Comparison of Adverse Effects Following First Dose of Covishield™ in Covid Vaccine Recipients with or without Comorbidities in a Tertiary Care Hospital

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Abstract
Background: The COVID-19 vaccines have significantly altered the course of the pandemic. While incredibly beneficial, some recipients may experience mild to moderate side effects post-vaccination, which are typically signs of the body building protection. The aim of the study is to compare the adverse effects following first dose of Covishield™ vaccination in vaccine recipients with or without comorbidities. **Material & Methods:** This cross-sectional study was conducted in Department of Medicine, Kurmitola General Hospital, Dhaka, Bangladesh, during the period from February 2021 to April 2021. Total 200 study subjects who received first dose of Covid-19 vaccine-"Covishield™" are included in this study. **Results:** In this study, majority were male (63.5%) with a mean age of 48.7 years (SD±6.2 years). Among the study subjects, 30.5% had comorbidities with HTN (62.3%) and DM (45.9%) being the most common. Among these, fever was a prevalent symptom, experienced by 49.2% of those with comorbidities compared to 33.1% without. Muscle pain was more common among those without comorbidities (25.9% vs 8.2%). Some symptoms like vertigo, weakness, diarrhea, and body ache were exclusive to those with comorbidities. Side effects varied across different comorbidities, with HTN patients reporting fever (21.3%) and DM patients experiencing fever (23%). **Conclusion:** The study demonstrates that adverse effects after vaccination were more common in individuals with comorbidities, with fever being the most prevalent. However, muscle pain was more common in individuals without comorbidities.

Keywords:- Comparison, Adverse Effects, Covishield™, Covid-19, Vaccine Recipients, and Comorbidities.

INTRODUCTION

COVID-19, an illness caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has led to a global pandemic that has significantly impacted public health and economies worldwide.[1] The World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern in January 2020, and a pandemic in March 2020. The disease is primarily transmitted from person to person through respiratory droplets when an infected person coughs, sneezes, talks, or breathes. These droplets can be inhaled into the lungs. It's also possible to become infected by touching a surface or object that has the virus on it, and then touching your own mouth, nose, or possibly your eyes.[2] At present, vaccination is the most effective strategy to create herd immunity, stop sickness, and control the spread of infection within a community and general population.[3] Vaccines can lessen a person's vulnerability to infection as well as their ability to disseminate the virus to others.[4] Oxford-AstraZeneca's (AZD1222), and Covishield™ vaccines are most often authorized and utilized in India and Bangladesh.[5] The introduction of multiple vaccines to counter the spread of this virus has offered a beacon of hope, yet concerns surrounding potential adverse effects, particularly in individuals with comorbidities, persist.[6] This study aims to encourage the general population to involve in social Covid-19 vaccination and find out the side effects of Covid vaccination in individuals with or without comorbidities. A comorbidity refers to the presence of one or more additional conditions co-occurring with a primary condition, and the prevalence of comorbidities has been associated with worse outcomes in individuals with COVID-19.[7] COVID-19 vaccination has proven to be safe and effective in preventing SARS-CoV-2 infection, hospitalization, and death.[8] However, adverse effects, although mostly mild and transient, have been reported following vaccination. These include fever, pain at the injection site, fatigue, headache, muscle pain, and chills.[9] Individuals with comorbidities, such as diabetes, cardiovascular diseases, and respiratory diseases, have been a particular concern due to their higher vulnerability to severe COVID-19 disease and death.[10] Additionally, the concern that these individuals might experience more severe or different vaccine side-effects due to their pre-existing conditions continues to be an area of active research. Numerous studies have explored the relationship between comorbidities and adverse effects post COVID-19 vaccination. Research from the CDC COVID-19 Response Team suggests that the frequency and severity of side effects do not significantly differ between individuals with or without comorbidities.[11] On the contrary, other studies imply that individuals with certain comorbidities may experience different or more severe adverse effects.[12] Considering the high global prevalence of comorbidities and the continuing mass COVID-19 vaccination programs, it is crucial to thoroughly understand how adverse effects vary between vaccine recipients with or without comorbidities.

Objectives

To compare the adverse effects following first dose of Covishield™ in Covid vaccine recipients with or without comorbidities.

MATERIAL AND METHODS

This cross-sectional observational study was conducted in Department of Medicine, Kurmitola General Hospital, Dhaka, Bangladesh, during the period from February 2021 to April 2021. Total 200 study subjects who received first dose of Covid-19 vaccine-"Covishield™" were included in this study. Consent of the individuals and guardians was taken before collecting data from whom has experienced side effects immediately after vaccination and transferred to Adverse event following immunization (AEFI) center in Kurmitola General Hospital and also, from the subjects who has received Covid-19 vaccine (Covishield™) experienced adverse effect at home after several hours or days. Their data have been collected over telephone and written down in 6 registered note books. After collection of data, all data were checked and cleaned. After cleaning, the data were entered into computer and statistical analysis of the results being obtained by using windows-based computer software devised with Statistical Packages for Social Sciences version 22. After compilation, data were presented in the form of tables, figures and charts, as necessary. Numerical variables were expressed as mean and standard deviation, whereas categorical variables were count with percentage. P value of less than 0.05 was considered statistically significant.

Inclusion criteria

- Individuals who received 1st dose of Covid-19 vaccine
- Adult from 18-80 years.

Exclusion criteria

- Those who received other vaccine within 2 months.
- Those who refuse to give consent for the study.

RESULTS

[Table 1] shows the demographic characteristics of the study subjects. In this study, the largest age group is 40-49 years old, which accounts for 38.0% of the subjects. The mean age of the subjects is 48.7 years (SD±6.2 years) and the age range spans from 23 to 78 years old. Regarding the subjects' sex, 63.5% are male and 36.5% are female. The table also outlines the prevalence of comorbidities among the subjects. 30.5% of the subjects have one or more comorbidities, whereas 69.5% do not. [Figure 1] demonstrates that out of the individuals with comorbidities, seven individuals, or 11.5% of the total, have asthma. Hypertension (HTN) is the most common condition in the group, affecting 38 individuals, which corresponds to 62.3% of the total. Diabetes Mellitus (DM) is the second most common, with 28 people or 45.9% of the total. Ischemic Heart Disease (IHD) and Fatty liver each affect 4 people, accounting for 6.6% each of the total population. Chronic Kidney Disease (CKD) is found in 3 people or 4.9% of the population. The least common comorbidity is previous infection with Covid-19, with only one individual (or 1.6% of the population) having had this condition. [Table 2] demonstrates the comparison of adverse effects between study subjects with comorbidities and without comorbidities. Fever was found to be the most prevalent side effect, being reported by almost half (49.2%) of study subjects with comorbidities and nearly one third (33.1%) of

those without, a difference that was statistically significant (P=0.0312). Other significant differences were seen in cases of Muscle pain, which was more frequent in study subjects without comorbidities (25.9%) than in those with comorbidities (8.2%, P=0.0044), and the side effects of Vertigo, Weakness, Diarrhea, and Body ache, all of which were reported significantly more often in study subjects with comorbidities, yet were completely absent in those without (P=0.0087, P=0.0087, P=0.0023, and P=0.0023, respectively). Notably, the incidence of Headache was not statistically different between the two groups (P=0.3607), being reported by 4.9% of study subjects with comorbidities and 8.6% of those without. Table-III presents the distribution of side effects with comorbidities among a group of 61 study subjects. For Asthma study subjects, 1 individual each (1.6% of the total) experienced fever, vertigo, nausea, weakness, body ache, muscle pain, and breathlessness. Hypertension (HTN) study subjects experienced fever (13 study subjects, 21.3%), nausea, vertigo, diarrhea, cough, and muscle pain (each 3 study subjects, 4.9%), dizziness, headache, weakness,

body ache, vomiting, and breathlessness (each 2 study subjects, 3.3%). Diabetes Mellitus (DM) study subjects had fever (14 study subjects, 23%), cough (4 study subjects, 6.6%), and dizziness, headache, vertigo, nausea, body ache, vomiting, and muscle pain (each 2 study subjects, 3.3%). Ischemic Heart Disease (IHD) study subjects reported fever and diarrhea (each 1 study subject, 1.6%). Fatty Liver study subjects reported vertigo and weakness (each 1 study subject, 1.6%). Chronic Kidney Disease (CKD) study subjects had fever, cough, and vomiting (each 1 study subject, 1.6%). Lastly, those with a previous Covid-19 infection reported fever and nausea (each 1 study subject, 1.6%).
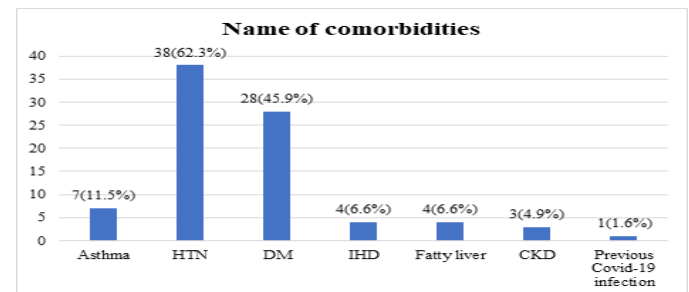

Figure 1: Types of comorbidities among the study subjects (N=61)

Table 1: Demographic characteristics of the study subjects (N=200).

Characteristics		n	%
Age (Years)	<30	6	3.0
	30-39	14	7.0
	40-49	76	38.0
	50-59	65	32.5
	60-69	34	17.0
	≥70	6	3.0
	Mean± SD	48.7±6.2	
	Range	23-78	
Sex	Male	127	63.5
	Female	73	36.5
Comorbidities	Yes	61	30.5
	No	139	69.5

Table 2: Comparison of adverse effects between study subjects with comorbidities and without comorbidities (N=200).

Side effects	With comorbidities (n=61)		Without comorbidities (n=139)		P-value
	n	%	n	%	
Dizziness	4	6.6	4	2.9	0.2216[ns]
Fever	30	49.2	46	33.1	0.0312[s]
Headache	3	4.9	12	8.6	0.3607[ns]
Vertigo	3	4.9	0	0.0	0.0087[s]
Nausea	4	6.6	2	1.4	0.0472[s]
Weakness	3	4.9	0	0.0	0.0087[s]
Diarrhea	4	6.6	0	0.0	0.0023[s]
Body ache	4	6.6	0	0.0	0.0023[s]
Cough	4	6.6	3	2.2	0.1221[ns]
Muscle pain	5	8.2	36	25.9	0.0044[s]
Vomiting	4	6.6	7	5.0	0.6482[ns]
Breathlessness	2	3.3	2	1.4	0.3757[ns]
Abdominal pain	0	0.0	3	2.2	0.2442[ns]
Runny nose	0	0.0	2	1.4	0.3543[ns]
Allergy	0	0.0	1	0.7	0.5135[ns]
Itching	0	0.0	5	3.6	0.1344[ns]

Statistical analysis was done by unpaired Student t-test.
s= Significant
ns= Not significant

Table 3: Distribution of side effects with comorbidities (N=61).

Side effects	Asthma	HTN	DM	IHD	Fatty liver	CKD	Previous Covid-19 infection
Dizziness	0	2 (3.3%)	2 (3.3%)	0	0	0	0
Fever	1 (1.6%)	13 (21.3%)	14 (23%)	1 (1.6%)	0	1 (1.6%)	1(1.6%)
Headache	0	2(3.3%)	2(3.3%)	0	0	0	0
Vertigo	1 (1.6%)	3(4.9%)	3(4.9%)	0	1(1.6%)	0	0
Nausea	1 (1.6%)	4(6.6%)	2(3.3%)	0	0	0	1(1.6%)
Weakness	1 (1.6%)	1(1.6%)	0	0	1(1.6%)	0	0
Diarrhoea	0	3(4.9%)	1(1.6%)	1(1.6%)	0	0	0
Body ache	1(1.6%)	1(1.6%)	2(3.3%)	0	0	0	0
Cough	0	3(4.9%)	4(6.6%)	0	0	1(1.6%)	0
Muscle pain	1(1.6%)	3(4.9%)	3(4.9%)	0	0	0	0
Vomiting	0	2(3.3%)	2(3.3%)	0	1(1.6%)	1(1.6%)	0
Breathlessness	1(1.6%)	1(1.6%)	0	0	0	0	0

DISCUSSION

This present study was conducted to compare the adverse effects following first dose of Covishield™ in vaccine recipients with or without comorbidities. The demographics of the study participants show a preponderance towards middle age (40-49 years), males (63.5%), and those without comorbidities (69.5%). These findings are consistent with larger vaccination studies, which indicate that younger adults and males are often more likely to be vaccinated early due to occupational exposure risks.[13] The prevalence of comorbidities among study subjects was 30.5%, with hypertension (62.3%) and diabetes mellitus (45.9%) being the most common. These comorbidities are known to exacerbate the severity of Covid-19 infection.[14,15] Interestingly, the least common comorbidity was a previous Covid-19 infection, at 1.6%. Fever, the most common side effect, appeared in almost half (49.2%) of study subjects with comorbidities and nearly one third (33.1%). This is a statistically significant difference (P=0.0312) and aligns with previous research demonstrating fever as a common systemic reaction post-vaccination.6 However, muscle pain was significantly more common among study subjects without comorbidities (25.9%) compared to those with comorbidities (8.2%). This may suggest an augmented immune response in the healthier population, given that muscle pain following vaccination is often a sign of the immune system's reaction to the vaccine.[6] In contrast, Vertigo, Weakness, Diarrhea, and Body ache were observed only in study subjects with comorbidities. These side effects, although statistically significant (P=0.0087, P=0.0087, P=0.0023, and P=0.0023,

respectively), could possibly indicate heightened sensitivity or underlying health complications due to the comorbid conditions.[16] In the study of Ganesan S et al,[17] and Riad A et al,[18] shows that vaccine recipients with comorbidities had reported a statistically significant higher percentage of adverse effects which supports the findings of our study. Notably, none of the subjects with asthma experienced dizziness, while fever was a common experience across most comorbidity categories, consistent with the general post-vaccination symptomatology.[6] Breathlessness, a more serious side effect, was reported only in subjects with asthma and hypertension, underlining the potential vulnerability of these patient groups.[13] While the Covid-19 vaccine elicits a range of side effects, the occurrence and severity of these effects appear to vary depending on the presence and type of comorbidities. This highlights the need for personalized post-vaccination monitoring and symptom management, especially for those with pre-existing conditions. However, it is important to stress that the benefits of vaccination significantly outweigh these transient side effects in preventing severe Covid-19 infection and its potential complications.[6]

Limitations of the study

In our study, there was small sample size and absence of control for comparison. Study population was selected from one center in Dhaka city, so may not represent wider population. The study was conducted at a short period of time.

CONCLUSIONS

The study demonstrates that adverse effects after vaccination were more common in individuals with comorbidities, with fever being the most prevalent. However, muscle pain was more common in individuals without comorbidities. Certain side effects, including vertigo, weakness, diarrhea, and body ache, were solely present in individuals with comorbidities. Each comorbidity demonstrated a unique pattern of side effects. It is imperative to consider the presence of comorbidities for personalized patient care post-vaccination. Further research is recommended to understand these patterns better.

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