

Disease Severity and Clinical Outcome of Coronavirus Vaccinated Patients Following Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection

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Abstract:

Background and aims: The severity of illness and mortality in coronavirus disease (COVID-19) may be curtailed by vaccination. We assessed the disease severity and clinical outcome in coronavirus vaccinated patients following SARS-CoV-2 infection.

Methods: We conducted an observational study among the SARS-CoV-2 infected patients who received one or two doses of a single generic type of coronavirus vaccine (ChAdOx1 nCoV-19, Covishield®, Serum Institute of India) at the outset of vaccine rollout program in Bangladesh. Eligible patients treated at home, outpatient basis, or hospitalized between April 10, 2021, and June 18, 2021, were included. Demographic characteristics, clinical presentation, comorbidities, radiological features, disease severity, treatment protocol, and outcomes were evaluated. The primary endpoint was disease severity (mild, moderate, severe, and critical).

Introduction:

The coronavirus disease (COVID-19) pandemic has casted a deep impact on the healthcare system worldwide and pushed the global economy into deep recession.¹ It would not be possible to overcome the crisis without administration of an effective vaccine to

The secondary endpoint was clinical outcome (complete recovery or death) at day 28.

Results: The cohort included total 61 patients. Age ranged between 23–82 year; majority were male (62.3%). Ninety five percent patients received a single dose of vaccine. Most of the patients had mild symptoms (63.9%), and treated at home (67.2%). Most of the patients recovered utterly (95.1%) without any death. Vaccination showed reduced disease severity (RR 0.93, 95% CI, 0.87-0.99).

Conclusions: In this study it was observed that coronavirus vaccine may significantly lessen disease severity, improve clinical outcome, and prevent death among SARS-CoV-2 infected patients.

Keywords: Coronavirus vaccine, COVID-19, SARS-CoV-2

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the mass population, and to achieve the herd immunity.² Soon after identification of the virus, scientists all over the world dedicated themselves in vaccine research. Several manufacturers successfully developed coronavirus vaccine in less than twelve months – an extraordinary achievement, which usually takes a decade or longer to develop a new vaccine.³⁻⁶ The visionary and timely adopted initiatives taken by the policymakers of Bangladesh could allocate vaccines in the shortest possible time. In this study we assessed the disease severity and clinical outcome of coronavirus vaccinated patients following SARS-CoV-2 infection at the initial period of vaccine rollout program in Bangladesh.

Methods:

We conducted an observational study among SARS-CoV-2 infected patients (positive reverse transcriptase polymerase chain reaction [RT-PCR] for SARS-CoV-2) who had received one or two doses of a single generic type of coronavirus vaccine (ChAdOx1 nCoV-19, Covishield®, Serum Institute of India). The study was conducted at the Mugda Medical College Hospital,

Dhaka between April 10, 2021, and June 18, 2021. Patients were followed up longitudinally at the inpatient and outpatient department and also over telephone. Demographic characteristics, clinical presentation, comorbidities, radiological features, disease severity, treatment protocol, and outcomes were evaluated. The primary end point was disease severity (mild, moderate, severe, and critical), and the secondary end point was clinical outcome (complete recovery or death) at day 28. Chi square (χ^2) test was done for the calculation of continuous and categorical variables. Relative risk ratio with 95% confidence intervals with respect to vaccination status and disease severity following SARS-CoV-2 infection was calculated from Fisher's exact test. Statistical package for the social sciences (SPSS) version 23.0 was used for statistical analysis of data. A p value <0.05 was considered statistically significant.

Results:

The cohort included 61 confirmed cases of SARS-CoV-2 infection who received at least one dose of coronavirus vaccine. The mean age was 52.7 years, ranging between 23-82 years. Majority of the patients were male (62.3%) [Table-1]. Fever (78.3%) and cough (63.9%) were the most everyday presentations. The most common comorbidity was hypertension (44.3%), followed by diabetes mellitus (36.1%) [Table-1]. Ninety five percent of patients received the first dose of the coronavirus vaccine, and most were infected after one month following vaccination (64.16%) [Table-2]. Most of the patients had mild disease (63.9%), and were treated at home (67.2%) [Figure-1]. The majority (67.2%) had oxygen saturation (SpO_2) above 96% at ambient air; supplemental oxygen was required in 23% of patients [Table-1]. High resolution computed tomography scan of the chest (HRCT) was done in 32 patients; among them, most (56.3%) had a CT severity index <20 [Table-1]. Most patients (95.1%) recovered completely, and there was no death [Figure-1]. Vaccination showed reduced disease severity, and those who received two doses of vaccine had milder form of the disease than single dose (RR 0.93, 95% CI, 0.87-0.99). However, the difference was insignificant (p -value 0.813) [Table-3].

Table-I

Demography, clinical features, CT severity score and place of treatment

| Characteristics | Frequency (%) |
|--------------------------------|--------------------|
| Age, mean (\pm SD) | 52.7 (\pm 12.7) |
| Range (year) | 23.0-82.0 |
| Sex | |
| Male | 38 (62.3%) |
| Female | 23 (37.7%) |
| Co-morbidities | |
| Hypertension | 27 (44.3%) |
| Diabetes | 22 (36.1%) |
| Asthma | 8 (13.1%) |
| Ischemic heart disease | 5 (8.2%) |
| Hypothyroidism | 2 (3.3%) |
| Chronic kidney disease | 1 (1.6%) |
| COPD | 1 (1.6%) |
| Benign enlargement of prostate | 1 (1.6%) |
| Stroke | 1 (1.6%) |
| Beta-thalassaemia | 1 (1.6%) |
| Obesity | 1 (1.6%) |
| Tuberculosis | 1 (1.6%) |
| Symptoms | |
| Fever | 48 (78.7%) |
| Cough | 39 (63.9%) |
| Flu-like symptoms | 23 (37.7%) |
| Body ache | 19 (31.1%) |
| Dyspnoea | 13 (21.3%) |
| Anosmia | 9 (14.8%) |
| Diarrhoea | 6 (9.8%) |
| Palpitation | 3 (4.9%) |
| Chest pain | 2 (3.3%) |
| Ageusia | 2 (3.3%) |
| Headache | 2 (3.3%) |
| Delirium | 1 (1.6%) |
| Hiccup | 1 (1.6%) |
| Nausea/vomiting | 1 (1.6%) |
| SpO_2 | |
| $d^{\ast}80$ | 3 (4.9%) |
| 81-85 | 2 (3.3%) |
| 86-90 | 1 (1.6%) |
| 91-95 | 14 (23%) |
| 96-100 | 41 (67.2%) |
| CT Severity score | |
| $d^{\ast}20$ | 18 (56.3%) |
| 21-40 | 6 (18.8%) |
| 41-60 | 4 (12.5%) |
| 61-80 | 4 (12.5%) |
| Management | |
| Home | 41 (67.2%) |
| Hospital | 20 (32.8%) |

Table-II

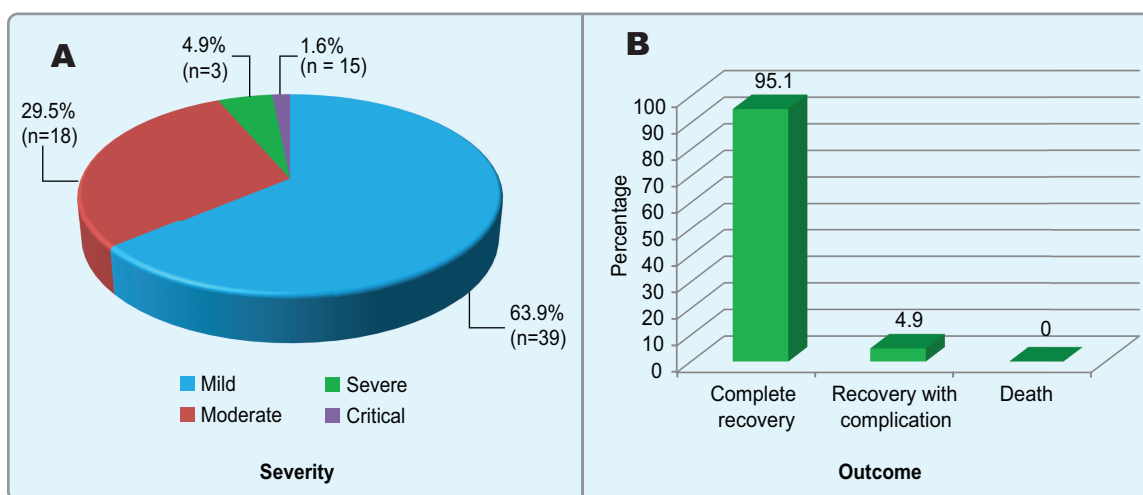
| <i>Vaccination status and time elapsed since vaccination and appearance of symptoms</i> | |
|---|---------------|
| Vaccination status | Frequency (%) |
| Single dose | 58 (95.1%) |
| Two doses | 3 (4.9%) |
| Time elapsed since vaccination and appearance of symptoms (days) | |
| d¹⁵ | 6 (9.8%) |
| 16-30 | 15 (24.6%) |
| 31-45 | 20 (32.8%) |
| 46-60 | 20 (32.8%) |

Table-III

| <i>Relation between vaccination status and disease severity</i> | | | | |
|---|-------------------------------------|------------------------|------------------|---------------------|
| Disease severity | Vaccination status | | RR (95% CI) | P value |
| | 1 st dose(n=58) n (%) | Complete(n=3) n (%) | | |
| Mild/moderate | 54 (93.1) | 3 (100.0) | 0.93 (0.87-0.99) | 0.813 ^{ns} |
| Severe/critical | 4 (6.9) | 0 (0.0) | | |

ns= not significant

P value reached from Fisher exact test

**Fig.-1:** Disease severity and outcome of vaccinated patients**Discussion:**

In Bangladesh, the COVID-19 vaccine rollout program began on February 7, 2021, primarily only for the frontliners and those above 40. The program started with a single generic type vaccine (ChAdOx1 nCoV-19, Covishield®, Serum Institute of India). Later, other vaccine types and wider population groups were

included in the program. At the outset, there was uncertainty and unwillingness to receive vaccine among the mass people. As time elapsed, people had developed awareness and taboo against vaccination was broken. A recent study shows that vaccine acceptance has developed among 74.5% Bangladeshi adults.⁷ Since writing this report, 128.8 million Bangladeshi have

received at least one dose of the COVID-19 vaccine, 70.8% people are fully vaccinated, and 11.32% of the population has a booster dose.⁸ The government is working hard to gather the majority of the people under the vaccination umbrella and planning to extend coverage up to 5-year age group. The main challenge is ensuring a constant vaccine supply and covering the rural population, illiterates, and slum dwellers.

Our study's observations match the findings of others regarding the efficacy of the coronavirus vaccine in reducing disease severity.⁹⁻¹⁰ In this study, it was observed that those who received two doses of vaccine had a milder form of the disease; even a single dose significantly reduced disease severity, improved clinical outcome, and prevented death among SARS-CoV-2 infected patients. Mass awareness about vaccination should be disseminated in media; vaccination program should be more assessable to most people within the shortest possible time.

The study has several limitations. First, the sample size is too small. The reason behind that, we conducted the study at the very earlier period of the vaccine rollout program with a study duration only two months. Second, as most of the patients received a single dose, clinical outcome following second dose could not be evaluated. Third, we followed-up the patients for 28 days. If we could track the patients for a longer period, a complete outcome evaluation could be possible.

Points of strength include, it is a real-world study at the outset of vaccine rollout program in Bangladesh, and to the best of our knowledge, the first study at that time, aiming to get an output on vaccine efficacy and on the light of the report, alleviating fear about a new vaccine.

Conclusion:

This observational study shows that even a single dose coronavirus vaccine may have a countable effect on disease severity and clinical outcome, as well as minimizing mortality following SARS-CoV-2 infection. Vaccine campaign should be continued to develop an effective herd immunity.

Conflict of interest:

There is no potential conflict of interest to declare.

Author contribution:

NKS and MR conceptualized the study and wrote the draft. NKS, MR, SF and MAR collected data and followed-up the patients bodily or over telephone as

appropriate. All the authors reviewed the final manuscript and made corrections as required.

Disclaimer:

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