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Side effects associated with homogenous and heterogenous doses of Oxford–AstraZeneca vaccine among adults in Bangladesh: an observational study

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Assessment of side effects associated with COVID-19 vaccination is required to monitor safety issues and acceptance of vaccines in the long term. We found a significant knowledge gap in the safety profile of COVID-19 vaccines in Bangladesh. We enrolled 1805 vaccine recipients from May 5, 2021, to April 4, 2023. Kruskal-Wallis test and χ2 test were performed. Multivariable logistic regression was also performed. First, second and third doses were administered among 1805, 1341, and 923 participants, respectively. Oxford–AstraZeneca (2946 doses) was the highest administered followed by Sinopharm BIBP (551 doses), Sinovac (214 doses), Pfizer-BioNTech (198 doses), and Moderna (160 doses), respectively. Pain at the injection site (80-90%, 3200–3600), swelling (85%, 3458), redness (78%, 3168), and heaviness in hand (65%, 2645) were the most common local effects, and fever (85%, 3458), headache (82%, 3336), myalgia (70%, 2848), chills (67%, 2726), muscle pain (60%, 2441) were the most prevalent systemic side effects reported within 48 h of vaccination. Thrombosis was only reported among the Oxford–AstraZeneca recipients (3.5-5.7%). Both local and systemic effects were significantly associated with the Oxford–AstraZeneca (*p-value* < 0.05), Pfizer–BioNTech (*p-value* < 0.05), and Moderna (*p-value* < 0.05) vaccination. Chronic urticaria and psoriasis were reported by 55-60% of the recipients after six months or later. The highest percentage of local and systemic effects after 2nd and 3rd dose were found among recipients of Moderna followed by Pfizer-BioNTech and Oxford–AstraZeneca. Homogenous doses of Oxford–AstraZeneca and heterogenous doses of Moderna and Pfizer-BioNTech were significantly associated with elevated adverse effects. Females, aged above 60 years with preexisting health conditions had higher risks. Vaccination with Pfizer-BioNTech (OR 4.34, 95% CI 3.95–4.58) had the highest odds of severe and long-term effects followed by Moderna (OR 4.15, 95% CI 3.92–4.69) and Oxford–AstraZeneca (OR 3.89, 95% CI 3.45–4.06), respectively. This study will provide an integrated insight into the safety profile of COVID-19 vaccines.

Keywords Side effects, COVID-19 vaccines, Long-term, Heterogenous, Bangladesh

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The coronavirus disease of 2019 (COVID-19) pandemic have severely affected every aspect of our life from 2019. Almost 705 million cases and 7 million deaths of COVID-19 have been documented worldwide[1,2]. Vaccines against COVID-19 were introduced on an emergency basis on the last quarter of 2020[3]. An estimated 13.6 billion doses of COVID-19 vaccine have been administered as of 15 May, 2024 globally. An early study projected about 20 million deaths have been reduced due to vaccination from 2020 to 2021 in more than 180 countries[3,4].

The world health organization prequalified COVID-19 vaccines based on several promising platforms including adenovirus vector vaccines (Oxford–AstraZeneca, Sputnik V, Janssen), inactivated virus vaccines (Sinopharm BIBP, CoronaVac, Covaxin, Valneva), mRNA vaccines (Pfizer–BioNTech, Moderna), and subunit vaccines (Novavax, Sanofi–GSK)[3–5]. Majority of these vaccines showed moderate to high efficacy (70-85%) varying among different localities[5]. However, after initiation of vaccination, concerns about safety and effectiveness affected the global acceptance of COVID-19 vaccines and still is a burning issue.

Mass vaccination of COVID-19 started on 7th February, 2021 in Bangladesh[6,7]. The first authorized vaccine for emergency use was Oxford–AstraZeneca followed by Sputnik V and Sinopharm BIBP. Later, emergency use of Pfizer-PF (Comirnaty), Moderna, Sinovac, and Janssen was also approved by the government of Bangladesh[6–9]. According to the WHO plan, vaccination was targeted for 70% of the total population. As of May, 2024, 1st dose was administered in about 88.6% of total population followed by 2nd dose in 83.3%, 3rd dose in 48% of 2nd dose receivers, respectively[1–3,6–9]. Among the seven vaccines introduced in Bangladesh, the highest number of doses were from Sinopharm BIBP (114.1 million) followed by Pfizer-BioNTech (80.6 million), Sinovac (61.3 million), AstraZeneca (56.3 million), Pfizer-PF (Comirnaty) (35.1 million), Moderna (15.8 million) and Janssen (0.6 million), respectively[1,6]. Though vaccination program was started on an emergency crisis, the safety profile and long-term health effects of these vaccines were unassessed in resource limited settings like Bangladesh. Amidst the concern of assessment of side effects of COVID-19 vaccine, Oxford–AstraZeneca vaccine has been withdrawn recently due to safety concern. Both short-term and long-term side effects of COVID-19 vaccine in Bangladesh are also poorly assessed. Significant lack of study and knowledge prevails on safety and side effects of COVID-19 among adults in Bangladesh. This lack of assessment of safety profile and long-term side effects are responsible for reduced trust and acceptance of COVID-19 vaccines.

The main aim of this study was to determine the prevalence and diversity of both short and long-term side effects of Oxford–AstraZeneca vaccine taken as homogenous doses and heterogenous doses among the adult population in Bangladesh.

Results

Sociodemographic characteristics

We included 1805 adults from 64 districts in Bangladesh to determine the adverse effects of COVID-19 vaccination. Male to female ratio was 2:1 (1161:644). All of the participants were aged 20 years or above. Majority of the participants were aged between 20 and 29 years (38.2%, 692 of 1805) followed by 50–59 years (25.2%, 454 of 1805), 40–49 years (22.5%, 406 of 1805) and 30–39 years (7.2%, 130 of 1805), respectively (Table 1). Non-smoker (69%, 1245 of 1805) was prevalent followed by smoker (31%, 560 of 1805). About 12% of them reported various preexisting health conditions including CVDs, hypertension, diabetes, asthma, COPD, autoimmunity and obesity. Access to health facilities was moderate to majority of them (48%, 867 of 1805) living in urban and suburban areas (83.3%). About 22% (402 of 1805) of the participants reported COVID-19 infection before vaccination. As a first dose, Oxford–AstraZeneca (90.2%, 1628 of 1805) was the most administered vaccine followed by Sinopharm BIBP (9.8%, 177 of 1805); as a second dose, Oxford–AstraZeneca (61.4%, 824 of 1341) was the most common followed by Sinopharm BIBP (11.4%, 153 of 1341), Sinovac (10.7%, 143 of 1341), Pfizer-BioNTech (9.2%, 123 of 1341), and Moderna (7.3%, 98 of 1341), respectively; as a third dose, Oxford–AstraZeneca (53.5%, 494 of 923) and Sinopharm BIBP (23.9%, 321 of 923) were the most commonly administered vaccines among them (Table 1). Majority of the vaccine recipients were from Dhaka (30%) followed by Mymensingh (24%), Chattogram (15%), Khulna (11%) and Dinajpur (8%), respectively (Fig. 1).

Adverse effects profile

The adverse effect profiling among the vaccinated participants indicated that majority of the events occurred within 24 h of vaccination both by Oxford–AstraZeneca (73.7%) and Sinopharm BIBP (53%), followed by 24–48 h (15%) and 2–7 days (9%), respectively. Adverse effects after vaccination lasted for more than 6 months among 22.3% (213 of 954) recipients of Oxford–AstraZeneca and 24.3% (28 of 115) of Sinopharm BIBP recipients. About 59% of the participants experienced adverse effects after 1 month or above of the first dose vaccination (Table 2).

Incidence of short-term side effects gradually decreased from 92.5 to 64.7% from the first dose to the second dose vaccine recipients, respectively and followed by third dose (57.6%) recipients. Majority of the adverse effects were documented within 24 h of second dose and third dose vaccination. Long-term side effects appeared after 1 months or above we found in higher frequency after second dose (64.65%), followed by third (61.32%) and first (59.2%) dose vaccination. Among the second dose recipients both long- and short-term side effects were prevalent in the Oxford–AstraZeneca homogenous group (56%) than heterogenous group (Table 3). However, among the third dose recipients, the adverse effects were more prevalent among the heterogenous group (61%) than homogenous group (Table 4).

The frequency of breakthrough cases after vaccination was higher among the Oxford–AstraZeneca (20%) recipients as first or second dose followed by Sinopharm BIBP (15%). Breakthrough cases were more common among the respondents of third dose (28.3%) followed by first (25.7%) and second dose (20.2%) vaccine. Both in second and third doses higher prevalence of breakthrough cases were reported among the homogenous

Variables	First dose, $N=1805$ (%)	Second dose, $N=1341$ (%)	Third dose, $N=923$ (%)
Sex			
Male	1161 (64.3)	790 (58.9)	545 (59)
Female	644 (35.7)	551 (41.1)	378 (41)
Age groups (years)			
20–29	692 (38.2)	326 (24.3)	214 (23.2)
30–39	130 (7.2)	114 (8.5)	87 (9.4)
40–49	406 (22.5)	369 (27.5)	254 (27.5)
50–59	454 (25.2)	418 (31.2)	289 (31.3)
60–69	114 (6.3)	108 (8.1)	75 (8.1)
Above 70	9 (0.5)	6 (0.4)	4 (0.4)
Occupation			
Student	854 (47.3)	612 (45.6)	415 (45)
Employed	746 (41.3)	532 (39.7)	378 (41)
Unemployed	205 (11.4)	197 (14.7)	130 (14)
Smoking history			
Smoker	560 (31)	446 (33.3)	212 (23)
Non-smoker	1245 (69)	895 (66.7)	711 (77)
Health status			
Preexisting health conditions	217 (12)	187 (13.9)	125 (13.5)
Hospitalization	11 (0.6)	8 (0.6)	13 (1.4)
ICU admission	7 (0.4)	5 (0.4)	6 (0.7)
Residence			
Urban	981 (54.3)	623 (46.5)	542 (58.7)
Suburban	523 (29)	467 (34.8)	321 (34.8)
Rural	301 (16.7)	251 (18.7)	60 (6.5)
Access to health services*			
Poor	317 (17.6)	231 (17.2)	124 (13.4)
Moderate	867 (48)	678 (50.6)	287 (31.1)
Good	621 (34.4)	432 (32.2)	512 (55.5)
COVID-19 infection before vaccination			
Infected	402 (22.3)	362 (27)	245 (26.5)
Negative	1403 (77.7)	979 (73)	678 (73.5)
COVID-19 vaccine type			
Oxford–AstraZeneca	1628 (90.2)	824 (61.4)	494 (53.5)
Sinopharm BIBP	177 (9.8)	153 (11.4)	221 (23.9)
Pfizer-BioNTech	0	123 (9.2)	75 (8.1)
Sinovac	0	143 (10.7)	71 (7.7)
Moderna	0	98 (7.3)	62 (6.1)

Table 1. Demographic characteristics of the participants. *The ability of people to reach hospitals/clinics/doctors/health care providers and services and the ability of hospitals/clinics/doctors/health care providers to be reached by people.

vaccinated participants of Oxford–AstraZeneca (17.2% and 30.2%, respectively) than Sinopharm BIBP and heterogenous vaccinated participants (Table 2, 3, 4).

Adverse effects severity

Severity of adverse effects were defined and categorized into five groups, namely very mild, mild, moderate, severe and very severe based on the previously published articles.

First dose: Majority of the Oxford–AstraZeneca vaccine recipients reported moderate side effects (44%) followed by mild (32%), severe (12%) and very mild (11%), respectively. On the contrary, Sinopharm BIBP recipients had mild side effects (54%) in higher frequency followed by very mild (27%) and moderate (18%) effects. Both short- and long-term side effects were significantly higher among Oxford–AstraZeneca vaccine recipients (92% and 57%, respectively) than Sinopharm BIBP recipients (Fig. 2A).

Second dose: Frequency of adverse effects after second dose of Oxford–AstraZeneca and Sinopharm BIBP were similar to the severity of first dose. Both for Moderna (56%) and Pfizer-BioNTech (51%), moderate effects were prevalent followed by mild (23% and 28%) and severe (16% and 17%) effects, respectively. Further, Sinovac recipients reported mild effects (55%) in higher percentage followed by very mild (33%) and moderate (18%).

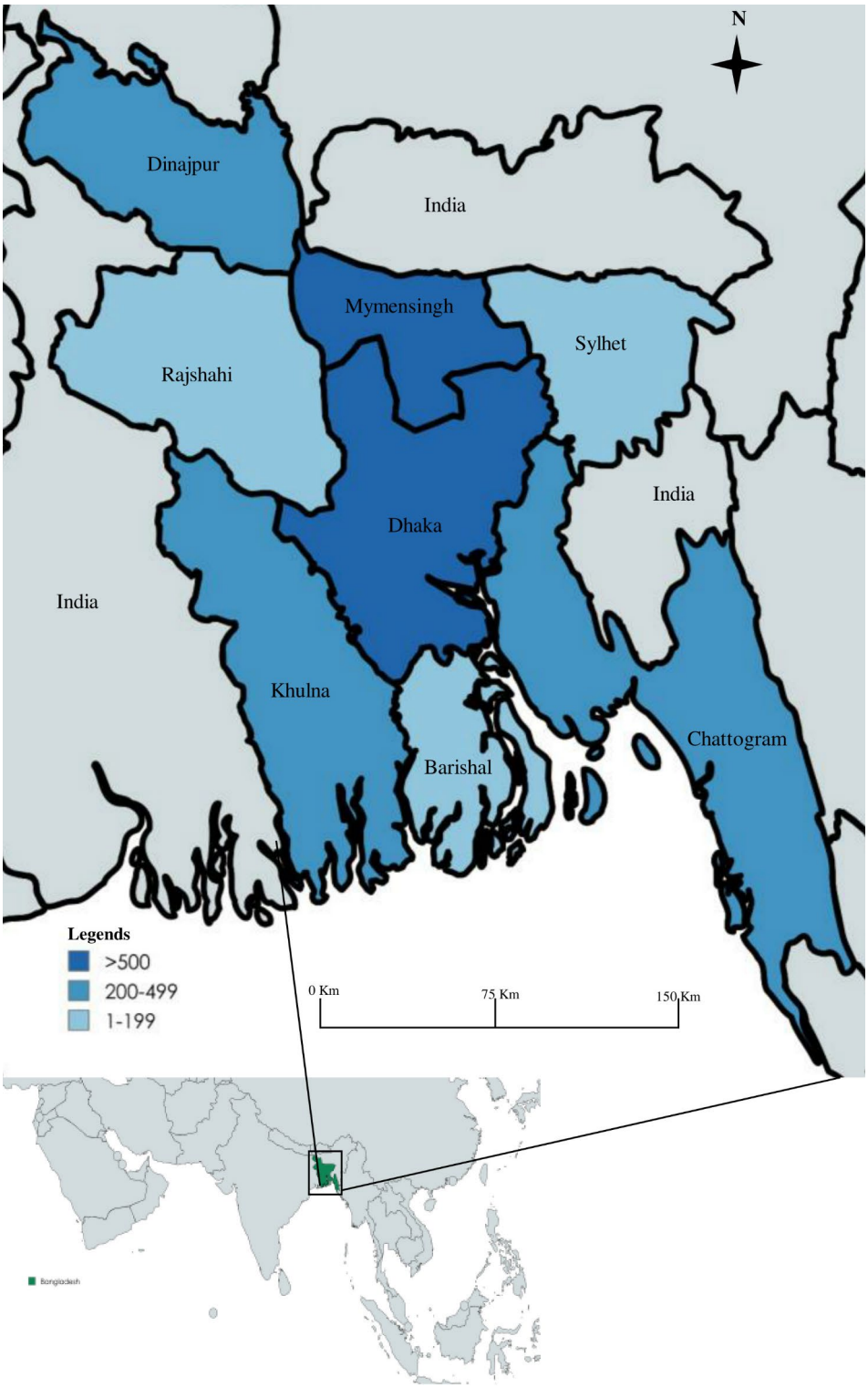

Fig. 1. Map of study area and areas of survey.

Moderna, Pfizer-BioNTech and Sinovac recipients experienced higher frequency of both short- and long-term side effects (68-85% and 57-64%, respectively) than Oxford–AstraZeneca or Sinopharm BIBP recipients in second dose (Fig. 2B).

Third dose: Frequency of severe and very severe adverse effects reduced (< 6%) after third dose than first and second dose vaccination among the participants. Higher percentage of moderate side effects was reported among the Moderna and Pfizer-BioNTech recipients (> 38-43%) than other vaccines. Participants with Moderna (84% and 65%) and Pfizer-BioNTech (78% and 58%) vaccination experienced higher percentage of short and

Factors	OA (%)	S (%)	*P* value
Breakthrough cases[#]			0.001
Yes	219 (26)	43 (24.3)	
No	623 (74)	134 (75.7)	
	N = 842	*N* = 177	
Onset of side effects (Short-term)			< 0.001
Within 24 h	1124 (73.7)	82 (52.9)	
From 24 h to 48 h	213 (13.97)	41 (26.4)	
From 49 h to 7 days	134 (8.8)	19 (12.2)	
From 8 days to 14 days	54 (3.5)	13 (8.3)	
	N = 1525	*N* = 155	
Onset of side effects (Long-term)			0.005
From 30 days to 3 months	425 (44.6)	52 (45.3)	
From 91 days to 6 months	316 (33.1)	35 (30.4)	
Above 6 months	213 (22.3)	28 (24.3)	
	N = 954	*N* = 115	

Table 2. Short-term and long-term side effects after first dose vaccination. *P* value < 0.05 was considered significant. OA- Oxford–AstraZeneca; S- Sinopharm BIBP. # a case of covid-19 in which a vaccinated individual becomes infected with the SARS-CoV-2.

Factors	OA–OA (%)	OA - S (%)	OA-Sv (%)	OA-M (%)	OA-PB (%)	S-S (%)	S-Sv (%)	S-M (%)	S -PB (%)	*P* value
Breakthrough cases[#]										0.001
Yes	73 (17.2)	20 (19.6)	16 (19.3)	8 (25)	12 (25.5)	7 (25)	9 (21.4)	13 (28.9)	11 (34.4)	
No	352 (82.8)	82 (80.4)	67 (80.7)	24 (75)	35 (74.5)	21 (75)	33 (78.6)	32 (71.1)	21 (65.6)	
N	425	102	83	32	47	28	42	45	32	
Onset of side effects										0.005
Within 24 h	171 (39.2)	76 (62.8)	27 (62.7)	35 (52.2)	63 (70)	12 (63.1)	22 (55)	22 (71)	11 (52.4)	
From 24 h to 48 h	131 (30)	32 (26.4)	9 (21)	21 (31.3)	17 (18.9)	4 (21)	12 (30)	6 (19.4)	5 (23.8)	
From 49 h to 7 days	91 (20.9)	11 (9.2)	4 (9.3)	8 (11.9)	6 (6.7)	2 (10.5)	5 (12.5)	2 (6.5)	4 (19)	
From 8 days to 14 days	43 (9.9)	2 (1.6)	3 (7)	3 (4.5)	4 (4.4)	1 (5.4)	1 (2.5)	1 (3.2)	1 (4.8)	
N	436	121	43	67	90	19	40	31	21	
Onset of side effects										< 0.001
From 30 days to 3 months	156 (30.1)	12 (44.4)	31 (36)	11 (34.3)	42 (47.2)	17 (50)	9 (42.8)	13 (44.8)	18 (58)	
From 91 days to 6 months	108 (20.8)	6 (22.2)	28 (32.6)	8 (25)	26 (29.2)	8 (23.5)	4 (19)	8 (27.6)	3 (9.7)	
After 6 months	254 (49)	9 (33.4)	27 (31.4)	13 (40.6)	21 (23.6)	9 (26.5)	8 (38.2)	8 (27.6)	10 (32.3)	
N	518	27	86	32	89	34	21	29	31	

Table 3. Short-term and long-term side effects after second dose vaccination. *P* value < 0.05 was considered significant. OA- Oxford–AstraZeneca; S- Sinopharm BIBP; PB- Pfizer-BioNTech; M- Moderna; Sv- Sinovac. # a case of covid-19 in which a vaccinated individual becomes infected with the SARS-CoV-2.

long-term effects followed by Oxford–AstraZeneca (58% and 65%) and Sinovac (48% and 58%), respectively (Fig. 2C).

Association of vaccination and side effects

First dose

After the first dose of vaccination, about 97.5% (1760 of 1805) recipients experienced adverse effects. All of the adverse effects were more prevalent among the recipients of Oxford–AstraZeneca than Sinopharm BIBP. Among the Oxford–AstraZeneca recipients, pain at the injection site (95.6%) was the most prevalent effect followed by fever (78.4%), myalgia (74.8%), headache (60.4%), heaviness in the injected hand (57.7%), redness at the injection site (52%) and chills (47.9%), respectively. Recipients of Sinopharm BIBP reported different skin problems including itchy skin (83%), psoriasis (64%), and urticaria (54%) as prevalent side effects followed by pain at the injection site (54%) and hand (49%), respectively. However, thrombosis after vaccination was only reported among 3.7% of the Oxford–AstraZeneca recipients (Table 5).

Factors	OA-OA-OA	OA-OA-S	OA-OA-Sv	S-S-S	S -S-Sv	S-S-PB	OA-Sv-M	OA-M-S	S -PB-PB	S-M-M	S-M-PB	*P* value
Breakthrough cases[#]												
Yes	57 (30.2)	43 (20.4)	65 (31.3)	8 (10.9)	7 (15.2)	3 (21.4)	2 (14.3)	8 (19)	3 (17.6)	1 (12.5)	4 (26.7)	0.003
No	132 (69.8)	168 (79.6)	143 (68.8)	65 (93.1)	39 (84.8)	11 (78.6)	12 (85.7)	34 (81)	14 (82.4)	7 (87.5)	11 (73.3)	
N	189	123	168	73	46	14	14	42	17	8	15	
Onset of side effects												
Within 24 h	51 (52)	65 (49.2)	38 (45.2)	26 (68.4)	21 (51.3)	15 (51.7)	12 (57.1)	16 (38.1)	13 (52)	9 (60)	6 (85.7)	0.001
From 24 h to 48 h	26 (26.5)	41 (31.1)	27 (32.1)	8 (21)	10 (24.4)	11 (37.9)	3 (14.3)	9 (21.4)	6 (24)	4 (26.7)	1 (14.3)	
From 49 h to 7 days	13 (13.3)	20 (15.2)	15 (17.9)	3 (7.9)	7 (17)	2 (6.9)	5 (23.8)	11 (26.2)	5 (20)	2 (13.3)	0 (0)	
From 8 days to 14 days	8 (8.2)	6 (4.5)	4 (4.8)	1 (2.7)	3 (7.3)	1 (3.5)	1 (4.8)	6 (14.3)	1 (4)	0 (0)	0 (0)	
N	98	132	84	38	41	29	21	42	25	15	7	
Onset of side effects												
From 30 days to 3 months	23 (22.8)	67 (44.1)	33 (33.3)	25 (31.6)	26 (38.8)	6 (31.6)	9 (37.5)	12 (48)	21 (48.8)	11 (42.3)	5 (45.5)	0.005
From 91 days to 6 months	31 (30.7)	34 (22.4)	27 (27.3)	21 (26.6)	19 (28.4)	8 (42.1)	11 (45.8)	8 (32)	9 (20.9)	7 (26.9)	2 (18.2)	
After 6 months	47 (46.5)	51 (33.6)	39 (39.4)	33 (41.8)	22 (32.8)	5 (26.3)	4 (16.7)	5 (20)	13 (30.2)	8 (30.8)	4 (36.4)	
N	101	152	99	31	35	19	24	25	43	26	11	

Table 4. Short-term and long-term side effects after third dose vaccination. OA- Oxford–AstraZeneca; S- Sinopharm BIBP; PB- Pfizer-BioNTech; M- Moderna; Sv- Sinovac. *P* value < 0.05 was considered significant. # a case of covid-19 in which a vaccinated individual becomes infected with the SARS-CoV-2.

Side effects, *N* (%)	OA *N* = 1601	S *N* = 159	All *N* = 1760	*P* value
Pain at the injection site	1531 (95.6)	86 (54.1)	1617 (91.9)	< 0.001
Redness and inflammation	832 (52)	17 (10.7)	849 (48.2)	< 0.001
Swelling	375 (23.4)	12 (7.5)	387 (22)	< 0.001
Pain in injected hand	497 (31)	78 (49.1)	575 (32.7)	< 0.001
Heaviness in injected hand	923 (57.7)	27 (17)	950 (54)	< 0.001
Fever	1255 (78.4)	8 (5)	1263 (71.8)	< 0.001
Headache	967 (60.4)	11 (6.9)	978 (55.6)	< 0.001
Myalgia	1198 (74.8)	17 (10.7)	1215 (69)	0.005
Chills	767 (47.9)	9 (5.7)	776 (44.1)	< 0.001
Nausea	612 (38.2)	14 (8.8)	626 (35.6)	0.05
Vomiting	219 (13.7)	2 (1.3)	221 (12.6)	< 0.001
Shortness of breath	265 (16.6)	8 (5)	273 (15.5)	0.002
Runny nose	42 (2.6)	1 (0.6)	43 (2.4)	< 0.001
Itchy skin*	721 (45)	132 (83)	853 (48.5)	< 0.006
Psoriasis*	655 (40.9)	102 (64.2)	757 (43)	< 0.001
Urticaria*	483 (30.2)	86 (54.1)	569 (32.3)	0.001
Olfactory disorder	159 (9.9)	18 (11.3)	177 (10.1)	< 0.001
Diarrhea	131 (8.2)	3 (1.9)	134 (7.6)	< 0.001
Thrombosis	59 (3.7)	0 (0)	59 (3.4)	< 0.001
Other complications	329 (20.5)	32 (20.1)	361 (20.5)	< 0.001
No side effects	27 (1.7)	18 (11.3)	45 (2.6)	0.005

Table 5. Side effects associated with first dose vaccination. OA- Oxford–AstraZeneca; S- Sinopharm BIBP; * >6 months. *P* value < 0.05 was considered significant.

Second dose

Local and systemic adverse effects after vaccination with Oxford–AstraZeneca and Sinopharm BIBP as homogenous dose in second shot reduced by 15–25% than first dose. However, various skin problems after 6

Side effects, *N* (%)	OA *N* = 802	S *N* = 125	PB *N* = 118	Sv *N* = 124	M *N* = 92	All *N* = 1261	*P* value
Pain at the injection site	341 (42.5)	59 (47.2)	102 (86.4)	82 (66.1)	91 (98.9)	675 (53.5)	0.001
Redness and inflammation	278 (34.7)	47 (37.6)	106 (89.8)	84 (67.7)	86 (93.5)	601 (47.7)	0.05
Swelling	324 (40.4)	39 (31.2)	111 (94.1)	43 (34.7)	83 (90.2)	600 (47.6)	< 0.001
Pain in injected hand	255 (31.8)	57 (45.6)	117 (99.2)	58 (46.8)	88 (95.7)	575 (45.6)	< 0.001
Heaviness in injected hand	187 (23.3)	53 (42.4)	106 (89.8)	44 (35.5)	89 (96.7)	479 (38)	< 0.001
Fever	489 (61)	25 (20)	84 (71.2)	32 (25.8)	91 (98.9)	721 (57.2)	< 0.001
Headache	356 (44.4)	34 (27.2)	92 (78)	41 (33.1)	84 (91.3)	607 (48.1)	0.005
Myalgia	389 (48.5)	28 (22.4)	85 (72)	39 (31.5)	76 (82.6)	617 (48.9)	< 0.001
Chills	254 (31.7)	41 (32.8)	79 (66.9)	16 (12.9)	81 (88)	471 (37.4)	0.004
Nausea	218 (27.2)	11 (8.8)	55 (46.6)	21 (16.9)	75 (81.5)	380 (30.1)	0.001
Vomiting	29 (3.6)	8 (6.4)	14 (11.9)	12 (9.7)	14 (15.2)	77 (6.1)	0.001
Shortness of breath	124 (15.5)	19 (15.2)	38 (32.2)	23 (18.5)	31 (33.7)	235 (18.6)	0.005
Runny nose	13 (1.6)	7 (5.6)	11 (9.3)	9 (7.3)	12 (13)	52 (4.1)	0.001
Itchy skin*	490 (61.1)	95 (76)	68 (57.6)	106 (85.5)	74 (80.4)	833 (66.1)	< 0.001
Psoriasis*	524 (65.3)	101 (80.8)	79 (66.9)	94 (75.8)	81 (88)	879 (69.7)	< 0.001
Urticaria*	374 (46.6)	78 (62.4)	104 (88.1)	108 (87.1)	79 (85.9)	743 (58.9)	0.005
Olfactory disorder	142 (17.7)	14 (11.2)	23 (19.5)	19 (15.3)	25 (27.2)	223 (17.7)	0.001
Diarrhea	86 (10.7)	6 (4.8)	13 (11)	4 (3.2)	11 (12)	120 (9.5)	0.005
Thrombosis	28 (3.5)	0 (0)	0 (0)	0 (0)	0 (0)	28 (2.2)	0.05
Other side effects	257 (32)	35 (28)	77 (65.3)	26 (21)	72 (78.3)	467 (37)	< 0.001
No side effects	22 (2.7)	28 (22.4)	5 (4.2)	19 (15.3)	6 (6.5)	80 (6.3)	0.005

Table 6. Side effects associated with second dose vaccination. OA- Oxford–AstraZeneca; S- Sinopharm BIBP; PB- Pfizer-BioNTech; M- Moderna; Sv- Sinovac; * >6 months. *P* value < 0.05 was considered significant.

Side effects, *N* (%)	OA *N* = 423	S *N* = 259	PB *N* = 21	Sv *N* = 42	M *N* = 24	All *N* = 769	*P* value
Pain at the injection site	312 (73.8)	101 (39)	20 (95.2)	19 (45.2)	21 (87.5)	473 (61.5)	< 0.001
Redness and inflammation	272 (64.3)	88 (34)	21 (100)	23 (54.8)	22 (91.7)	426 (55.4)	0.001
Swelling	321 (75.9)	147 (56.8)	18 (85.7)	28 (66.7)	21 (87.5)	535 (69.6)	0.005
Pain in injected hand	243 (57.4)	54 (20.8)	19 (90.5)	21 (50)	17 (70.8)	354 (46)	< 0.001
Heaviness in injected hand	233 (55.1)	28 (10.8)	19 (90.5)	17 (40.5)	18 (75)	315 (41)	< 0.001
Fever	289 (68.3)	92 (35.5)	21 (100)	19 (45.2)	23 (95.8)	444 (57.7)	< 0.001
Headache	154 (36.4)	123 (47.5)	20 (95.2)	27 (64.3)	21 (87.5)	345 (44.9)	0.001
Myalgia	211 (49.9)	68 (26.3)	16 (76.2)	16 (38.1)	16 (66.7)	327 (42.5)	0.001
Chills	155 (36.6)	36 (13.9)	18 (85.7)	13 (31)	18 (75)	240 (31.2)	0.005
Nausea	230 (54.4)	48 (18.5)	14 (66.7)	23 (54.8)	16 (66.7)	331 (43)	0.005
Vomiting	87 (20.6)	15 (5.8)	6 (28.6)	13 (31)	11 (45.8)	132 (17.2)	0.05
Shortness of breath	43 (10.2)	37 (14.3)	15 (71.4)	17 (40.5)	15 (62.5)	127 (16.5)	0.001
Runny nose	21 (5.0)	12 (4.6)	4 (19)	9 (21.4)	9 (37.5)	55 (7.2)	0.005
Itchy skin*	345 (81.6)	206 (79.5)	17 (81)	38 (90.5)	23 (95.8)	629 (81.8)	< 0.004
Psoriasis*	351 (83.0)	216 (83.4)	18 (85.7)	35 (83.3)	21 (87.5)	641 (83.4)	< 0.001
Urticaria*	324 (76.6)	185 (71.4)	19 (90.5)	39 (92.9)	18 (75)	585 (76.1)	0.001
Olfactory disorder	142 (33.6)	24 (9.3)	9 (42.9)	13 (31)	11 (45.8)	199 (25.9)	0.05
Diarrhea	21 (5.0)	15 (5.8)	5 (23.8)	5 (11.9)	8 (33.3)	54 (7)	0.001
Thrombosis	24 (5.7)	0 (0)	0 (0)	0 (0)	0 (0)	24 (3.1)	0.001
Other side effects	143 (33.8)	136 (52.5)	13 (61.9)	18 (42.9)	17 (70.8)	327 (42.5)	< 0.001
No side effects	71 (16.8)	62 (23.9)	4 (19)	9 (21.4)	8 (33.3)	154 (20)	0.005

Table 7. Side effects associated with third dose vaccination. OA- Oxford–AstraZeneca; S- Sinopharm BIBP; PB- Pfizer-BioNTech; M- Moderna; Sv- Sinovac; * >6 months. *P* value < 0.05 was considered significant.

months of the second dose increased among these vaccine recipients. Among the participants with the Moderna vaccine, the majority of the local and systemic side effects were found in the highest frequency (80-99%). Pain at the injection site (98.9%) and fever (98.9%) was the most common adverse effects among them followed by heaviness in the injected hand (96.7%), pain in the hand (95.7%), redness in the site (93.5%), and headache (91.3%), respectively. Similarly, among the Pfizer-BioNTech (70-95%) vaccine recipients, side effects were found more frequently than Oxford–AstraZeneca, Sinopharm BIBP, and Sinovac. We found around 60-80% of the second-dose recipients reported skin-related side effects including itchy skin, psoriasis, rash, and urticaria after three months. Events like thrombosis were only found among 3.5% of Oxford–AstraZeneca recipients (Table 6). Around 6.3% of participants reported no side effects after the second dose of vaccination.

Third dose

Side effects after the third dose of COVID-19 vaccines were reduced than the second or first dose among the participants. The recipients of Pfizer-BioNTech experienced elevated levels of local (86-100%) and systemic (60-75%) adverse effects than other vaccines. Further, the recipients of the Moderna vaccine reported elevated adverse effects; local effects (70-90%) and systemic effects (65-95%). Thrombosis persisted only among the Oxford–AstraZeneca recipients (5.7%) after the third dose (Table 7). Other significant adverse effects among the recipients of vaccines included altered sleep habits, restlessness, altered allergic reactions, muscle pain, back pain, increased ophthalmic allergies, and changed memorizing ability. About 20% of third-dose recipients reported no adverse effects. We found that vaccination of any one of these vaccines in homogenous or heterogenous shots was significantly associated with multiple adverse effects among the participants.

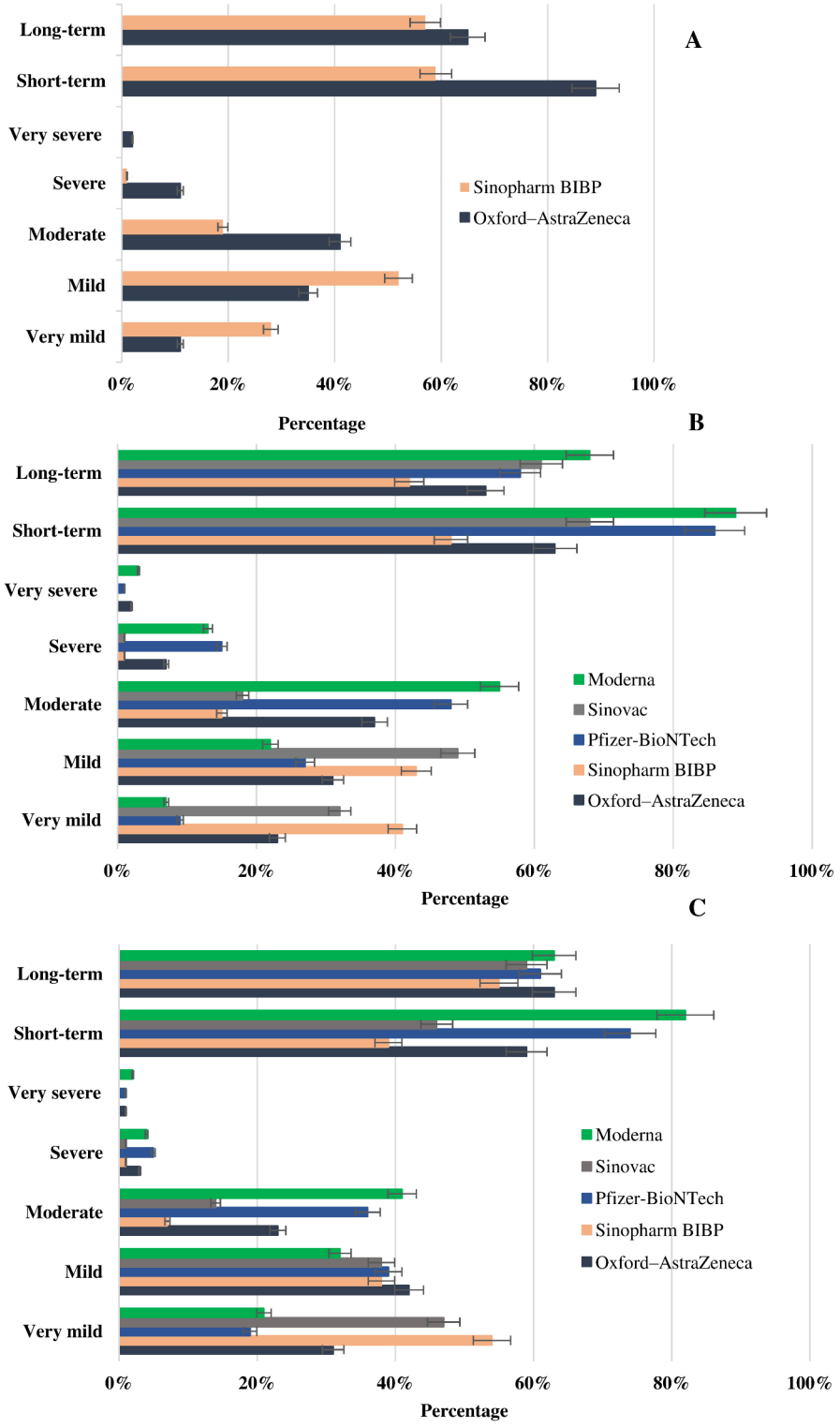

Fig. 2. Adverse effects severity among the recipients of (A) First dose, (B) Second dose and (C) Third dose.

Risk factors of adverse effects

A multivariable logistic regression model was built to determine the risk factors of adverse effects reported by the vaccine recipients. Vaccination with any one of these COVID-19 vaccines had the highest odds of adverse effects (OR 4.89, 95% CI 4.61–5.27) among the participants. Among other host factors, vaccine recipients' sex (OR 1.41, 95% CI 1.12–1.84), smoking habit (OR 1.21, 95% CI 1.03–1.54), previous COVID-19 infection (OR 2.43, 95% CI 2.15–2.87), preexisting diabetes (OR 1.34, 95% CI 1.02–1.54), autoimmune diseases (OR 1.34, 95% CI 1.01–1.43), asthma (OR 1.21, 95% CI 1.07–1.59) and COPD (OR 1.25, 95% CI 1.13–1.76) were significantly

associated with higher odds of adverse effects. Recipients of the Moderna (OR 4.29, 95% CI 3.87–4.58) vaccine had the highest odds of adverse effects followed by Oxford–AstraZeneca (OR 4.24, 95% CI 3.99–4.68), Pfizer-BioNTech (OR 3.12, 95% CI 2.88–3.45), Sinopharm BIBP (OR 2.78, 95% CI 2.41–3.13) and Sinovac (OR 2.33, 95% CI 2.11–2.84), respectively in Bangladesh. Further, the odds of adverse effects were significantly higher in the participants with homogenous or heterogenous shots and single and/or, double and/or triple doses of vaccine (Table 8).

We also determined the risk factors of developing severe or long-term side effects after vaccination among the study population. Similarly, we found that COVID-19 vaccination (OR 1.76, 95% CI 1.29–1.95), age (OR 1.15, 95% CI 1.05–1.53), sex (OR 1.89, 95% CI 1.52–1.95), previous infection (OR 1.76, 95% CI 1.29–1.95), COPD (OR 1.51, 95% CI 1.36–1.95), asthma (OR 1.65, 95% CI 1.34–1.97), tuberculosis (OR 1.43, 95% CI 1.26–1.94) and long COVID (OR 1.59, 95% CI 1.35–1.98) increased the odds of severe and long-term effects significantly. Further, recipients of heterogenous doses (OR 3.13, 95% CI 2.78–3.51) and double doses (OR 3.53, 95% CI 3.18–3.95) had higher odds of long-term and severe events. Among the administered vaccines, Pfizer-BioNTech (OR 4.34, 95% CI 3.95–4.58) had the highest odds of long-term and severe effects followed by Moderna (OR 4.15, 95% CI 3.92–4.69), Oxford–AstraZeneca (OR 3.89, 95% CI 3.45–4.06), Sinovac (OR 3.49, 95% CI 3.23–3.95), and Sinopharm BIBP (OR 3.16, 95% CI 3.03–3.71), respectively (Table 9).

Discussion

Vaccines against COVID-19 were necessary to prevent unprecedented death and morbidity worldwide[8–10]. Permission to use WHO-prequalified vaccines on an emergency basis was determined by local authorities based on initial data on safety and efficacy[3]. The safety profile of these vaccines needs continuous monitoring to evaluate health effects and confirm trust and acceptance among general people[11–14]. To the best of our knowledge, this is the first comprehensive study on the safety profile of COVID-19 vaccines among the Bangladeshi population. Our study found six major aspects of side effects of COVID-19 vaccines. First, the majority of the participants experienced local and systemic side effects after vaccination. These side effects were reported mostly (70-85%) within 48 h of the vaccination. Though these findings were similar to initial clinical trials and observational studies, the duration and intensity varied in this study[7,8,15–18]. Among the local effects pain at the injection site, hand, heaviness in injected hand, redness, back pain, muscle pain, and swelling were common (70-85%), while fever, headache, and myalgia were the prevalent systemic effects (80%). Longitudinal studies have already reported the long-term effects of COVID-19 vaccines among different populations[15]. Following this statement, we also found that COVID-19 vaccines are associated with long-term side effects after six months or above of

Characteristics	OR (95% Confidence interval)	*P* value
COVID-19 Vaccination	4.89 (4.61–5.27)	0.005
Age (per 10 years)	0.32 (0.1–0.91)	0.05
Sex (Female vs. male)	1.41 (1.12–1.84)	0.04
Occupation	0.32 (0.13–0.54)	0.2
Smoking habit	1.21 (1.03–1.54)	0.005
Health status (Healthy vs. comorbidity)	0.54 (0.21–0.93)	0.03
Residence	0.21 (0.1–0.4)	0.14
COVID-19 infection (Positive vs. negative)	2.43 (2.15–2.87)	0.001
Oxford–AstraZeneca	4.24 (3.99–4.68)	0.005
Sinopharm BIBP	2.78 (2.41–3.13)	< 0.001
Pfizer-BioNTech	3.12 (2.88–3.45)	0.001
Sinovac	2.33 (2.11–2.84)	0.005
Moderna	4.29 (3.87–4.58)	< 0.001
Single dose	3.56 (3.14–3.76)	0.004
Double doses	2.31 (2.15–2.97)	0.05
Triple doses	2.45 (1.89–2.76)	0.01
Homogenous doses	3.12 (2.59–3.31)	0.001
Heterogenous doses	2.85 (2.53–3.23)	0.005
Diabetes	1.34 (1.02–1.54)	0.03
CVDs	0.5 (0.25–0.71)	0.54
Hypertension	0.63 (0.23–0.78)	0.51
Autoimmune diseases	1.32 (1.01–1.43)	0.05
Influenza	0.68 (0.31–0.96)	0.07
HIV	0.42 (0.25–0.82)	0.005
Asthma	1.21 (1.07–1.59)	0.001
Anemia	0.6 (0.32–0.87)	0.4
COPD	1.25 (1.13–1.76)	0.01

Table 8. Odds of adverse effects among the participants. *P* value < 0.05 was considered significant.

Characteristics	OR (95% Confidence interval)	*P* value
COVID-19 Vaccination	3.67 (3.31–4.05)	0.001
Age (per 10 years)	1.15 (1.05–1.53)	0.001
Sex (Female vs. male)	1.89 (1.52–1.95)	0.05
Occupation	0.51 (0.22–0.81)	0.4
Smoking habit	0.43 (0.24–0.87)	0.02
Health status (Healthy vs. comorbidity)	0.34 (0.11–0.67)	0.07
Residence	0.48 (0.25–0.89)	0.35
COVID-19 infection (Positive vs. negative)	1.76 (1.29–1.95)	0.005
Oxford–AstraZeneca	3.89 (3.45–4.06)	0.005
Sinopharm BIBP	3.16 (3.03–3.71)	< 0.001
Pfizer-BioNTech	4.34 (3.95–4.58)	0.05
Sinovac	3.49 (3.23–3.95)	0.001
Moderna	4.15 (3.92–4.69)	< 0.001
Single dose	3.17 (2.92–3.54)	0.001
Double dose	3.53 (3.18–3.95)	0.005
Triple dose	2.83 (2.52–3.24)	0.001
Homogenous dose	2.78 (2.35–3.05)	0.05
Heterogenous dose	3.13 (2.78–3.51)	0.01
Diabetes	1.13 (1.01–1.42)	0.05
CVDs	0.3 (0.1–0.65)	0.61
Hypertension	0.24 (0.12–0.63)	0.05
Autoimmune diseases	1.25 (1.12–1.75)	0.01
Influenza	0.27 (0.1–0.57)	0.03
HIV	0.53 (0.17–0.83)	0.001
Asthma	1.65 (1.34–1.97)	0.001
Anemia	0.3 (0.24–0.63)	0.03
COPD	1.51 (1.36–1.95)	0.05
Tuberculosis	1.43 (1.26–1.94)	0.001
Bronchitis	0.8 (0.54–0.96)	0.001
Long COVID-19	1.59 (1.35–1.98)	0.01

Table 9. Odds of severe and long-term adverse effects among the participants. *P* value < 0.05 was considered significant.

vaccination[17–22]. Allergic skin, urticaria, and psoriasis were reported among 60–70% of the vaccine recipients after 6 months, which is an exclusive finding in this population compared to other studies. These conditions require detailed investigation and clinical experiments to determine the relationship of vaccination.

Second, we found a reduction in vaccine recipients from the first dose to the second dose and the second dose to the third dose. About 25.7% and 48.9% of recipients reduced from first to second and first to third dose, respectively, followed by 31.8% reduction from second to third dose. This finding is fully supported by both the national and international data on vaccination[1,6,11–14]. Previous studies also support that concern about safety profile may affect the acceptance of COVID-19 vaccines in settings with limited resources and developed countries[11–14]. We also found relatively higher percentages of breakthrough cases (15-25%) after vaccination among the study population. To increase the acceptance and trust of vaccines and prevent further health burden of COVID-19, effective and safe vaccines after appropriate trials should be disseminated. This statement is supported by previous studies[12,13]. Third, we found all of the vaccines were significantly associated with various adverse effects among the recipients. After the first dose, pain at the injection site, swelling, redness, heaviness in the injected hand, fever, headache, myalgia, chills, shortness of breath, vomiting nausea, olfactory problems, and diarrhea were significantly associated ($p\text{-}value < 0.05$) with Oxford–AstraZeneca and Sinopharm BIBP vaccine. After the second and third dose vaccination, these local and systemic effects were also found significantly associated with Moderna, Pfizer-BioNTech, Oxford–AstraZeneca, Sinopharm BIBP, and Sinovac vaccine. Health effects after six months of vaccination like psoriasis and urticaria were seen in higher percentage among the participants and significantly associated with these vaccines. This is a relatively new report among vaccine recipients in Bangladesh. Further, long-term reports of inflammatory skin conditions associated with vaccination have not been reported from Bangladesh. There are several previous reports of increased cases of psoriasis and urticaria due to COVID-19 vaccination in the USA, Belgium, Vietnam, China, and Taiwan[26–29]. Our findings are in good agreement with findings from previous studies[22–24,26–29].

Fourth, we found thrombosis among the participants was only associated with the Oxford–AstraZeneca vaccine. Event of thrombosis ranged from 3.5 to 5.7% among the recipients of homogenous Oxford–AstraZeneca vaccine. This statement is in good agreement with previous findings from numerous studies worldwide[30–35].

However, in some of the studies that reported events of thrombosis after Pfizer-BioNTech and Moderna doses in lower frequency, we found the association of only Oxford–AstraZeneca with thrombosis. In nearby country India, numerous reports of thrombosis and thrombocytopenia have been documented after vaccination of Oxford–AstraZeneca[36]. This is one of the first reports of thrombosis due to COVID-19 vaccination in Bangladesh. Fifth, we also reported comprehensive findings after both homogenous and heterogenous doses of COVID-19 vaccines. In homogenous doses of Oxford–AstraZeneca, we found a higher percentage of side effects than Sinopharm BIBP. However, a heterogenous second dose with Moderna had the highest percentage of local and systemic effects followed by Pfizer-BioNTech and Oxford–AstraZeneca. This finding is also relatively new in the Bangladeshi population and similar to previous findings in other countries[8,9,37–41]. Similarly, in the heterogenous third dose, Moderna was associated with the highest percentage of adverse effects, and Sinopharm BIBP with the lowest percentage of effects. Sixth, we determined the risk factors of adverse effects among the participants. We found the highest odds of developing different adverse effects with COVID-19 vaccination. Among the vaccines, Oxford–AstraZeneca (OR 4.24, 95% CI 3.99–4.68) and Moderna (OR 4.29, 95% CI 3.87–4.58) showed the highest odds of side effects followed by other vaccines. Host demographics including sex, practices like smoking habit, and preexisting health conditions including COPD, asthma, diabetes, and autoimmune diseases were associated with higher odds of adverse effects. These findings are completely in accordance with previous findings[7,8,10,17,31,41–44]. COVID-19 vaccination and use of Moderna, Oxford–AstraZeneca, and Pfizer-BioNTech vaccines had significantly higher odds of long-term and severe adverse effects.

This study has several limitations. They include, self-reported data from the participants, the number of participants with Moderna and Pfizer-BioNTech vaccines could be increased, and detailed histopathological data are missing. In the future, the inclusion of data from histopathological analysis could give more accurate predictions associated with COVID-19 vaccination. Though we designed the study in a prospective way to reduce the recall bias, there might be minor recall bias from a small number of the participants.

Conclusion

This study reported a high prevalence of side effects after COVID-19 vaccination in Bangladesh. Both local and systemic effects within 48 h of vaccination were more frequent among the recipients of Oxford–AstraZeneca, Moderna, and Pfizer-BioNTech vaccines. Long-term effects including urticaria, psoriasis, and skin allergic conditions after 6 months of vaccination were prevalent in the study population. This study created a comprehensive insight into short- and long-term side effects as well as health effects of homogenous and heterogenous doses of COVID-19 vaccines.

Methods

Ethical approval

The study was reviewed and approved by the Biosafety, Biosecurity & Ethical Committee at Jahangirnagar University, with an ethical approval number of BBEC, JU/M 2021/COVID-19/(8)1.

Study design and sampling

This prospective study was conducted using an observational design across Bangladesh. The study spanned from May 5, 2021, to April 4, 2023. Data collection involved a structured questionnaire. We collected the data from the participants after 1 h to the next two weeks of vaccination. For the long-term observation, they were given access to the questionnaire and instructions to report within the first three days of observation of any symptom. Convenience sampling was used to enroll the participants and they were invited through online platforms. Participants from all around the 64 districts in Bangladesh were included in this study. The study included all participants from different sex, race, religion, or occupation, ensuring a reduction in potential biases. Data acquisition encompassed both direct participants and hospitalized individuals seeking treatment for non-COVID-19 related illness, along with their visiting relatives. Informed consent was obtained from all participants. Relevant guidelines and regulations were followed to conduct this study. For grading the severity of the side effects, we used the Food and Drug Administration recommendations. Mild side effects were determined by following grade 1 (awareness of signs or symptoms but freely endured) and severe effects by grade 3 (inability to work or do usual activity) of the guideline[45]. Study participants reported side effects after administration of the first dose, second doses, and/or third doses separately. A single response from each participant was counted as valid.

Criteria for inclusion and exclusion

The inclusion criteria consisted of several parameters including, the participant must be a resident of Bangladesh, aged 18 years or above, having taken one or more doses of vaccine not other than Oxford–AstraZeneca, Sinopharm BIBP, Pfizer-BioNTech, Sinovac and Moderna, given complete information in the questionnaire, did not receive any dose of COVID-19 vaccine outside Bangladesh, have not taken any other vaccines before 2 years and after COVID-19 vaccination. Exclusion criteria consisted of different factors like participants not giving complete information on the questionnaire, aged below 18 years, not a resident of Bangladesh, having taken any of the doses of COVID-19 vaccines from outside Bangladesh, having taken other vaccines within the last 2 years, have severe COVID-19 infection and taken antiserum during treatment.

Data collection

The structured questionnaire was divided into three main sections. The first section included socio-demographic questions including age, sex, occupation, residential location, and prior COVID-19 infection history, previous health conditions, type of vaccine, and vaccination date. The second section focused on side effects after

vaccination, any adverse effects post-vaccination, their duration, occurrences of COVID-19 post-vaccination, and the severity of infections post-first vaccine dose, effects on different organs and systems. The third section included questions on post-dose effects and duration after the first dose, second dose, third dose or combined doses. The questionnaire, prepared in both Bangla and English, was disseminated nationwide. The sample size was determined based on existing literature and it was about $n = 1486$. However, our sample size was well above the calculated value. Prior to participation, the study's aims were explained in details to the participants.

Statistical analyses

The baseline data and responses to demographic questions were represented by using descriptive statistics such as mean, median, SD, and IQR. For these characteristics differences in responses for continuous variables, we used the Kruskal-Wallis test. We also performed the $\chi 2$ test for the responses including categorical variables. For the identification of responsible factors with the prevalence of different side effects among the vaccine recipients, we used a multivariable logistic regression model. The participants were allowed to access the questionnaire multiple times required to give responses after 2nd doses and 3rd doses of vaccines. We considered different factors in the multivariable model including included age of the participants (continuous variables with class interval of 10 years), ethnicity (Bangladeshi or outsider) sex given at birth (male or female), subjective socioeconomic conditions, residential areas (urban or rural), number of vaccine dose, type of COVID-19 vaccine, preexisting medical conditions (both non-communicable and infectious diseases and other health conditions), smoking history and blood grouping. We used another separate multivariable model to determine the associated factors responsible for no side effects, very mild, mild, moderate side effects vs. severe or very severe adverse effects by using previously described factors of the participants. We considered the findings statistically significant, if p-value were < 0.05. We used SAS version 9.4 (SAS Institute) and Microsoft Excel version 2023 (Microsoft, USA) for data analyses.

Data availability

All data supporting the findings of this study are available within the article.

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Author contributions

N.S. and S.K.D. made the study design, R.R.O, N.S. and T.S. conducted data collection, N.S., A.K., R.R.O., A.A., M.A.A., K.J.A., A.A.V. performed data analysis, N.S., A.K. and R.R.O. wrote the manuscript, N.S. C.O.G., J.P.M.G and S.K.D. reviewed the manuscript, N. S. and S.K.D. supervised the work. All authors have read and approved the final version of the manuscript.

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Declarations

Competing interests

The authors declare no competing interests.

Additional information

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