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Severity assessment of single-dose Oxford-AstraZeneca vaccinated individuals infected with severe acute respiratory syndrome coronavirus 2 in Southeast Bangladesh

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Abstract

Background and Aim: A vaccine program for coronavirus illness (coronavirus disease [COVID-19]) is currently underway in numerous regions of the world, including Bangladesh, but no health data on those who have been vaccinated are available at this time. The study aimed to investigate the health condition of people who had received their first dose of the Oxford-AstraZeneca vaccine and were infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Materials and Methods: To detect SARS-CoV-2, a standard virological approach, real-time reverse transcriptase-quantitative polymerase chain reaction (RT-qPCR), was used. Several health indicators from vaccinated patients were collected using pre-structured questionnaires during the infection phase.

Results: A total of 6146 suspicious samples were analyzed, and 1752 were found to be positive for SARS-CoV-2, with 200 people receiving the first dose of the COVID-19 vaccine. One hundred and sixty-five (82.5%) were not hospitalized among the vaccinated people, and 177 (88.5%) did not have any respiratory problems. Only 8% of patients required further oxygen support, and 199 (99.5%) did not require intensive care unit intervention. Overall, oxygen saturation was recorded at around 96.8% and respiratory difficulties did not extend more than 5 days during the infection period. Among the vaccinated COVID-19-positive people, 113 (56.5%) and 111 (55.5%) had typical physiological taste and smell. Surprisingly, 129 (64.5%) people had diverse comorbidities, with high blood pressure (27.9%) and diabetes (32 [24.8%]) being the most common. The major conclusion of the current study was that 199 (99.5%) of vaccinated patients survived in good health and tested negative for RT-qPCR.

Conclusion: According to the findings of this study, administering the first dose of the Oxford-AstraZeneca vaccine considerably reduces health risks during the COVID-19 infection period.

Keywords: assessment, comorbidity, coronavirus disease, health risk, Oxford-AstraZeneca vaccine.

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic is envisaged as the number one global public health crisis due to its high morbidity and drastic fatality rate. Since the reporting of the outbreak, it has infected over 153 million, of which over 3.2 million people died [1]. The longer survival rate of the virus in different environmental conditions and unprecedented transmission speed from human to human can aggravate the present ongoing outbreak situations [2]. In addition, the virus causes severe flu-like symptoms with greater respiratory difficulties and reports that one infected or carrier individual can easily infect others [3]. However, the estimated reproductive number (R_0) of SARS-CoV-2 is 2.2; that is, one coronavirus disease (COVID-19) individual can transmit the virus to 2.2 other healthy individuals [4]. A highly powerful vaccination is desperately needed to combat the virus's catastrophic impact on human health. For COVID-19 prevention, different vaccine platforms such as nucleic acid vaccines, recombinant protein vaccines, viral vector-based vaccines, and whole virus vaccines are targeted [5]. To date, 180 different vaccine candidates are currently developing vaccines against SARS-CoV-2 [6], of which different institutes

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and companies have developed more than 58 vaccines. Some vaccines are under clinical trials [7] and few of them got permission for mass vaccination by the World Health Organization (WHO) for the successful COVAX programs coleaded by Gavi, CEPI, and WHO. Oxford-AstraZeneca chimpanzee adenovirus vectored vaccine (ChAdOx1 novel coronavirus 2019 [nCoV-19]) received their license for vaccination program with a reported 90% efficacy against SARS CoV-2 after a second dose [7].

Nowadays, immunization campaign is continued in several countries, including Bangladesh [8], irrespective of age and sex, although senior citizens are experiencing a priority. The Bangladesh government started a free vaccination campaign against COVID-19 using the Oxford-AstraZeneca vaccine received from the Serum Institute of India. In the Chattogram division, the commencement was from February 7, 2021 [9]. However, the magnitude of vaccine response to the virus particle is widely varied. The significant consideration is that reinfection of previously infected or vaccinated individuals with the same virus is possible due to its high and rapid mutation rate and the nature of viruses [10]. However, human coronavirus does not induce lifelong immunity and antibody response due to the rapid fall of humoral immunity [11].

Moreover, the measurement of protective antibody titer against SARS-CoV-2 after vaccination is still underdeveloped. Unfortunately, after receiving the first dose (approximately 5×10^{10} viral particles) of the Oxford-AstraZeneca vaccine, a number of vaccinated people were reinfected with SARS-CoV-2. Considering the present COVID-19 pandemic crisis and vaccination status, the study aimed to determine the percentages of the first dose vaccinated individuals reinfected with SARS-CoV-2 and assess their health risk during the infection period.

Materials and Methods

Ethical approval and Informed consent

All the samples were collected as a part of the COVID-19 diagnosis that every individual provided with their interest and consent. However, before the sample collection, minimum discomfort was maintained in every patient, and verbal permission was taken before the collection of COVID-19 vaccination history as well as health-related information during the infection period. Finally, all procedures were carried out under the approval of the Ethical Committee (EC) of Chattogram Veterinary and Animal Sciences University (CVASU) approval No: CVASU/Dir (R and E) EC/2021/244(1).

Study period and area

The study was conducted during the campaign of single-dose vaccination, which began from February 15, 2021, to April 15, 2021 (2 months) before starting the COVID-19 2nd dose vaccination campaign. The present study was conveyed in the Chattogram division of Bangladesh, which comprises 11 districts [12]. Geographically, it is located in the southeast part of Bangladesh and is well recognized as one of the country's major seaports [13]. However, our study included only four districts among the 11 districts, namely, Khagrachhari, Rangamati, Bandarban, and Chattogram.

Study population

Any individual who received the first dose of COVID-19 vaccine from any healthcare center in Chattogram division irrespective of age and sex from the study area was included in the current study.

Sample collection

Nasal and oropharyngeal samples of the suspected individuals within the study area were sent to the COVID-19 detection laboratory of CVASU through Chattogram Medical College (CMC) and Bangladesh Institute of Tropical and Infectious Diseases (BITID). Individual samples were collected in separate collection tubes containing viral transport media, maintaining the WHO guidelines [14]. Samples were preserved at −20°C temperature immediately after collection and sent to the COVID-19 detection laboratory, maintaining the proper cool chain.

Molecular diagnosis

After receiving the suspected samples from authorities, individual samples were tested to detect SARS-CoV-2 by the real-time reverse transcriptase-quantitative polymerase chain reaction (RT-qPCR) method. Viral RNA was extracted using sample release reagent (SanSure Biotech, China, Ref. No - S1014E) following the manufacturer's indications. nCoV-19 nucleic acid diagnostic kit (PCR-Fluorescence Probing, Ref. No-S3102E) [15] was used to detect the *N* gene (ROX channel) and *ORF1ab* region (FAM channel) of SARS-CoV-2 from extracted samples' RNA. To regulate the PCR inhibition, the human RNA targeting *P* gene (CY 5 channel) was used as an internal control. RT-qPCR was performed on a QuantStudio™ 5 PCR system (Thermo Fisher Scientific, Waltham, Massachusetts, USA) with version 1.5.1 for analysis. Any samples showed ≤40 cycle threshold (Ct) value which was confirmed as positive for COVID-19.

Data collection

After laboratory confirmation of the SARS-CoV-2-positive cases, we traced each COVID-19 patient over the phone. Only single-dose vaccinated COVID-19-positive individuals were included to collect data on vaccination history and health-related demographic information during the infection period through a structured questionnaire. Vaccinated COVID-19-positive patients were traced until becoming free from viral infection as well as post-COVID-19 complication and COVID-19-negative test results. All data were sorted and coded in Excel sheet (Microsoft Excel 2016®, Washington, USA) for further summary and analysis.

Statistical analysis

After sorting, all the data were inserted in STATA-IC 13® software (StataCorp. College Station, TX, USA) to perform statistical analysis. Descriptive analysis was performed to calculate the prevalence of the target outcome. The prevalence of SARS-CoV-2 was calculated considering the number of COVID-19-positive cases as the numerator divided by the total number of samples as the denominator. The 95% confidence interval (CI) of the prevalence values was calculated by the modified Wald method using the GraphPad Quickcalcs Online tool (San Diego, CA, USA).

Results

Prevalence of COVID-19 vaccinated patients

A total of 6146 suspected samples were tested by targeting the SARS-CoV-2 virus within the study period; among them, 1752 (28.51%; 95% CI: 27.38-29.65) samples were found positive for COVID-19. We found 200 (11.42%; 95% CI: 9.96-13) individuals received the single dose of Oxford-AstraZeneca vaccine from the positive cases. Within the vaccinated COVID-19-positive individuals, 134 (67%; 95% CI: 60.02-73.47) were found male and the remaining 66 (33%; 95% CI: 26.53-39.98) were female.

In our study, we observed 165 (82.5%; 95% CI: 76.51-87.5), single-dose vaccinated COVID-19-positive patients were not admitted to hospital where according to sex, 110 (82.09%; 95% CI: 74.53-88.17) male and 55 (83.33%; 95% CI:72.13-91.37) female took treatment within home.

Prevalence of COVID-19 vaccinated patients in different Ct value categories

All of the vaccinated SARS-CoV-2-infected patients were categorized according to viral load, based on Ct value of tested RT-qPCR (Figure-1). Among the 200 patients, 18 (9%; 95% CI: 5.42-13.85) had exhibit high viral loads irrespective of age and sex, which comprise below or equal 20 Ct value and occupied category 1, where 20.01-25 Ct value, 25.01-30 Ct value, 30.01-35 Ct value, and 35.01-40 Ct value were in category 2, category 3, category 4, and category 5, accordingly. And most of the patients, 61 (30.5%; 95% CI: 24.2-37.39) were found in category 4. Individuals carried a high viral load within the age ranges 40-49-years-old during the test period.

Prevalence of general physiological symptoms with parameters

The primary and well-defined symptoms of the coronavirus are likely fever, coughing, and sneezing. In our findings, we noticed 144 (72%; 95% CI: 65.23-78.1) individuals appear fever with variable ranges while 182 (91%; 95% CI: 86.15-94.58) and 89 (44.5%; 95% CI: 37.49-51.68) COVID-19 patients did not have any sneezing and coughing during the infection period (Table-1). Irrespective of ages and sex, it was observed that within the vaccinated individuals, the common symptoms of sneezing and coughing were not extended more than 3 days and 7 days, respectively. However, 113 (56.5%; 95% CI: 49.33-63.48) and 111 (55.5%; 95% CI: 48.32-62.51) vaccinated individuals had their normal physiological taste and smell function during the infection period.

Respiratory difficulties and oxygen saturation

Shortness of breathing is one of the most significant symptoms of COVID-19 patients. We found 177 (88.5%; 95% CI: 83.24-92.57) vaccinated patients did not express any breathing difficulties, of them 122 (91.04%; 95% CI: 84.88-95.29) and 55 (83.3%; 95% CI: 72.13-91.3) male and female, respectively, found free from dyspnea. Moreover, in general, breathing difficulties of SARS-CoV-2-infected patients were persistent around 5 days (Table-2). Interestingly, 184 (92%; 95% CI: 87.33-95.36) COVID-19-positive vaccinated patients did not require any extra oxygen support from our source. The overall oxygen saturation levels of vaccinated COVID-19 patients were found 96.8% (95% CI: 96.5-97.2), where it was 97% (95% CI: 96.5-97.4) in male and 96.5% (95% CI: 95.9-97.1) in females.

Comorbidity

Within the vaccinated COVID-19 patients, a total of 129 (64.5%; 95% CI: 57.44-71.12) individuals carried different types of comorbidities, where hypertension (36) and diabetes (32) are found more prevalent. Among the comorbidity patients, 51 (39.5%; 95% CI: 31.04-48.52) individuals were identified they carried more than 1 comorbidity (Figure-2). Moreover, the study revealed that a significant number of males (83: 61.94%; 95% CI: 53.16-70.18) suffered from different types of comorbidity than females (46; 69.7%; 95% CI: 57.15-80.41). Our study found only 1 (0.5%; 95% CI: 0.01-2.75) individual died after taking the single dose of the Oxford-AstraZeneca vaccine within the infection period.

Discussion

Assessment of the safety and efficacy of COVID-19 vaccines against the SARS-CoV-2 among the different populations is essential for an effective global pandemic response. The present study reveals the severity of single-dose Oxford-AstraZeneca vaccinated people infected with SARS-CoV-2 in the Southeast part of Bangladesh. The overall prevalence of positive COVID-19 individuals was 28.51%, almost similar to 29.76% prevalence, reported in the early outbreak in the same study region [13]. The prevalence of single-dose vaccinated (Oxford-AstraZeneca) individuals from the positive cases was 11.42%, of which 67% and 23% were found male and female, respectively. However, infection after single-dose vaccination was also reported among health care workers in California, the USA, which was 2.59% at different time intervals [16]. The reason for reinfection after vaccination might be due to the frequent mutation of SARS-CoV-2, which has less protection against certain variants

Table-1: Prevalence of different physiological conditions of vaccinated COVID-19 individuals during SARS-CoV-2 infection period.

Variables	Covariables	COVID-19 patients		Male		Female	
		n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Hospitalized	Yes	35	17.5 (12.5-23.49)	24	17.91 (11.82-25.47)	11	16.67 (8.62-27.87)
	No	165	82.5 (76.51-87.5)	110	82.09 (74.53-88.17)	55	83.33 (72.13-91.37)
Fever	Yes	144	72.0 (65.23-78.1)	97	72.39 (64.0-79.75)	47	71.21 (58.75-81.69)
	No	56	28.0 (21.9-34.77)	37	27.61 (20.24-36.0)	19	28.79 (18.3-41.25)
Coughing	Yes	111	55.5 (48.32-62.51)	76	56.72 (47.88-65.24)	35	53.03 (40.34-65.44)
	No	89	44.5 (37.49-51.68)	58	43.28 (34.76-52.11)	31	46.97 (34.56-59.66)
Sneezing	Yes	18	9.0 (5.42-13.85)	11	8.21 (4.17-14.21)	7	10.61 (4.37-20.64)
	No	182	91.0 (86.15-94.58)	123	91.79 (85.79-95.83)	59	89.39 (79.36-95.63)
Shortage of breathing	Yes	23	11.5 (7.43-16.75)	12	8.96 (4.71-15.12)	11	16.67 (8.62-27.87)
	No	177	88.5 (83.24-92.57)	122	91.04 (84.88-95.29)	55	83.33 (72.13-91.37)
Oxygen support	Yes	16	8.0 (4.64-12.67)	10	7.46 (3.64-13.3)	6	9.09 (3.41-18.74)
	No	184	92.0 (87.33-95.36)	124	92.54 (86.7-96.36)	60	90.91 (81.26-96.59)
Loss of taste	Yes	87	43.5 (36.52-50.67)	54	40.3 (31.92-49.11)	33	50.0 (37.43-62.57)
	No	113	56.5 (49.33-63.48)	80	59.7 (50.89-68.08)	33	50.0 (37.43-62.57)
Loss of smell	Yes	89	44.5 (37.49-51.67)	57	42.54 (34.04-51.37)	32	48.48 (35.99-61.12)
	No	111	55.5 (48.32-62.51)	77	57.46 (48.63-65.96)	34	51.52 (38.88-64.01)
Comorbidity	Yes	129	64.5 (57.44-71.12)	83	61.94 (53.16-70.18)	46	69.70 (57.15-80.41)
	No	71	35.5 (28.88-42.56)	51	38.06 (29.81-46.84)	20	30.3 (19.59-42.85)
Type of comorbidity	Single	78	60.47 (51.48-68.96)	43	51.81 (40.56-62.92)	35	76.09 (61.23-87.41)
	Multiple	51	39.53 (31.04-48.52)	40	48.19 (37.08-59.43)	11	23.91 (12.59-38.77)
Intensive care unit support	Yes	1	0.5 (0.01-2.75)	1	0.75 (0.02-4.09)	0	0 (0-5.43)
	No	199	99.5 (97.25-99.99)	133	99.25 (95.91-99.98)	66	100 (94.56-100)
Prognosis	Death	1	0.5 (0.01-2.75)	1	0.75 (0.02-4.09)	0	0 (0-5.43)
	Survive	199	99.5 (97.25-99.99)	133	99.25 (95.91-99.98)	66	100 (94.56-100)

%=Percentage, CI=Confidence interval, COVID-19=Coronavirus disease, SARS-CoV-2=Severe acute respiratory syndrome coronavirus 2

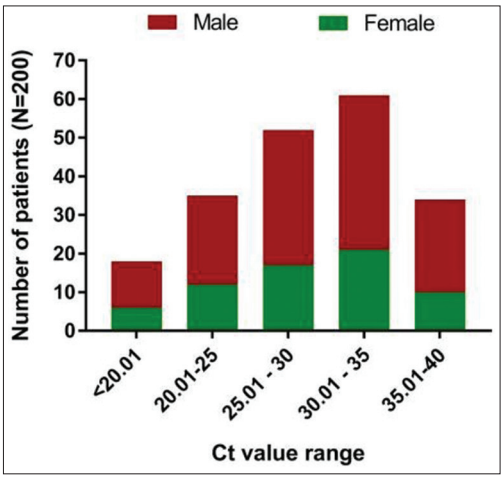

Figure-1: Category of severe acute respiratory syndrome coronavirus 2 infected vaccinated patients based on viral load using cycle threshold (Ct) value of reverse transcriptase-quantitative polymerase chain reaction. Where category 1: ≤20 (Ct); category 2: 20.01-25 (Ct); category 3: 25.01-30 (Ct); category 4: 30.01-35 (Ct); and category 5: 35.01-40 (Ct).

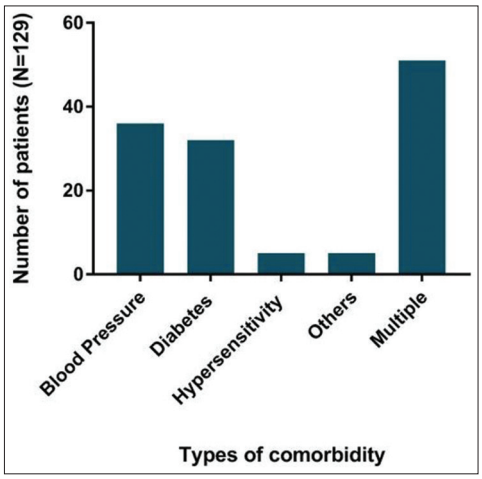

Figure-2: Prevalence of different comorbidity retaining coronavirus disease patients infected with severe acute respiratory syndrome coronavirus 2 after vaccination. Here, other comorbidity types include cardiac disorder, kidney disease, and liver disease.

such as the UK variant (B.1.1.7), South African variant (B.1.351), and Brazilian variant (P1/P2), which were recently detected in Bangladesh [17]. Since the Oxford-AstraZeneca vaccine was designed by targeting the spike protein gene, frequent mutation of this region may alter the immunological response and fail to give protection. The newly emerged variants are said to have greater transmissibility and continuously harbor new genetic changes, impacting clinical manifestation and vaccine effectiveness [17]. Another study [18] also reported two-dose regimen of ChAdOx1-nCoV-19 did not show protection against mild-moderate COVID-19 caused by B.1.351 variant. However, experiments reveal that a single standard dose of Oxford-AstraZeneca vaccine provided around 76% protection against symptomatic patients with COVID-19 [19].

Among the vaccinated positive individuals, 82.5% did not need any hospital care, and they received nursing staying at home. This finding

Table-2: Different physiological parameters of vaccinated COVID-19 patients during the infection period.

Variables	COVID-19 patients		Male		Female	
	Mean±SE (95% CI)	Min-Max	Mean±SE (95% CI)	Min-Max	Mean±SE (95% CI)	Min-Max
COVID-19 positive result after onset of vaccination (days)	32±1.2 (29.7-34.3)	1-61	32±1.4 (29.1-34.8)	1-61	32±2 (28.1-35.9)	3-57
Duration of fever (days)	3.9±0.2 (3.5-4.4)	1-15	3.9±0.3 (3.4-4.5)	1-10	3.9±0.4 (3.1-4.6)	1-15
Body temperature (Fahrenheit)	100.9±0.1 (100.7-101.2)	99-104	100.9±0.1 (100.6-101.2)	99-104	101±0.2 (100.7-101.3)	99-104
Duration of coughing (days)	6.4±0.4 (5.5-7.2)	1-25	6.5±0.6 (5.4-7.6)	1-25	6.1±0.7 (4.7-7.5)	2-21
Duration of sneezing (days)	2.9±0.5 (1.8-4)	1-8	2.5±0.6 (1.2-3.9)	1-8	3.7±1 (1.1-6.2)	2-8
Duration of shortness of breathing (days)	4.8±0.7 (3.4-6.3)	1-12	5±1.1 (2.5-7.5)	3-12	4.6±0.9 (2.4-6.8)	1-8
Oxygen saturation level (%)	96.8±0.2 (96.5-97.2)	90-99	97±0.2 (96.5-97.4)	90-99	96.5±0.3 (95.9-97.1)	90-99

*SE=Standard error, Min=Minimum, Max=Maximum, %=Percentage, CI=Confidence interval, COVID-19=Coronavirus disease

supports [20], who also reported 80% reduction of hospital admission after a single dose of vaccination with Oxford-AstraZeneca. The reason behind lower hospital admission rates might be due to the protection and efficacy given by the vaccine against severe clinical symptoms [7]. Body immunity developed in response to vaccines which also reduces the severity of infections and subside the systemic clinical manifestation, thus ultimately preventing mortality [21].

The present findings reported 28%, 44.5%, and 91% vaccinated individuals did not show any symptoms of fever, coughing, and sneezing, respectively, during the infection period. The duration and severity of all symptoms were also found low. Furthermore, 56.5% and 55.5% of individuals had no normal taste and smell sensation changes. The reason for milder symptoms of COVID-19-positive vaccinated individuals might be due to the quick immune response generated by ChAdOx1-nCoV-19 maintaining a specific antibody titer that inhibits viral replication and reduces viral loads [19,22].

Breathing difficulties and low oxygen saturation are commonly noticed in severe COVID-19 patients. However, in our study, 88.5% of single-dose vaccinated individuals did not show any sign of dyspnea and their average oxygen saturation level was found normal (96.8%). This is because SARS-CoV-2 infection is generally mild in the majority of individuals. However, it is well defined that the Oxford-AstraZeneca vaccine is developed based on the SARS-CoV-2 spike protein gene, which replicates inside the host cell after immunization and produces significant T-cell responses against it, which prevents SARS-CoV-2 spike protein binding to angiotensin-converting enzyme 2 (ACE-2) receptor of lungs and also capable of neutralizing the virus inside the host body [21,23]. Very few vaccinated individuals develop respiratory difficulties due to comorbidities, secondary bacterial infection, and an initial defect in antiviral host defense mechanisms [24]. The recent emergence of the UK, B.1.1.7 (also called 501Y.V1) includes eight amino acid changes within the spike. One of these, N501Y (Asn 501 Tyr), increases the affinity of the spike to bind its cellular target ACE-2 receptor and causes severe lung damage during the replication process. And thus, underlying causes significantly reduce oxygen consumption as well as blood oxygen saturation level and probably this is the main trigger for breathing difficulties in COVID-19-positive individuals [23,25].

The presence of comorbidities is linked to the severity of COVID-19 and is substantially associated with significant morbidity and mortality [26]. Although 17.5% vaccinated yet infected patients were admitted to the hospital, no serious health risk was observed despite the presence of comorbidities in 64.5% of individuals. Among different kinds of comorbidities, hypertension was highest (27.9%) followed by diabetes (24.8%). SARS-CoV-2 utilizes ACE-2 receptors expressed at the surface of the host cells to access inside the cell. Certain comorbidities are associated with increased ACE-2 receptor expression and increased production of proprotein convertase, which improves viral entrance into host cells. [26]. However, comorbidities, especially diabetes, increase the susceptibility of SARS-CoV-2 infection [27] and significantly reduce the body's immunity function. Moreover, it also enhances the acute cytokine storm, pulmonary dysfunction and hypercoagulation of SARS-CoV-2 infected patients [27]. About

199 (99.5%) individuals were found alive up to negative COVID-19 test results, while only one individual with a history of kidney transplantation and presence of multiple comorbidities died.

Iacobucci [20], also reported minimum adverse events or deaths in ChAdOx1 nCoV-19 single-dose vaccine recipients. Oxford-AstraZeneca vaccines are effective in reducing COVID-19 infections and protecting against severe disease in adults.

However, only vaccinated individuals were considered for this study, where a comparison study between vaccinated and non-vaccinated individuals is also important for an effective vaccine efficacy study. It is also better to sequence the viruses that infect the vaccinated individuals and help identify the strain and nature as well as molecular dynamics of SARS-CoV-2. The study was conducted in a certain geographical location of Bangladesh. However, elaborate studies including a large number of vaccinated individuals in all the divisions of Bangladesh are recommended for future studies that make a clear understanding of vaccine efficacy against COVID-19.

Conclusion

The present investigation evidently focused on the SARS-CoV-2 onfall even though reception of 1st single-dose Oxford-AstraZeneca COVID-19 vaccine. However, the hearty finding is 82.5% of single-dose vaccinated COVID-19 patients did not require any hospital care, and 88.5% of individuals did not face any respiratory difficulties. Despite different comorbidities in the vaccinated patients, only 8% of the study population required extra oxygen support and a negligible (0.5%) number of patients admitted into intensive care unit. The study concludes that vaccination with a single-dose Oxford-AstraZeneca vaccine significantly reduced the severity and mortality of COVID-19 patients in Southeast Bangladesh. Finally, we propose that the studies of SARS-CoV-2 infection after vaccination should be integrated, development of highly effective and durable immune responses producing vaccines that curb the COVID-19 pandemic.

Authors' Contributions

EAR: Planned, designed the study, and prepared the initial draft of the manuscript. EAR, PD, MSI, TAN, and TD: Executed laboratory tasks, data entry, and manuscript preparation. PD and TD: Analyzed and summarized the data. MSI: Literature review. SC and GBD: Supervised the study and revised the final manuscript. All authors read and approved the final manuscript.

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Competing Interests

The authors declare that they have no competing interests.

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