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ORIGINAL ARTICLE

Adverse Effects of Covid-19 Vaccine; an Observational Studymainly Focusing on the Cutaneous Reactions in Both Genders

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ABSTRACT

Objective: COVID-19 caused a deleterious impact on the health care system globally.The roll out of vaccines seems to be the only effective way to curtail the spread of disease.The purpose of this study is to assess the dermatological adverse effect of post COVID-**19**vaccination on a gender basis.

Methodology: This was an observational,cross-sectional,questionnaire-based survey conducted in Pakistan.The sample comprises 518 participants. The questionnaire was self-designed. The trial lasted six months, from August 1, 2022, until January 31, 2023. We used a non-probability sampling technique.Dermatological adverse effects like burning pain, redness, rashes, and lymphadenopathy at the injection site were recorded.Fever was also noted. All the participants have received booster shots or double doses of any one of CCOVID-19 vaccines, such as AstraZeneca, Pfizer, Sinovac, Sinopharm,Pakvac, etc. A p-value of less than 0.05 was considered statistically significant.Qualitative data was reported as frequency and percentage, and quantitativedata was reported as standard deviation and mean.

Results: The study included 518 subjects, of whom 262 were males and 256 were females. The mean age of male is 42.70±14.05 years and female is 39.04±14.6years with a significant difference observed between them (p=0.004). The most common complaint among dermatological adverse effects after first was pain. 106(40.5%) male and 132(51.6%) female reported painwith a significant difference observed between them (p=0.011) followed by swelling which was reported by 92(35.1%) males and 120(46.9%) females with a significant difference observed between them (p=0.006).Burning was reported in 92(35.1%) male and 148(57.8%) female with a significant difference observed between them(p<0.001). Fever was also quite commonly reported in both male 116(44.3%) and female 178(69.5%) with significantdifference observed between them (p<0.001),Likewise post 2nd dose of vaccination, pain was most commonly noted in 90(34.4%) male and female 124(48.4%) female with significant difference observed between them (p=0.001). Moreover, burning was reported by 80(30.5%) malesand 132(51.6%) females with a significant difference observed between them (p<0.001). rashes were reported by76(29.0%) males and 100(39.1%) females with a significant difference observed between them (p=0.016), lymphadenopathy was also significantly associated with genders, (p<0.001).

Conclusion: This study concluded that the burning pain,redness,rashes,and lymphadenopathywere the most prevalent side effects in male and female post 1st and 2ndCOVID-19 vaccination.Furthermore fever was also reported in majority of subjects.In addition to this higher percentage of side effects were recorded in females as comparedto males.

Keywords: COVID-19 vaccination, vaccine adverse effects, pain, fever.

INTRODUCTION

COVID-19 is an infectious disease that has rapidly spread worldwide. It is caused by a novel coronavirus called the severe acute respiratory syndrome coronavirus (SARS CoV-2) virus.COVIDhas caused a huge health burden worldwide. According to the WHO, more than 5, 72,000 death have been reported worldwide(1). It was first discovered in Wuhan, China, and then it quickly started spreading throughout the world. Based on the phylogenetic study, the coronavirus was given the name severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses. Due to the soaring cases of COVID- 19 and the high death rate, on March 12 WHO finally assessed that COVID-19 can be classified as a pandemic(2).

The most common mode of transmission is from person to person, the exact route of transmission is unknown, butlike other respiratory viruses, it is most likely to be transmitted through droplets and close contact. The evidence of transmission through the fecal-oral route or conjunctival route is unknown(3). Furthermore, airborne transmission has not been proven yet. The majority of people experience symptoms within 12 to 13 days of contact, and the median incubation time of the virus is around 5 days, ranging from 1 to 14 days (4).

The COVID-19 virus exhibits a wide range of clinical symptoms, , from asymptomatic presentation to severe pneumonia, acute respiratory distress syndrome, respiratory failure, or multiple organ failure. The majority of people who have COVID-19 experience flu-like symptoms like fever runny nose, and cough, and several people remain asymptomatic(5) In some cases, the disease leads to an acute lung injury known as pneumonia, as well as coagulopathy. The most common feature of severe COVID-19 cases and the main factor contributing to fatal outcomes is pulmonary injury. In addition to this, gastrointestinal symptoms are frequently noticed. The severity of the disease was linked to hepatic enzyme impairment. In critically ill COVID-19 patients, a higher rate of acute renal injury was identified (5). Elderly patients reported more severe symptoms. Furthermore, the majority of patients with serious COVID-19 symptoms possess comorbidities like hypertension, diabetes, atherosclerosis, COPD, Coronary heart disease, obesity, etc(6).

There is no specific treatment for COVID-19 that has been discovered to date. Management of patients is done by providing supportive care that includes oxygenation, ventilation, and fluid management(7). Interferon atomization inhalation and combination therapy with low-dose systematic corticosteroids and antivirals have been promoted as essential COVID-19 therapeutic strategies (6,7).

As the clinical manifestation of novel SARS CoV 2 varies from person to person, it ranges from asymptomatic to acute respiratory distress syndrome and multi-organ failure. So the exact diagnosis is so complicated. Patient history, clinical findings, and validation by several laboratory detection techniques, including computed tomography (CT) scan, nucleic acid amplification test (NAAT), and serological tests, are the main components of the usual clinical diagnosis of COVID-19. Early screening and diagnosis are made by nasopharyngeal and/or oropharyngeal swabs, bronchoalveolar lavage fluid, sputum, bronchial aspirates, or blood specimens(8).

Globally, there is broad agreement that developing a COVID-19 vaccine is most likely the best strategy for permanently containing the pandemic (9).The constant work is carried out to develop a vaccine, which results in 105 vaccines in a clinical trial and 18 vaccines that are approved to be used. Among these vaccinations are those that are protein-based, viral vector-based,

nucleic acid vaccine, and whole virus-based live attenuated or inactivated vaccines. The only hope for eradicating COVID-19 infection is the COVID-19 vaccine (10).

Whole virus vaccines include live vaccines, which contain the weakened form of the virus and inactive vaccines, which contain virus genetic material that is disrupted either by heat or radiation. Both live and inactive vaccines are conventional forms of vaccine, so they are safe to use and trigger an immune response against the disease in the body. There are 16 inactivated and 2 live vaccines in the clinical development stage (11).

Protein-based vaccinations come in two varieties: subunit and virus-like particle vaccines. For subunit vaccines, recombinant protein techniques are used to create viral antigenic fragments Compared to whole virus vaccinations, they are reasonably safe, simple to make, and well-tolerated(11). However, the drawback is that they provide less immunity, so adjuvants are frequently used along with subunit vaccines. Virus-like particles contain empty virus shells that exactly imitate coronavirus but they are not infectious; rather, they provide immunity (11,12).

A viral vector vaccine is produced by weakening the viruses chemically so that they cannot cause disease and only trigger immunity without developing disease(11,12)

Another kind of vaccine is a nucleic acid vaccine. This is the first time that any nucleic acid vaccine has been approved to be used in public.SARS-CoV-2 nucleic acid vaccines utilize genetic code to produce a SARS-CoV-2 protein that triggers an immune response. These instructions are included in the form of DNA or RNA (12).

COVID vaccines are the only way to curb the pandemic,however no side effects are also linked with COVID vaccines.According to studies, a number of participants suffered fatigue, discomfort at the site of injection,headache, and fever post vaccination(14).Most of the side effects are mild and self-limiting, however, high grade fever and severe bodyache is associated with Astrazenica and Pfizer(13).Dermatological adverse effects and delayed large local reaction are frequently seen post COVID vaccination which includes redness,erythema ,burning ,pain, urticaria, itchiness, mobilliform eruptions, pityriasis rosea, swelling, burning and in some cases lymphadenopathy(14).

Although numerous trials have been carried out outside of Pakistan, there is relatively little information available regarding the adverse effects of the COVID 19 vaccine. This study was carried out to determine the incidence of COVID vaccine adverse effects in both genders in the Pakistani population.

METHODOLOGY

It is an observational, randomized, cross-sectional, and questionnaire-based study on the dermatological adverse effects of various COVID vaccinesin both genders. The data collection was started from August 1, 2022, until January 31, 2023, for a period of six months. We used a non-probability sampling technique. This study was performed after approval from the ethical review committee

This study included 518 participants. All the participants were vaccinated.Non-vaccinated individuals were excluded from the study. All the participants have received booster shots or double doses of any one of COVID--19 vaccines, such as AstraZeneca, Pfizer, Sinovac, Sinopharm,Pakvac, etc.

We collected information from participants through a questionnaire survey. The questionnaire was self-designed. Demographic information of participants(age, weight, gender), was collected. Furthermore, the dose and type of vaccine were also recorded. A history of diabetes and hypertension was also taken. Any prior COVID exposure was also noted. In addition to this pain, burning, redness, lymphadenopathy, and fever, post 1st and 2nd doses of COVID vaccination were recorded. Each adverse reaction was noted on a subjective basis. The satisfaction level of subjects was also recorded.

Data was analyzed and evaluated using SPSS version 20.0. Different demographic parameters are compared by using the mean, standard deviation, and other descriptive statistics. A p-value of less than 0.05 was recognized as statistically significant. The frequency and percentage of adverse effects between males and females were recorded through the chi-square test**.**

RESULTS

The responses of 518 participants were recorded in this study. The mean age of the male was 42.70 ±14.05 years, and mean age of the female was 39.04±14.67 years, with significant difference between them (p=0.004), themean weight of 67.22±14.46 and 66.19±17.40 kg for male and female, respectively, with an insignificant difference between them (p=0.464).The mean height was recorded to be 5.44±5.28 and 5.184±0.70feet for males and females, respectively, with a significant difference between them (p<0.001). The mean duration of hypertension for male was recorded to be 5.50±5.28 years and for female were recorded to be 4.22±2.1287 year with an insignificant difference between them (p=0.091). The mean duration of diabetes mellitus was recorded to be 4.19±4.4913 years for males and 3.69±2.48 years for females with an insignificant difference between them (p=0.475). About 56(21.4%) males had a positive history of hypertension, and 58(22.7%) females had a positive history of hypertension with an insignificant difference between them (p= 0.725). Around 62 (23.7%) and 48(18.8%) males and females, respectively had diabetes, with an insignificant difference between both genders (p=0.172).Furthermore 54(20.6%) and 55(21.5%) males and females, respectively, had experienced COVID-19 with an insignificant difference between both genders (p=0.807). In addition to this, 250 (95.4%)and 240(93.8%) males and females, respectively, denied any previous exposure to COVID-19. with an insignificant difference between both the genders (p=0.401). Most of the participants, 94 (35.9%)and 88 (34.4%)male and female, respectively, received Sinovac, followed by Sinopharm, which was received by 60 (22.9%) and 63 (24.6%) males and females, respectively. Moreover, Pfizer was received by 52 (19.8%) males and 55(21.5%)females. AstraZeneca was received by 20 (7.6%) males and 40 (15.6%) females. A small number of subjects received Cansino 24(9.2%)males and 7 (2.7%)females and Pakvac12(4.6%)males and 3 (1.2%) females, with a significant difference between both the genders(p=0.001). Furthermore,26(9.9%) males and 32 (12.4%) females were vaccinated with first dose,190 (72.5%) and 170 (66.4%) males and females respectively were vaccinated with both doses and 46 (17.6%)males and 56(21.1%)females received booster doses, with aninsignificant difference between them (p= 0.316), as shown in Table I.

Table 1: The demographic details of vaccinated participants (n=518).

Variable		Male Mean±SD n(%)	Female Mean±SD n(%)	p-value
Age (years)		42.70±14.05	39.04±14.67	0.004
Weight (kg)		67.22±14.46	66.19±17.40	0.464
Height (feet)		5.44±0.72	5.184±0.70	<0.001
Hypertension Duration (years)		5.50±5.28	4.22±2.1287	0.091
Diabetes Mellitus Duration (years)		4.19±4.4913	3.69±2.48	0.475
Hypertension	Yes	56(21.4%)	58(22.7%)	0.725
	No	206(78.6%)	198(77.3%)	
Diabetes Mellitus	Yes	62(23.7%)	48(18.8%)	0.172

	No	200(76.3%)	208(81.3%)	
COVID-19 Infection	Yes	54(20.6%)	55(21.5%)	0.807
	No	208(79.4%)	201(78.5%)	
Previous COVID-19 Exposure	Yes	12(4.6%)	16(6.3%)	0.401
	No	250(95.4%)	240(93.8%)	
Type of Vaccine	Sinopharm	60(22.9%)	63(24.6%)	0.001
	Cansino	24(9.2%)	7(2.7%)	
	Sinovac	94(35.9%)	88(34.4%)	
	Astrazeneca	20(7.6%)	40(15.6%)	
	Pfizer	52(19.8%)	55(21.5%)	
	Pakvac	12(4.6%)	3(1.2%)	
Vaccination status	Vaccinated with first dose	26(9.9%)	32(12.5%)	0.316
	Vaccinated with second dose	190(72.5%)	170(66.4%)	
	Vaccinated with Booster Dose	46(17.6%)	54(21.1%)	

Table 2: Side Effects of Vaccination after 1st dose

Variable	Male		Female		p-value
	Yes n(%)	No n(%)	Yes n(%)	No n(%)	
Pain at the site of injection	106(40.5%)	156(59.5%)	132(51.6%)	124(48.4%)	0.011
Swelling at the site of injection	92(35.1%)	170(64.9%)	120(46.9%)	136(53.1%)	0.006
Redness at the site of injection	42(16.0%)	220(84.0%)	56(21.9%)	200(78.1%)	0.090
Lymphadenopathy	58(22.1%)	204(77.9%)	64(25.0%)	192(75.0%)	0.443
Fever (temperature >37.8 ˚C)	116(44.3%)	146(55.7%)	178(69.5%)	78(30.5%)	<0.001
Rashes	62(23.7%)	200(76.3%)	92(35.9%)	164(64.1%)	0.002
Burning at injection site	92(35.1%)	170(64.9%)	148(57.8%)	108(42.2%)	<0.001

Table 3: Side Effects of Vaccination after 2nd dose

Variable	Male		Female		p-value
	Yes n(%)	No n(%)	Yes n(%)	No n(%)	
Pain at the site of injection	90(34.4%)	172(65.6%)	124(48.4%)	132(51.6%)	0.001
Swelling at the site of injection	90(34.4%)	172(65.6%)	99(38.7%)	157(61.3%)	0.307
Redness at the site of injection	24(9.2%)	238(90.8%)	32(12.5%)	224(87.5%)	0.221
Lymphadenopathy	50(19.1%)	212(80.9%)	100(39.1%)	156(60.9%)	<0.001
Fever (temperature >37.8 ˚C)	96(36.6%)	166(63.4%)	110(43.0%)	146(57.0%)	0.141
Rashes	76(29.0%)	186(71.0%)	100(39.1%)	156(60.9%)	0.016
Burning at injection site	80(30.5%)	182(69.5%)	132(51.6%)	124(48.4%)	<0.001

Table 4: The association of level of Satisfaction with the vaccines between genders.

Variable		Male n(%)	Female n(%)	p-value
Overall subject level of satisfaction with the vaccines	Very Satisfied	68(26.0%)	52(20.3%)	0.076
	Satisfied	142(54.2%)	137(53.5%)	
	Neutral	44(16.8%)	63(24.6%)	
	Dissatisfied	8(3.1%)	4(1.6%)	

Afterreceiving the 1st dose of COVID vaccine, most of the subjects 106 (40.5%)males and 132(51.6%) females reported pain at the site of administration, with a significant difference observed between genders (p=0.011), followed by swelling, which was reported by 92(35.1%) males and 120(46.9%) females with a significant difference observed between genders (p=0.006). The study further stated that redness was experienced by 42(16%)males and 56(21.9%) females, with an insignificant difference observed between genders (p=0.090). Furthermore, 58 (22.1%) males and 64 (25%) females reported lymphadenopathy, with no statistically significant difference between genders (p=0.443). A relatively large number of subjects reported fever 116(44.3%) males and 178(69.5%) females, with a significant difference observed between genders (p<0.001). The study also found that 62(23.7%) males and 92 (35.9%) females reported rashes, with a significant difference observed between genders (p=0.002). In addition to this, burning was reported by 92 (35.1%) males and 148(57.8%) females, with a significant difference observed between genders (p<0.001). An over-all higher proportion of females experienced more adverse effects as compared to males after the 1st dose of vaccination, as shown in Table II.

After receiving the 2nd dose of COVID vaccine, pain was reported by a large number of subjects that was 90 (34.4%) males and 124(48.4%), with a significant difference observed between genders, (p=0.001). Swelling was also experienced by 90 (34.4%) males and 99(38.7%) females, with an insignificant difference observed between genders, (p=0.307). Furthermore, redness was reported by 24(9.2%) of males and 32(12.5%) females, with an insignificant difference observed between genders, (p=0.221). Lymphadenopathy was reported by 50 (19.1%) males and 100 (39%), with a significant difference between genders, (p<0.001). A relatively greater number of subjects reported fever which included 96(36.6%) males and 110(43.0%) females, with an insignificant difference observed between genders (p=0.141). Moreover, 76(29%) males and 100(39.1%) females experienced rashes, with a significant difference observed between genders, (p=0.016).Burning was observed by 80(30.5%) males and 135(51.6%) females with a significant difference between them (p<0.001). Females experienced more side effects after the second dose of vaccination than males. , as shown in Table III.

This study revealed that 68(26.0%)males and 52(20.3%) females were extremely satisfied, whereas 142(54.2%) males and 137(53.5%) females were satisfied.Furthermore, 44(16.8%) males and 63(24.6%) females expressed no comments about the vaccine. Moreover, only 8 (3.1%) males and 4 (1.6%) females were not satisfied with the vaccines, with an insignificant difference observed between genders (p=0.076), as shown in Table IV.

DISCUSSION

The COVID-19 epidemic has had a dramatic impact on the global healthcare infrastructure. It is regarded as posing a significant

health threat. The delivery of COVID-19 vaccines has proven to be the most effective strategy for limiting the pandemic to yet. Despite the COVID-19 vaccinations' widespread acceptance and the protection they provide, concerns about vaccine safety and about their potential adverse effects have persisted throughout immunization campaigns(15). The purpose of this cross-sectional study is to determine the frequency of side effects based on gender in Pakistan's general population following COVID-19 vaccination.

A survey was conducted among healthcare workers in the Czech Republic. A total of 877 participants were included in the study, out of which 89.8% experienced injection site pain ($p<0.001$), 25.6% reported swelling and ($p=0.785$), 23% reported redness ($p= 0.082$),16.2% reported lymphadenopathy ($p=0.388$) and 21.7% and reported fever ($p=0.073$)(16). This result is on the higher side as compared to our current study, the possible reasons could be the type of vaccines, ethnic differentiation, or underlying pathology. However, in this study, females reported more adverse effects, which are consistent with our study.

A cross-sectional questionnaire-based survey was conducted among the Iranian population. A total of 867 subjects were included. Dermatological reactions were observed in 30% of the population and females were most affected(17). The results of this study showed a similar female preponderance as our study.

A retrospective cross-sectional survey was conducted in Iraq. The survey comprises 843 participants. Of which, 664 were female. The participants reported swelling, redness, and rashes, and females were found to be more affected than females. In this study, 77% of females and 65%males experienced side effects(18) likewise, our study females experienced more side effects than males.

Another cross-sectional study was conducted using a telephonic survey in Saudi Arabia. A total of 528 participants were included. Out of which 265 were female and 263 were male.More women than men have experienced side effects. Fever is present in 51.7 % of females and 32.3 % of males. (19)These results match our study, where females experienced more side effects than males.

A cross-sectional survey-based study was carried out to determine the dermatological side effects of COVID-19 vaccine among healthcare workers in Turkey.

Injection site pain was reported by 46.8% of females and 30.6% of females, swelling was reported by 3.4% of females and0.8% of males redness was reported by1.3% of females and 1.6% of males(20)Participants' percentage of side effects differs from our percentage. . However, likewise our study, this study also shows that females suffered more adverse effects.

Another cross-sectional survey conducted in Iran among healthcare professionals, studied 503 participants with side effects. Injection site pain was reported in 69.6% of females, and 51.1% males, rashes were reported in 1.8%male and 1.4% female, and redness was reported in 3.6% females and 4.8% males. According to this study, overall, females reported more adverse effects(21). This study concludes with the same results as our study.

Another research was conducted to determine the adverse effects of COVID-19 vaccines. Throughout this study, 1736 volunteers participated. When the vaccines were injected, 34.56% of the subjects said they caused discomfort, redness, rashes, and edema since they were reactogenicvaccines(22). This conclusion is very similar to that of the current study, in which 33.75% of individuals reported experiencing discomfort, 31.5% reported swelling, and 26.6% reported having rashes.

Similar to this, cohort observational research was conducted in Jordan. Participants in this observational cohort were interviewed over the phone using a semi-structured format. Questions centred on the adverse reactions that followed each dose of these vaccines. In all, 1,004 persons were enrolled. In addition, injection site pain was likewise the most frequently reported adverse event for the second dosage (29%)(23),which is a little bit closer to our study, which shows that the most frequently reported side effects were soreness at the injection site (33.2%).

To evaluate the COVID-19 vaccine's adverse effects, a survey was conducted in Jordan. 409 people in total participated in the study. Fever, pain, edema, and burning at the injection site were the most frequent side effects; roughly 36.4% of participants reported fever and 36.0% reported pain at the injection site. This result is consistent with our studies(24). Similar percentages and frequencies of discomfort, edema, and burning were also reported in the current investigation.

Likewise, an online survey-based cross-sectional study was conducted to determine the prevalence of COVID-19 vaccination adverse effects among Pakistan's general population. Through social media sites, a self-administered online poll was disseminated (i.e., Facebook, WhatsApp, Instagram, and Twitter). A total of 434 replies were included in the analysis and were deemed valid.82.0% reported pain at the injection site, 11.1% reported urticaria (25), and our study reported lower rates of pain at the injection site. However, the study reported that women experience more side effects than men, which is quite similar to our study. Similarly, research conducted in Germany concluded that females suffered more from the adverse effects of the Covid-19 vaccine (26) than males, which is consistent with our findings. According to research conducted among healthcare workers in Saudi Arabia, females experienced more side effects than males (27) which was consistent with our study.

Similar to this, a study was carried out in Saudi Arabia, and their satisfaction level with COVID immunization was evaluated. Overall, the immunization process was well received by participants, and they were quite satisfied with the results(28). The resultsare similar with our findings, which showed that most individuals were satisfied with their COVID vaccine.

This study has some limitations, like small size of the sample and the collection of data through subjective means. Future studies could find it interesting to examine side effects with a larger sample size.

CONCLUSION

This study concluded that pain, burning, redness, rashes, and lymphadenopathy, were the most frequently seen dermatological adverse effects afterthe 1st and 2nd doses of COVID-19 vaccination. Additionally, fever was also found to be prevalent in participants after COVID-19 vaccination. Furthermore,it was also proved that both males and females experienced dermatological adverse effects, however, females were more likely to suffer from adverse effects than males.

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