rashes	0	0
14	Anaphylaxis	0	0

SECTION B 2. Frequency Distribution of Delayed Adverse Events of Covishield Vaccination   N=709

SL NO:	DELAYED ADVERSE EVENTS	f	%
1	Nil	240	33.9
2	Pain at site	91	12.8
3	Fatigue	237	33.4

4	Chills	119	16.8
5	Head ache	210	29.6
6	Nausea	42	5.9
7	Joint pain	185	26.1
8	Fever	275	38.8
9	Vomiting	20	2.8
10	Flu-like s/s	20	2.8
11	Dizzy	45	6.4
12	Abdominal pain	12	1.7
13	Excessive sweating, rashes	2	0.28
14	Anaphylaxis	0	0

SECTION-C-1. ASSOCIATION BETWEEN PREDOMINANT IMMEDIATE ADVERSE EVENTS OF VACCINATION (PAIN AT VACCINATION SITE) AND SOCIO-PERSONAL VARIABLES N=709

With Age Group						
Socio-Personal Variable-Age	Adverse event Pain at site		With /without Adverse events other than Pain at site		df	Chi-Square Value
	f	%	f	%		
20-29	250	98.0%	5	2.0%		9.604 (Fisher's Exact Test Value)
30-39	261	92.9%	20	7.1%	4	

With Gender				
Socio-Personal Variable-Gender	Adverse event Pain at site	With /without Adverse events other than Pain at site	df	Chi-Square Value

	f	%	f	%		
Male	224	92.9%	17	7.1%	1	3.488
Female	450	96.2%	18	3.8%		

With Occupation

Socio-Personal Variable-Occupational Category	Adverse event Pain at site		With /without Adverse events other than Pain at site		df	Chi-Square Value (Fisher's Exact Test Value)
	f	%	f	%		
Physician	80	69.0%	36	31.0%	4	7.810
Nurse	161	59.6%	109	40.4%		
Paramedical	112	61.9%	69	38.1%		
Administration	23	59.0%	16	41.0%		
Supporting Service	57	55.3%	46	44.7%		

with presence of comorbidities

Socio-Personal Variable-Presence of comorbidities	Adverse event Pain at site		With /without Adverse events other than Pain at site		df	Chi-Square Value
	f	%	f	%		
Presence of comorbidities	527	95.6%	24	4.4%	1	1.777
Absence of comorbidities	147	93.0%	11	7.0%		

With presence of contraindications to Vaccination

Socio-Personal Variable-Presence of contraindications	Adverse event Pain at site		With /without Adverse events other than Pain at site		df	Chi-Square Value
	f	%	f	%		
Presence of contraindications	623	95.4%	30	4.6%	1	2.065
Absence of contraindications	51	91.1%	5	8.9%		

With History of Covid-19 infection

Socio-Personal Variable-Presence of History of Covid-19 infection	Adverse event Pain at site		With /without Adverse events other than Pain at site		df	Chi-Square Value
	f	%	f	%		
Infected	171	97.7%	4	2.3%	1	3.479
Non-Infected	503	94.2%	31	5.8%		

SECTION-C-2. ASSOCIATION BETWEEN PREDOMINANT DELAYED ADVERSE EVENTS OF VACCINATION (FEVER) AND SOCIO-PERSONAL VARIABLES N=709

With Age Group						
Socio-Personal Variable-Age	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
20-29	148	58.0%	107	42.0%	4	7.306
30-39	173	61.6%	108	38.4%		
40-49	83	61.0%	53	39.0%		

| 50-59 | 13 | 68.4% | 6 | 31.6% | | |
| 60-69 | 16 | 88.9% | 2 | 11.1% | | |

with Gender						
Socio-Personal Variable-Gender	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
Male	164	68.0%	77	32.0%	1	7.478
Female	269	57.5%	199	42.5%		

with Occupation						
Socio-Personal Variable-Occupational Category	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
Physician	80	69.0%	36	31.0%	4	4.822
Nurse	161	59.6%	109	40.4%		
Paramedical	112	61.9%	69	38.1%		
Administration	23	59.0%	16	41.0%		
Supporting Service	57	55.3%	46	44.7%		

With presence of comorbidities						
Socio-Personal Variable-Presence of comorbidities	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
Presence of comorbidities	342	62.1%	209	37.9%	1	1.034
Absence of comorbidities	91	57.6%	67	42.4%		

With presence of contraindications to Vaccination						
Socio-Personal Variable-Presence of contraindications	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
Presence of contraindications	390	59.7%	263	40.3%	1	6.315
Absence of contraindications	43	76.8%	13	23.2%		

With History of Covid-19 infection						
Socio-Personal Variable- Presence of History of Covid-19 infection	Adverse event Fever		With /without Adverse events other than Fever		df	Chi-Square Value
	f	%	f	%		
Infected	90	51.4%	85	48.6%	1	9.089
Non-Infected	343	64.2%	191	35.8%		

V.   Results:

Section-A- Frequency Distribution of Sample characteristics based on socio personal variablesAmong 709 participants, majority of the participants (37.7%) belong to the age group of 30-39 and 36% of the participants belong to the age group of 20-29, 66%were females and 34% were males, most of the participants (38.1%) were nurses and 25.5% were paramedical. About 77.7% were having no co morbidities. Other comorbidities identified among the participants Asthma (0.8%), Migraine/Anaemia/Dyslipidaemia (0.3%) andArthritis, DVT, PCOD, Psoriasis, Tonsillitis.Majority of the participants (92%) were having no contraindications to Covishield and75.3% were not having History of Covid 19 infection

Section-B-1. Frequency Distribution of Immediate Adverse Events of Covishield Vaccinationshows that majority of the participants (84 %) were not having any Immediate Adverse Events with Covishield Vaccination. Of those who had immediate adverse events, predominant one identified was Pain at Vaccination Site and Headache (4.9%)

Section-B-**2.** shows that majority of the participants (33.9%) were not having any Delayed Adverse Events with Covishield Vaccination. Of those who had Delayed adverse events, predominant one identified was Fever (38.8%)

Section-C-1. Association Between Predominant Immediate Adverse Events of Vaccination (Pain At Vaccination Site) And Socio-Personal Variables
There is a statistically significant association between predominant immediate Adverse event - Pain at vaccination site with Age (p<0.05).Chi- Square Value to find the association with Gender, with Occupation, with presence of comorbidities, with presence of contraindications to Vaccination and with History of Covid-19 infection shows no statistically significant association (p>0.05)

Section-C-2. Association Between Predominant Delayed Adverse Events of Vaccination (Fever) And Socio-Personal Variables
There is statistically significant association between predominant Delayed Adverse event of Fever with with Gender, Presence of comorbidities, with Socio-Personal Variable- History of Covid-19 infection (p<0.05)
.Chi- Square Value to find the association between predominant delayed Adverse event – fever with Age, with Occupation and with presence of contraindications to Vaccination shows no statistically significant association (p>0.05)

VI.   Discussions

Analysis of the collected data was done using descriptive and inferential statistics. Frequency distribution used to identify percentage distribution of the socio-personal variables, the proportion of Adverse events and Chi square tests (Pearson Chi-Square value and Fisher's Exact Test value) were used to find the association of adverse events with selected socio-personal variables (age, Gender, occupational category, presence of comorbidities, presence of Contraindications to Covishield Vaccine and history of Covid-19 infection).

Section-A- Discussion on Sample characteristics based on socio personal variables
Results showed majority of the participants (37.7%) belong to the age group of 30-39 and 36% of the participants belong to the age group of 20-29. Out of the 709 samples 66% of the participants were females and 34% were males. Among the participants (38.1%) were nurses and 25.5% were paramedical. About 77.7% of the participants were having no co morbidities and 92% having no contraindications to Covishield. Results identified that majority of the participants (75.3%) were not having History of Covid 19 infection.

Section-B-1. Percentage distribution of Immediate Adverse Events
Findings implicated that majority of the participants (84 %) were not having any Immediate Adverse Events with Covishield Vaccination. Of those who had immediate adverse events, predominant one identified was Pain at Vaccination Site and Headache (4.9%)

Section-B-2. Percentage distribution of Delayed Adverse Events
Findings also revealed about 33.9% of the participants were not reported to have any Delayed Adverse Events with Covishield Vaccination. Of those who had Delayed adverse events, predominant one identified was Fever (38.8%)
All the symptoms were mild and lasted less than 1 week. None reported with any severe AEFI

For Section-A &B:
This study findings are related with findings of another study at Bangladesh- Adverse Events Following COVISHIELD Vaccination Among Adult Population in Bangladesh. Among the 305 participants, 173 were males (56.4%), with their mean age being 47 years. The adverse events were significantly higher following the 1st dose compared to the 2nd dose (*p* < 0.001). The most frequent adverse event was pain at the injection site that was reported among 99 (32.5%) after the 1st dose and 85 (27.9%) after the 2nd dose.

Fever was recorded among 61 (20%) in 1st dose and 37 (12.1%) in the 2nd dose. Fatigue, malaise, generalized body ache, and headache were recorded 6.9%,16.4%, 16.4%, and 6.9%, respectively. However, none of the participants had severe life-threatening adverse events.

Related Study Findings: adverse events reported consistent with the findings of A prospective observational study in South India-Adverse events following ChAdOx1 nCoV-19 Vaccine (COVISHIELD) amongst health care workers:Total of 981 recipients were enrolled in the study. demographic data revealed 77.2% males & 22.8% females, as per profession Doctors(9.5%), Nurses(4%), Paramedicals (86.4%), age group maximum belonged to 18-30 yrs. (48.4%)Common adverse events included feeling unwell (N-186, 19%), headache (N-171, 17.4%), fever (N-123, 12.5%), fatigue (N-121, 12.3%) and muscle ache (N- 110,11.2%). 66 non - serious adverse events were reported between 8 and 14 days (day15). No adverse events were reported in the last two weeks. 2 serious adverse events (negligible) were noted in the first 48 hours .

Section-C Association of adverse events of Covishield Vaccination with socio-personal variables were analyzed using Chi square test.

Chi square test was applied to check the association between the predominant immediate adverse event, pain at vaccination site and Socio- personal variables and also between the predominant delayed adverse event fever with Socio- personal variables. (Age, Gender, occupational category, presence of comorbidities, presence of Contraindications to Covishield Vaccine and history of Covid-19 infection).

From the findings it was identified:

There is statistically significant association found between predominant immediate adverse event - pain at vaccination site with age.

There is statistically significant association found between predominant delayed adverse event fever with gender, with presence of co morbidities, with history of covid-19 infection

The analysis of survey revealed no other significant association with the socio-personal variables. Therewas no relevant study findings available that supports the above results

Suggestions

• The study could have done with other available Vaccines also.
• The study could have been done to identify adverse events of Vaccination with first and Second Dose separately.
• The study could have done in General Public also.

• **Implications**
• These results could help to get valuable information that improve knowledge base, help to create better awareness among the public on adverse events and in turn promote more participation with more acceptance towards Covishield vaccines.
• It aids to prepare IEC materials to utilize in awareness sessions.
• It may also help to modify protocols and guidelines to proceed with the vaccination venture.

VII.   Conclusion:

This descriptive survey revealed majority of Vaccinated employees with Covishield Vaccination, 84% were not having any immediate adverse events within 30 minutes and about 33.9% not having any delayed Adverse Events from 30 minutes with in 1week after Vaccination.All the symptoms were mild and lasted less than 1 week. None reported with any severe AEFI

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