

ADVERSE EFFECTS FOLLOWING COVID-19 IMMUNIZATION IN KHYBER PAKHTUNKHWA: PAKISTAN

Ayesha Zafar¹, Saima Abid², Naveeda Sarwar², Adil Zareef³, Nauman Khan², Abdul Basit², Rida Ubaid², Zarafshan Johar², Ulfat Kamal², Hira Afridi², Shehryar Khan², Lutfullah², Abdul Majid², Mian Haider Khan², M. Talha Khan²

¹Department of Neurology, Lady Reading Hospital Peshawar

²Department of Community Medicine, Pak International Medical College Peshawar

³North West School of Medicine

ABSTRACT

Background: Adverse event following immunization (AEFI) is defined as any untoward medical occurrence following immunization and does not necessarily have a causal relationship with the use of the vaccine.

Objective: To determine the adverse effects following (AEFI) of COVID 19 vaccines in the population of Khyber Pakhtunkhwa (KP).

Methods and materials: Descriptive Cross-sectional study was conducted from June to September 2021 on four hundred and three sample size of KP, selected using Cochran's formula. AEFI's were investigated among vaccinated male and female above 18 years. Data was collected through a self-constructed validated questionnaire and was analyzed through SPSS 25.

Results: Out of total 403, 219 (54.3%) did not reported any AEFI, 184 (45.4%) complaint of mild and only one (0.2%) reported severe AEFI. The most common AEFI was pain at the injection site 99 (24.6%) followed by mild fever 20 (5.0%), body aches 17(4.2%) and headache 13 (3.2%). 165 (40.9 %) observed the AEFI within 48 hours while 238 (59%) observed it after 48 hours of immunization. Only 8 (2%) pregnant women and 11(2.7%) lactating mothers vaccinated themselves.

Conclusion: Majority of the study population in KP did not suffer from any AEFIs after COVID 19 vaccination. Pregnant and lactating mothers were hesitant to vaccinate.

Key words: Pandemic, Covid 19 immunization, vaccine, pregnant, lactating mothers, AEFI, Pakistan.

INTRODUCTION

Adverse event following immunization (AEFI) means any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the use of the vaccine¹. It may be any unfavorable or unintended sign, an abnormal laboratory finding, a symptom or a disease². If not dealt with rapidly and effectively, it can

undermine vaccine confidence and ultimately have dramatic consequences for immunization coverage and disease incidence. Initially, with the COVID-19 vaccination roll out in Pakistan during February 2021 Sinopharm, Sinovac and CanSino were introduced to the health care workers followed by Astra Zeneca, Pfizer and PakVac³. Vaccine hesitancy was observed in KP due to adverse events reported worldwide i.e., bleeding disorders etc. and rumors/ negative propaganda of deaths^{4,5}. According to experts COVID-19 vaccines are not hazardous for the fetus or breast-feeding infant⁶⁻¹². However, it was observed that there was vaccine hesitancy among public especially pregnant and lactating mothers due to lack of trials in this particular group and misconceptions about

Correspondence:

Dr. Saima Abid

Associate Professor, Pak International Medical College

Peshawar KP

Cell: +923410002272

Email: saimabidrr@gmail.com

adverse effects on baby¹³. According to the WHO, like any other vaccine, COVID 19 Vaccines can have adverse effects. Some of the adverse effects of COVID-19 vaccines reported were of mild to moderate intensity and for shorter duration of time lasting for few days. The most common adverse effects included pain at the injection site, fever, weakness, headache, muscle ache and diarrhea¹⁴. Rare side effects of vaccines may include anaphylaxis and other severe neurological effects among people with the history of allergy and anxiety respectively¹⁵. According to the experts, adverse effects after vaccination are normal and are not alarming. Rather it depicts that the vaccine is working and immune system of the vaccinated person is responding to the antigen and is getting ready to fight back the infection. Such adverse effects are usually self-limiting and for short duration¹⁴. However, it does not mean that vaccines were ineffective on people with no adverse effects. Being new vaccines in local settings, there was a deficiency of the information on short term adverse effects following COVID -19 vaccination among local population of Khyber Pakhtunkhwa. In order to address the rumors and enhance the vaccine confidence, there was a need to determine the magnitude of AEFIs amid local resident. Results of this study may be use as a reference for the future studies as well as for the policy makers.

MATERIAL AND METHOD

After ethical permission from ASRB, this cross-sectional survey was conducted from 1st July to 30th September 2021 on four hundred and three sample size based on Cochran's formula with 50% prevalence, 95% confidence interval and 0.05% margin of error on 18 years and above population of Khyber Pakhtunkhwa. Data was collected through pre-tested self-constructed questionnaire, including open and close ended dichotomous and multiple-choice questions. Under 18 years, unvaccinated, belonging to other provinces, unwilling to participate in the survey were excluded. Data was analyzed using MS Excel and SPSS. Frequency, percentages, Chi square test were calculated and T test was applied to compare mean differences.

RESULTS

When asked about "what make them choose to vaccinate themselves": 51.9 % said that that "it was their personal decision", for 6.9 % it was a family

Table 1: Demographic Characteristics of the study population

Demographic Characteristics	N	%
Gender		
Male	188	46.7
Female	215	53.1
Age (mean age= 29.37%, SD ±11.1)		
17-37	323	80
38- 58	68	16.8
59-79	12	2.9
Marital Status		
Single	262	65
Married	137	34
Don't want to disclose	4	1
Educational Status		
Illiterate	8	2.0
Undergraduate	190	47.1
Graduate	90	22.3
Post Graduate	115	28.5
Location (Divisions)		
Peshawar	219	54.3
Mardan	19	4.7
Kohat	16	4.0
D.I. Khan	2	0.5
Malakand	41	10.2
Hazara	31	7.7
Other places	75	18.6

AEFIs values for gender Male ($\bar{x}=6.47$), female ($\bar{x}=5.30$), t-test = $p < .05$. Cohan's $d = 0.34$ with medium effect size.

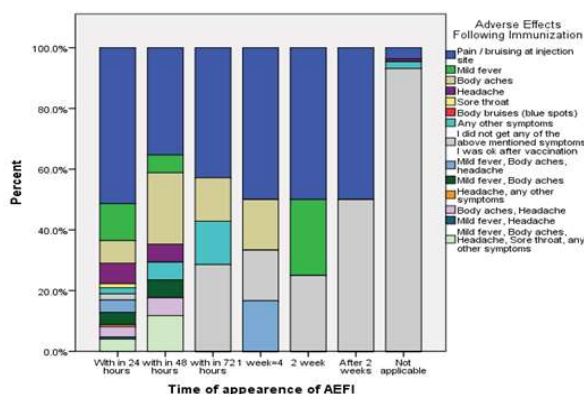


Figure 1: Percentage of population, with side effects days following immunization and type of side effects.

decision, 4.2% said it was a compulsion by the employer, 10.4 % said to meet the government requirements, 2.2 % to fulfil travel requirements, and 22.3 % said to protect the community. 69.7 % completed the second dose, 13.9 % didn't get the second dose while 10.4 % said that they have received the code

Table 2: Choice of vaccine by the vaccinated population (n=403)

Type of vaccine	N	%
Single Dose (Ad5-ncov)	20	5.0
PakVac	5	1.2
CanSino – (Chinese)	15	3.7
Double Dose	360	89.3
Pfizer (RNA-BNT-162b2)	14	3.5
Moderna (mRNA-1273)	13	3.2
AstraZeneca AZD1222 (ChAdOx1)	5	1.2
Sinopharm (BBIBP- Corv)- Chinese	172	42.7
Sinovac (CoronaVac)- Chinese	156	38.7
Unvaccinated	1	0.2
Don't Know	22	5.5

Table 3: Pre-existing co-morbidities among vaccinated population

Pre-existing comorbidities	N	%
Diabetes	7	1.7
Diabetes with Hypertension	7	1.7
Diabetes with Asthma	1	0.2
Hypertension and Asthma	2	0.5
Diabetes with other disease	4	1.0
Asthma	10	2.5
Hepatitis B/C	4	1.0
Hypertension	14	3.5
Other Disease	19	4.7
No Disease	335	83.1

Table 4: Vaccine Coverage among Pregnant and Lactating mothers

Title	N	%
Vaccine Coverage among pregnant women		
Vaccinated	8	2.0
Not Vaccinated	109	27
Not applicable	286	71
Vaccine Coverage among lactating women		
Vaccinated	11	2.7
Not Vaccinated	103	25.6
Not applicable	289	71.5

for the second vaccine and will vaccinate soon.

Vaccine coverage among pregnant and lactating mothers are given in table 4.

Out of 403 respondents, 219 (54.3%) did not reported any AEFIs, 184 (45.4%) complaint of mild AEFIs while 1(0.2%) case of severe AEFI was reported. Detail of AEFI reported is given as figure 1. To treat AEFI, 84 (20.8%) rested at home, 83 (20.6%) took pain killers beside staying at home, 6 (1.5%) consulted a doctor while 1 (0.2%) was admitted to hospital.

277 (68.7%) were certain that covid vaccines are safe, 17(4.2%) believe that these are not safe while 109 (27%) stayed neutral. 340 (84.4%) will advise and 18 (4.5%) will not advice others to vaccinate, while 45 (11.2%) stayed neutral.

DISCUSSION

Adverse effects following immunization of COVID -19 vaccines, their severity and coping experiences were determined in the population of Khyber Pakhtunkhwa, mean age of 29.37+11.1, study population included more female (53.1%) than male. At the time of the data collection 69.7% already received both doses of the vaccine, 13.9% single dose, while 10.4% registered to get vaccinate soon, in a similar study, conducted in USA, a total of 81.71% of Health Care Workers received the both doses of the vaccines while 18.29% took only the first dose¹⁶. In KP vaccine acceptancy for double dose Chinese vaccines was more than single dose locally manufacture vaccine. In contrast, in USA single dose was preferred over double dose vaccines¹⁶.

Similar to a study conducted in federal capital of Pakistan, preferred choice of vaccine in descending order in KP were: Sinopharm, Sinovac, Pfizer, Moderna, CanSino, AstraZeneca and PakVac¹⁸. Considerable population was not aware of the vaccine they were vaccinated with.

In KP, co-morbidities were not found in considerable (83.1%) of the vaccinated population, the rest have chronic conditions in descending order of frequency i.e., Hypertension, Asthma, Diabetes, Diabetes with hypertension, Diabetes with other disease, Hepatitis, Hypertension with Asthma, Diabetes with Asthma, other diseases. In USA diseases found among vaccinated population in descending order were Thyroid diseases, hypertension, chronic

lung disease, gastrointestinal issues, osteoarthritis, mental illness, autoimmune disease, diabetes mellitus, blood disorders, heart disease, cancer/tumor and rheumatoid arthritis¹³.

More than half of the study population did not experience any adverse effects in KP. Most common adverse effects (descending order) registered were: pain at the injection site, fever, body aches, headache and sore throat. Frequency of AEFI were common in younger and males compare to elderly and female recipients. However, there was no significant association (Chi square test $X^2=17.84$, $p=0.811$) between age groups and adverse side effects of immunization. Phi and Cramer's V have weak association between age groups. Statistically, there was no difference of gender with T test $< .05$.

Adverse effects in UAE were similar to current study with the exception of fever. Similar to our study were common among young's and females¹⁹. In USA pain at the injection site, fatigue, headache, body aches, fever, nausea, sweating, dizziness, decreased appetite, muscle stiffness, sleep problems, and brain fogging were the most common AEFIs (descending order)¹⁴.

In KP, 36.7% experienced the AEFI within 12-24 hours, 4.2% in 24-48 hours, 1.7% in 48-72 hours, 1.5% within a week, 1% in 2 weeks and 0.2% after 2 weeks. Among (25.6%) adverse effects lasted 1-3 days, 12.4% 24 hours, 5% 4-7 days, 1.5% more than 7 days with hospitalization required in 0.7%. In India, 79% AEFI were recorded within 12 hours post vaccination²⁰.

Majority 20.8% of the symptoms were relieved by resting at home and taking analgesics i.e., Paracetamol (20.6%) in KP and were comparable to Indian population²⁰, very small number (1.5%) consulted doctor and only one case was admitted to the hospital.

Consistent with the global situation Only 2% pregnant and 2.7% lactating women vaccinated themselves in KP while concern about vaccine safety was the major reason for hesitancy recorded among 27% pregnant and 25.6% breast feeding mothers^{21,22}. Vaccine hesitancy was noted to be 63% in a study conducted on pregnant ladies in Ankara²¹. Likewise, in Qatar 25% perinatal women exhibited vaccine hesitancy towards COVID-19 immunization²².

COVID vaccine acceptance in KP was 68.7% similar to 77.6% in the world^{24,25}. Whereas, among Africans it is 58.8%, Caribbeans 68.7%, Bangladeshis 72.7%²⁵. Furthermore, in KP study population 4.2% were vaccine hesitant due to concern about vaccine safety.

This study includes self-reported symptoms through anonymous responses using a web-based survey. The AEFI were not clinically verified.

CONCLUSION

Majority of the study population in KP did not suffer from any AEFIs after COVID 19 vaccination. Pregnant and lactating mothers were hesitant to vaccinate.

RECOMMENDATION

1. Policy makers to enhance vaccine confidence through awareness campaigns especially among pregnant and lactating mothers.
2. Generalize further researches on this topic with bigger sample size and with clinical and Laboratory confirmations of the self-reported adverse effects.

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