Research Article

Side effects of COVID-19 vaccination in Pakistani population: A cross sectional study

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Objectives: **Data from clinical trials around the world show that the COVID-19 vaccines are effective in terms of reducing hospitalizations need for respiratory support and deaths. However, to assess common or uncommon adverse events of the COVID-19 vaccines, data from real world experiences need to be evaluated to resolve the speculations associated with the vaccines.**

Materials and Methods: **A questionnaire based on demographic details, vaccination details, side effects experienced, the duration of side effects and COVID-19 status was administered to study participants during this cross-sectional study.**

Results and Discussion: **A total of 1162 responses were collected from fully vaccinated individuals, where Sinovac was the highly administered vaccine (40%). Most of the vaccinated participants (94%) did not contract SARS-CoV-2 infection following vaccination; however, the rate of hospitalization (4.2%) and development of extreme complications (1.4%) was lower in those who contracted the disease after vaccination compared to those who contracted COVID-19 before being fully vaccinated (7.1%). The most frequent side effects of vaccination reported were moderate pain at the site of injection administration, muscle pain, headache, fever, fatigue, swelling, redness or pain at the site of injection, nausea and joint pain. Only 2% of the participants encountered extreme daily routine difficulties while most of the side effects resolved within one week (30%).**

Conclusion: **The present study reports mild post vaccination side effects and low incidence of SARS-CoV-2 following COVID-19 vaccination. These results may help in improving the public perception and confidence towards COVID-19 vaccination in the Pakistani population.**

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Short Title: COVID-19 vaccination in Pakistan.

Introduction

Vaccination against COVID-19 remains the largest global immunization effort. Approximately 71.1% of the global population has received at least one dose of the vaccine[1]. In Pakistan alone, more than 303 million doses of the vaccine have been administered so far. Four viral vector-based vaccines, Oxford AstraZeneca, Sputnik V, CanSino and PakVac; two RNA vaccines, Pfizer-BioNTech and Moderna; and two attenuated viral vector vaccines, Sinopharm and Sinovac, have been approved for administration in Pakistan[2]. The effectiveness of these vaccines in reducing hospitalizations, need for respiratory support and deaths have been evaluated in several clinical trials[3][4][5][6]. The expected side effects of these vaccines include injection site pain, swelling, redness etc. and activated immune response such as fever, headache, fatigue, myalgia etc[7]. (Supplementary Table 1). However, rare reports of serious reactions such as thrombosis, thrombocytopenia, anaphylactic shock and unconsciousness have also been reported[8][9].

In Pakistan, a heterogeneity regarding vaccine acceptance rate exists that might be influenced by factors such as effectiveness and possible side effects of the vaccines, which may hinder the success of the immunization campaign[10][11][12]. With 61% of the population fully vaccinated, the country is still behind other countries of the region such as Bangladesh, India, China and Iran where 75 to 90% of the population is fully vaccinated[1]. Therefore, it is important to study the complete profile of the adverse reactions linked to these vaccines to resolve the speculations associated with it.

Previous studies conducted in Pakistan reported mild adverse reactions of the vaccines and the factors associated with these side effects[13][14][15].

The present study not only aims to assess the adverse reactions and the impacts of different factors in a relatively larger cohort, but also to compare the side effects and severity of COVID-19 before and after the vaccination.

Methods

Study design

This cross-sectional study was conducted between April 2022 to August 2022. The study was approved by Institutional Review Board & Ethics Committee (IRB&EC). The questionnaire was adapted from Bolze *et al*[16] and modified according to the Pakistani context. The questionnaire consisted of questions relating to i) demographic details such as age, gender, residence etc. ii) smoking status, comorbidities, Body Mass Index (BMI) iii) vaccination status, type and date of vaccination, number of doses iv) side effects and side effects experienced post vaccination, duration of these side effects and difficulties faced due these v) COVID-19 status i.e., dates, duration, and severity of the infection. Detailed questionnaire has been provided in the supplementary material.

Sample size and Data collection

The online tool OpenEpi was used to calculate the sample size for this study. As of mid-March, 2022, 101,881,176 people had been fully vaccinated against COVID-19 in Pakistan, which was taken as the population size. The sample size recommended was 385. However, a greater number of participants (1162) were included in the study based on the convenient sampling approach. Flow diagram representing detailed sampling approach has been provided in the supplementary material. Data was collected by interview-based questionnaire technique from fully vaccinated individuals. The data was collected from all provinces of Pakistan i.e., Punjab, Sindh, Balochistan, Khyber Pakhtunkhwa, Gilgit and Azad Kashmir and Islamabad Capital Territory.

Statistical Analysis

The data was documented in Microsoft Office Excel (Microsoft Corporation, USA) and analyzed using IBM SPSS statistics version 26. Demographic features like gender, age, smoking, area of residence, BMI and blood groups were described by frequencies and percentages. The association of demographic features; gender, age, BMI and COVID-19 history with the post vaccination side effects was assessed by binary logistic regression models and results were reported as probability (p-value), odds ratio (OR) and 95% confidence interval (CI). Similarly, the impact of vaccination status on COVID-19 infection side effects, hospitalization and development of complications was also determined by

binary logistic regression and results were plotted as forest plot. The CI limit was set at 95% with a margin of error of 5%.

Results

General characteristics of the study population

A total of 1162 responses were collected from fully vaccinated individuals. Ten percent of the participants had received a single booster dose while only 1% had received a second booster dose as well. The participants were aged between 15 to 80 years with mean age 25·4±9·42 years. The majority of the participants were female (60%) aged between 20-40 years (65%); nonsmokers (92%); belonging to Punjab province (56%) and with normal Body mass index (33%) (Table 1). BMI was classified according to Asian BMI classification criteria[17].

Vaccination status

The majority of the participants received the Sinovac vaccine (40%), followed by Sinopharm (38%) and Pfizer BioNTech (13%) for their primary vaccination. Of the 1162 participants, only 114 (10%) participants had received a booster dose, among which 77 (68%) received Pfizer BioNTech whilst 18 received Sinopharm (16%) (Table 2).

Side effects following COVID-19 Vaccination

The most common post vaccination side effects reported by the participants after receiving primary vaccine included moderate pain at the injection site, muscle pain, fatigue, fever, headache, feeling unwell, swelling at injection site, severe pain at injection site, dizziness, redness at injection site, nausea, joint pain and difficulty in concentrating on work (Fig. 1). Moderate pain at injection sites was the most prominent symptom after administration of CanSino vaccine (35%), followed by Sputnik V (33%) and Pfizer vaccine (30%). The administration of the Pfizer vaccine resulted in muscle fatigue among 26% of the study participants. Sixty three percent participants reported fever after immunization with Moderna vaccine, followed by PakVac (55%) and CanSino (40%) vaccine. (Fig. 1, Supplementary Table 2).

Pfizer BioNTech being the most common booster COVID-19 vaccine and with a high rate of post vaccination side effects. After receiving Pfizer BioNTech, 34% reported fatigue, 32% reported

moderate pain at the injection site while 31% reported fever (Fig. 2, Supplementary Table 3).

Characteristics	Frequency (Percentage)
Gender	
Female	692 (60)
Male	470 (40)
Age Groups (years)	
<20	315 (27)
20 to 40	753 (65)
41 to 60	76 (6)
>60	18 (2)
Smoking status	
Smokers	99 (8)
Nonsmokers	1063 (92)
Area of residence	
Punjab	654 (56)
Islamabad	365 (31)
KPK	87 (7)
Sindh	28 (2)
AJK	19 (2)
Balochistan	7 (1)
Gilgit	2 (˜1)
Body Mass Index (BMI)	
Underweight	250 (22)
Normal	389 (33)
Overweight	163 (14)
Obese	360 (31)
Blood Group	

Characteristics	Frequency (Percentage)
A+	203 (17)
A-	29 (2)
B+	350 (30)
B-	27 (2)
AB+	92 (8)
AB-	18 (2)
O+	204 (18)
O-	45 (4)
Don't know	195 (17)

Table 1. Demographic details of the study participants (n=1162)

Vaccine Brand	Primary vaccination		Booster Doses	
	Shot 1 n (%)	Shot 2 n (%)	Initial booster n (%)	Second booster n (%)
Sinovac	460 (40)	460 (43)	2 (2)	2 (13)
Sinopharm	383 (33)	383 (36)	18 (16)	4 (25)
Pfizer-BioNTech	149 (13)	149 (14)	77 (68)	9 (56)
CanSino*	78 (7)	0 (0)	1 (1)	0 (0)
Moderna	54 (5)	54 (5)	13 (11)	0 (0)
PakVac*	18 (2)	0 (0)	2 (2)	1 (6)
Oxford AstraZeneca	14 (1)	14 (1)	0 (0)	0 (0)
Sputnik V	6 (1)	6 (1)	0 (0)	0 (0)
Johnson & Johnson	0 (0)	0 (0)	1 (1)	0 (0)
Total	1162	1066	114	16

Table 2. Vaccination status of the study participants

**single dose vaccines*

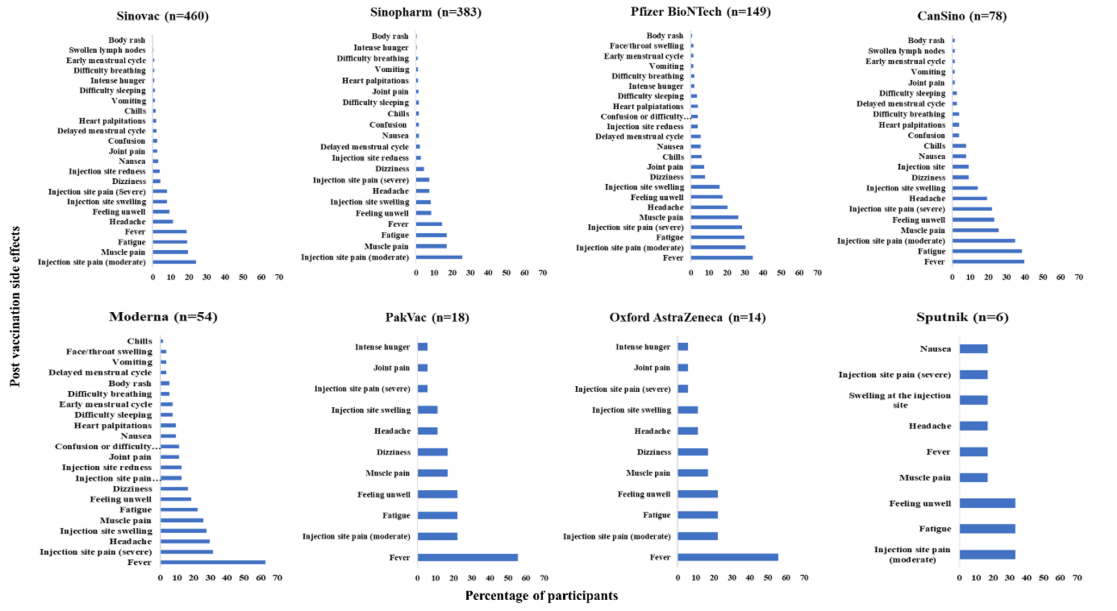

Fig. 1. Spectrum of COVID-19 vaccination side effects following primary vaccine shots

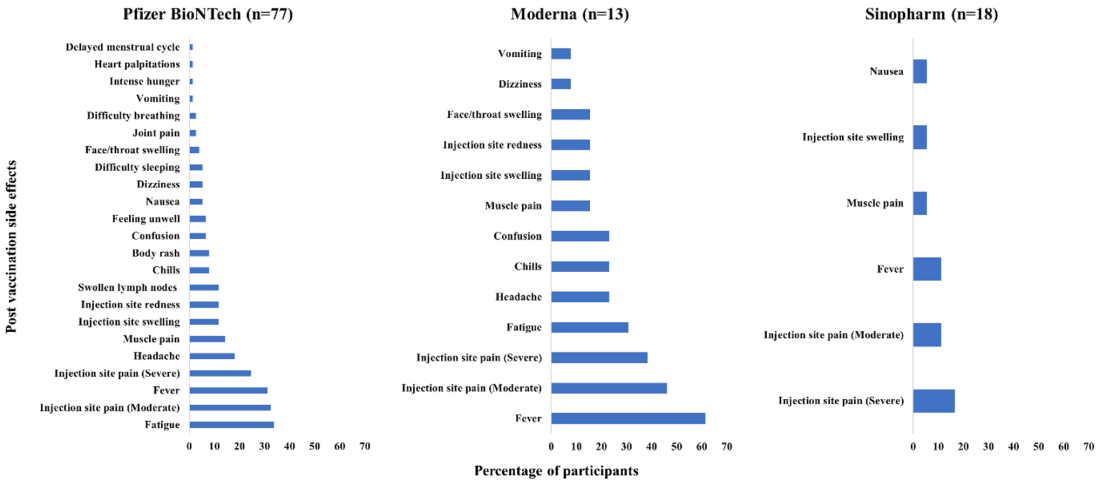

Fig. 2. Spectrum of COVID-19 vaccination side effects following booster doses

Association of gender, age and BMI and pre-vaccination COVID History of participants with side effects of primary COVID-19 vaccination

Binary logistic regression analysis of the side effects of major vaccines administered in the participants i.e. Sinovac, Sinopharm, Pfizer, CanSino and Moderna were performed with independent

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variables i.e. age, gender, BMI and pre-vaccination COVID history (Supplementary Tables 4-8). For Sinovac, age [p=0·034; OR=0·969 (95% CI=0·941-0·998)] and BMI [p=0·025; OR=0·952 (95% CI=0·913-0·994)] showed varied association with moderate pain at injection site, while BMI and age were also significantly associated with fatigue, muscle pain, severe pain at injection site, dizziness and nausea. For the Sinopharm vaccine, moderate pain at injection site and swelling at injection site were associated with age, while fever and fatigue were found associated with BMI (Table 3). Severe pain at the injection site was associated with gender [p=0·025, OR=0·206 (95% CI= 0·052-0·82)] in participants vaccinated with the Moderna vaccine. While no side effects showed any significant association with any independent variable for Pfizer and CanSino vaccines (Supplementary Tables 6,7). Participants with COVID-19 history prior to vaccination, showed no association with any side effect for any vaccine (Supplementary Tables 4-8).

Association of existing illnesses with side effects of primary COVID-19 vaccination

Thirty-two participants (11%) reported that they had any existing illnesses or at least one comorbid condition at the time of vaccination. Among these 26 (20%) had diabetes and 22 (17%) had hypertension. Other comorbid conditions included allergies, asthma, sinusitis, polycystic ovary syndrome and typhoid. Side effects such as a general feeling of un wellness (p=0·017) and swollen lymph nodes (0·016) were marginally higher in the participants with at least one comorbid condition as compared to the ones with no comorbid condition. All other post vaccination side effects were not statistically associated with the presence of known illnesses (Supplementary Table 9).

Impact of COVID-19 vaccination on daily routine of the participants

After being immunized with the primary shot 1, more than 80% participants vaccinated with Sinovac, Sinopharm, Pfizer, CanSino, PakVac and Sputnik felt mild or no difficulty in their daily routines, while for Moderna and Oxford AstraZeneca vaccines 63 and 78% participants faced mild or no difficulty in their daily routines, respectively. Participants vaccinated with Moderna and Pfizer vaccines reported 7% and 5% extreme difficulties in their daily routines respectively, while for all other vaccines there was 1% or no extreme difficulty reported in their daily routines (Fig. 3, Supplementary Table 10).

Vaccine Type	Side effects following Vaccination	Independent Variables	S.E.	*p* value	OR	95% C.I.	
						Lower Bound	Upper Bound
Sinovac	Moderate pain at injection site	Age	0·015	0·034	0·969	0·941	0·998
		BMI	0·022	0·025	0·952	0·913	0·994
	Fatigue	BMI	0·025	0·001	0·912	0·869	0·958
	Muscle pain	BMI	0·024	0·010	0·941	0·898	0·986
	Severe Pain at injection site	BMI	0·034	0·035	0·931	0·870	0·995
	Dizziness	BMI	0·047	0·034	0·905	0·826	0·993
	Nausea	Age	0·02	0·014	1·052	1·010	1·095
Sinopharm	Moderate pain at injection site	Age	0·011	0·045	1·021	1.000	1·043
	Fever	BMI	0·032	0·045	0·938	0·880	0·999
	Fatigue	BMI	0·03	0·008	0·923	0·869	0·979
	Swelling at injection site	Age	0·015	0·032	1·032	1·003	1·061
Moderna	Severe Pain at injection site	Gender	0·705	0·025	0·206	0·052	0·820

Table 3. Binary logistic regression analysis of COVID-19 vaccination side effects

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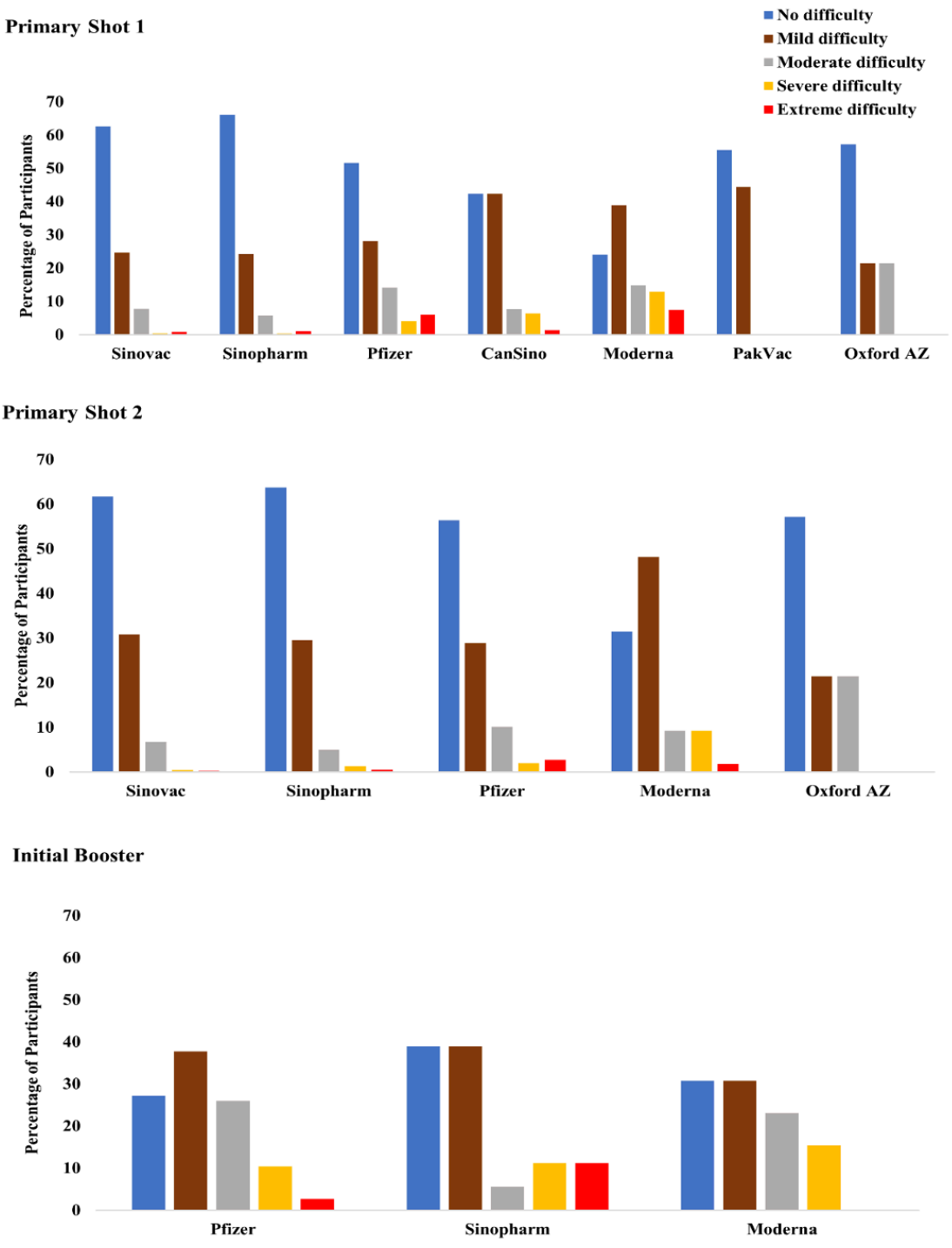

Fig. 3. Impact of different COVID-19 vaccines on daily routine of participants

After being vaccinated with second dose of primary vaccine, more than 92% participants vaccinated with Sinopharm and Sinovac vaccine reported mild or no difficulties in their daily routines. The

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participants vaccinated with the second dose of Pfizer (3%) and Moderna (2%) vaccines reported extreme difficulties (Fig. 3, Supplementary Table 11).

One hundred fourteen participants (9·8 %) received an initial booster dose. All of these participants vaccinated with PakVac, Sinovac, CanSino and Johnson and Johnson vaccines reported mild or no difficulties in their daily routines. While most of the participants reported mild or no difficulties (Fig. 3, Supplementary Table 12).

Most of the participants being immunized with a second booster dose of Pfizer vaccine, reported mild or moderate difficulties in their daily routines, while only 2 participants reported severe or extreme difficulties. Number of the participants, who received each vaccine's booster dose 2, was less than 10, so it was not represented in the figure 3 and 4 (Supplemental Table 13).

Side effects resolving time following COVID-19 vaccination

After being immunized with primary vaccine dose one of Sinovac, Sinopharm and PakVac, more than 85% participants reported that their post vaccination symptoms subsided in less than a day or two days. Fifty one percent participants immunized with the Moderna vaccine reported that their symptoms resolved in one or two days, whilst post vaccination symptoms of 41% subsided in a week. At the same time 2% and 3% of participants immunized with Sinopharm and Pfizer vaccines respectively reported 4 weeks as their symptoms resolution time (Fig. 4, Supplementary Table 14).

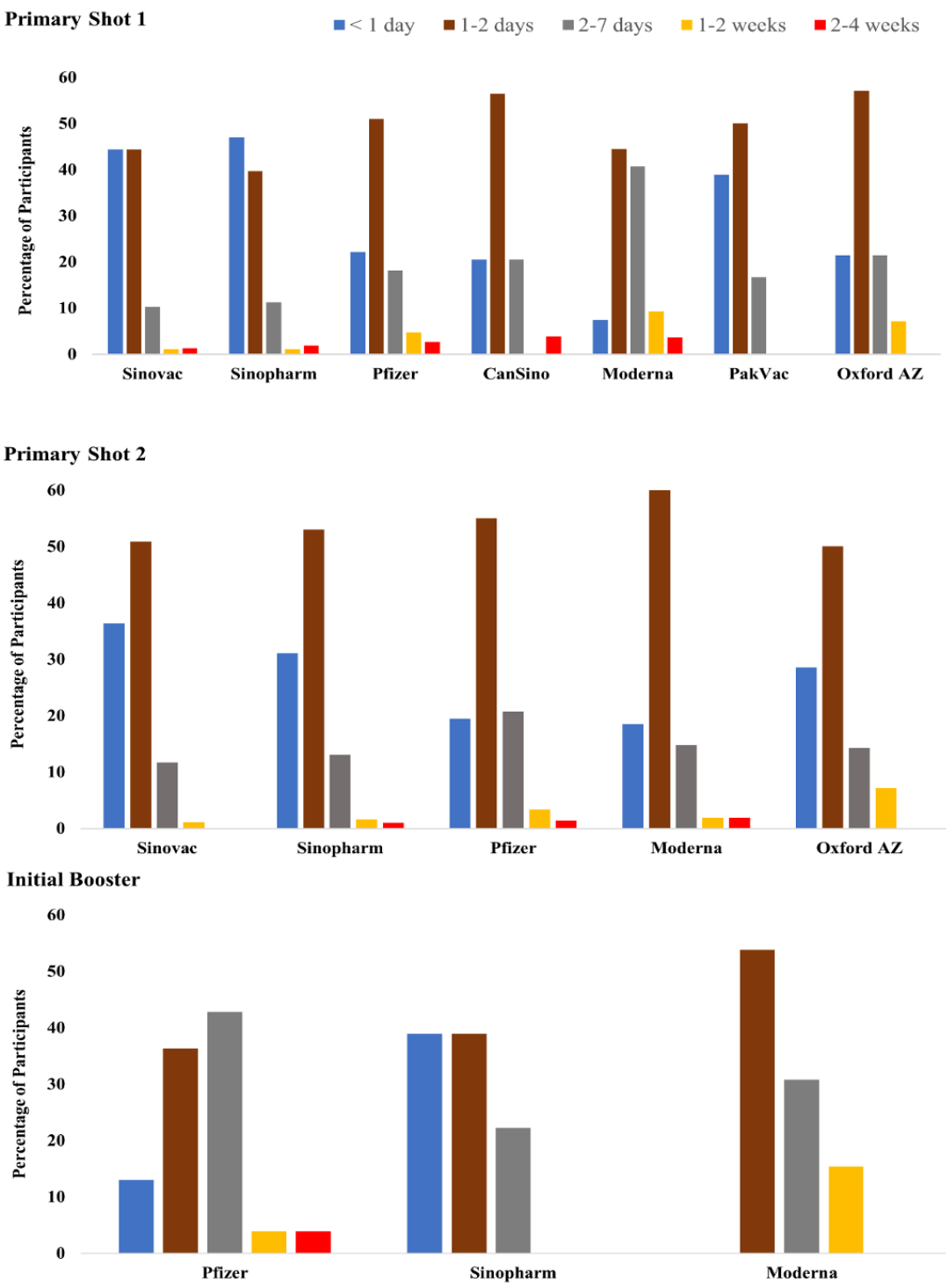

Fig. 4. COVID-19 vaccination Symptoms go-off time

More than 80% of the participants vaccinated with the primary vaccine second shots, Sinovac, Sinopharm and Moderna, reported that their symptoms went off in a day or two days, while 77% and

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79% participants vaccinated with Pfizer and Oxford AstraZeneca reported that their symptoms went off in one to two days. Twenty one percent of the participants vaccinated with Pfizer vaccine reported that their post vaccination symptoms resolved in 2-7 days (Fig. 4, Supplementary Table 15).

Pfizer booster vaccine was the major administered booster vaccine, among those participants who received the first dose of the initial booster dose. Most of the participants (>90%) who received initial booster dose 1 of Pfizer and Sinopharm, reported that their vaccination side effects were resolved within one week. Only 3 participants, immunized with Pfizer initial booster dose, reported that it took 2-4 weeks to go-off their symptoms (Fig. 4, Supplementary Table 16). More than 85% of the participants, who received Pfizer and Sinopharm second booster dose, reported that their side effects resolved within a week. Only one participant each vaccinated with a second booster dose of Pfizer and Sinovac reported that it took more than a week to resolve their vaccination symptoms (Supplemental Table 17).

SARS-CoV-2 infection before and after COVID-19 vaccination

Two hundred and twelve participants (18%) out of 1162 reported that they had COVID-19 infection either before or after the vaccination. Out of 1162 participants, 141 (12%) had COVID-19 infection before getting vaccinated (Infection date range: January 2020-September 2021), while 71 (6%) had infection after getting fully vaccinated (Infection date range: April 2021-May 2022), 6 (0·51%) reported to contract infection twice after vaccination, while only one (0·08%) participant contracted infection thrice following vaccination. Those who contracted reinfection twice or thrice were vaccinated with Sinopharm, Sinovac and CanSino. Among those infected with vaccination, 13 participants (1%) reported that they were hospitalized due to COVID-19 symptoms. Only 3 (4·2%) out of 71 participants were hospitalized due to COVID-19 infection after being fully vaccinated, while 10 (7·1%) out of 141 participants were hospitalized before being fully vaccinated (p=0·809). Eleven participants (<1%) reported development of complications like pneumonia, memory disturbances, recurrent bronchitis, myocarditis, kidney damage and lung fibrosis after contracting COVID-19 infection. Their vaccination status was analyzed and among these 10 (7·1%) were not vaccinated at the time of contracting COVID-19, only one of the cases (1·4%) developed complications of lung fibrosis despite being vaccinated (p=0·173). COVID-19 symptoms, hospitalization rate and development of complications were analyzed in in participants before and after vaccination, with the help of multinomial logistic regression and loss of smell [p=0·016, OR=0·180 (95%CI=0·045-0·729)], heart

palpitations [p=0·047, OR=0·117 (95%CI=0·014-0·970)] and tinnitus [p=0·049, OR=10·229 (95%CI=1·012-103·422)] were found significant (Fig. 5).

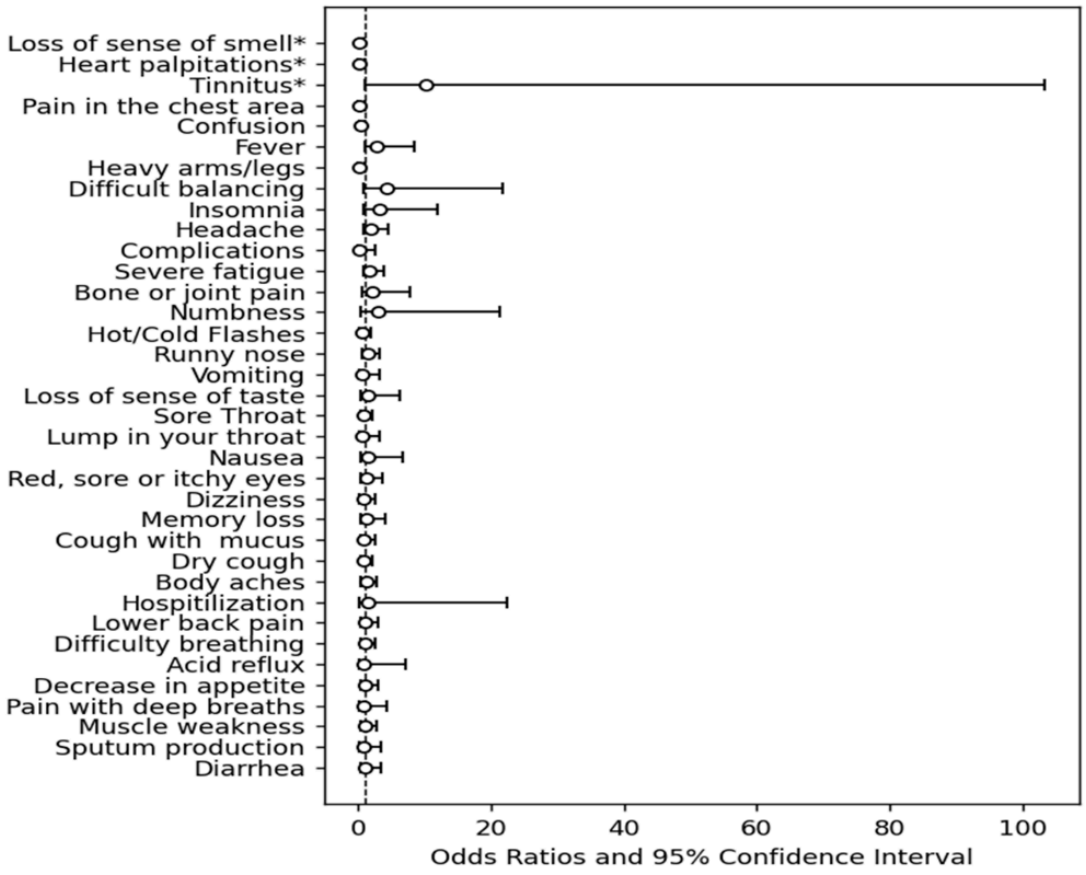

Fig. 5. Forest plot (multinomial logistic regression) revealing the association between vaccination status and COVID-19 related symptoms, hospitalization and development of complication

Discussion

The present study provides a detailed profile of side effects associated with COVID-19 vaccines administered in Pakistan and their impact on daily life. Moderate to severe pain at the site of injection administration, muscle pain, headache, fever and fatigue were the most frequently reported side effects of vaccination. Gender, age, BMI and/or presence of at least one comorbid condition were associated with the spectra of these side effects. The majority of the participants of the study reported no or mild difficulties due to the post vaccination side effects, which resolved within one to two days

for 45% of the participants (n=523). Other studies conducted in Pakistan analyzing the impacts of primary vaccination corroborate our study results[13][14]. However, another study has also reported some serious adverse reactions in Pakistani population like limb paralysis, heart attack, diplopia, renal failure and death[15]. Studies conducted in India and Bangladesh also reported mild post vaccination side effects[18][19]. Moreover, studies conducted in other regions of the world also reported mild side effects after vaccination, regardless of the type and manufacturer of the vaccine[20][21][22][23][24][25][26].

Vaccines against COVID-19 have the potential to produce long-lasting immunity, especially when it comes to reducing the severity of the illness. Fully immunized people exhibit persistent high protection from severe COVID-19 that can reduce hospitalization from 23·5% to 14·3%[26][27]. Our study results show that COVID-19 symptoms, hospitalization rate (reduced from 7·1% to 4·2%) and development of extreme complications (reduced from 7·1% to 1·4%) were less in those who had the infection post vaccination compared to those who had COVID-19 prior to the vaccination. These results are comparable to other studies which have been conducted to evaluate the effectiveness of vaccines in reducing the incidence of infection, need for hospitalization and ICU admission[28][29][30][31]. In the present study, SARS-CoV-2 infection rate reported by participants prior to vaccination was 12% as compared to 6% in the vaccinated participants. This is in contrast to an Indian study which has reported that 26% of vaccinated people contracted infection whilst 45% of the people without vaccination contracted infection[18].

We have shown that 94% of the participants did not contract infection after vaccination, while those 6% vaccinated, who contracted infection, had low incidence of infection, less hospitalization, no difficulty in daily routine and less development of severe outcomes as compared to non-vaccinated. So, it can be inferred that being vaccinated is safe and there are no extreme side effects and complications involved.

The present study has some limitations for instance a greater number of participants were female, from younger age groups, mostly from Punjab province therefore the study results cannot be generalized for the overall Pakistani population. Since the data on adverse impacts of vaccines and COVID-19 infection history is based on self-reported symptoms, clinical validation of these is not available. The impact of confounding factors such as comorbid conditions in the development of these symptoms cannot be validated. Moreover, time periods will be different for COVID-19 infections

occurring pre and post vaccination, and thus the SARS-CoV-2 variant will be different and can also account for symptom differences.

Conclusion

COVID-19 vaccination is the global health priority and according to world health organization (WHO), every person has the right to access vaccines and should get vaccinated in order to combat the pandemic. This study was conducted in order to analyze the safety and efficacy of the COVID-19 vaccination in Pakistan. This study shows that most of the side effects related with vaccination are general and mild, most of the side effects resolve within one week and vaccination does not affect daily routine in most of the cases. There were less than 1% participants who developed post vaccination complications and required hospitalization. The present study might be helpful in clearing the perceptions and speculations related to COVID-19 vaccination. Further studies with larger cohorts representing all the rural and urban regions of Pakistan are recommended to get a holistic picture of the Pakistan population.

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Conflicts of interest/Competing interests

None of the authors has any conflict of interest.

Ethics approval

The study was approved by Institutional Review Board & Ethics Committee (IRB&EC), Shifa Tameer-e-Millat University Islamabad.

Authors' contributions

FS contributed to the conception and design of the study. QA, MK, AA, ZA and SJ contributed to contacting the participants for data gathering. QA and AN analyzed the data and all authors contributed to the interpretation of data. QA, MK and FS drafted and submitted the manuscript and

directly accessed, verified the data. All authors critically reviewed the manuscript and approved the final draft.

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