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Original Research Article

COVID-19 patients' clinical profile and outcome with respect to their vaccination status: A prospective observational multicentre cohort study during third wave in Western India

Atul K. Patel [a,*], Dhruv Patel [b], Manoj Shevkani [c], Aniket Shah [d], Surabhi Madan [e], Swati Gohel [f], Chirag Chhatwani [g], Aakash Doshi [h], Vipul Patel [i], Kalpesh Sukhwani [j], Hiten Kareliya [k], Vipul Shah [l], Pratik Savaj [m], Manish Rana [n], Ketan K. Patel [a], Harsh Bakshi [n]

[a] *Infectious Diseases Department, Sterling Hospital, Ahmedabad 380052, India*
[b] *Infectious Diseases and Tropical Medicine Clinic, Gala Business Center II, Off C G Road, Ahmedabad 380006, India*
[c] *Avron Hospital, Navarangpura, Ahmedabad 380013, India*
[d] *Infectious Diseases, Shraddha Hospital, 14 Harihar Society, Maninagar, Ahmedabad 380008, India*
[e] *Marengo CIMS Hospital, Off Science City Road, Sola, Ahmedabad, India*
[f] *Narayana Multispeciality Hospital, Rakhiyal Cross Road, Rakhiyal, Ahmedabad 380023, India*
[g] *Ashirwad Infectious Disease Clinic (AIDC), 313-315, Zenon Apartment, Opp. Unique Hospital, Off. Ring Road, Surat 395007, India*
[h] *Wokhardt Hospital, Kalawad Road, Rajkot, India*
[i] *Infectious Diseases Care Clinic (IDCC), 302 Shubham Super Speciality Hospital, Near Sardar Patel Statue, Ahmedabad 380013, India*
[j] *KD Hospital, Vaishnodevi Circle, Ahmedabad, India*
[k] *Prime Infection Care, OP Road, Vadodara, India*
[l] *Healthcare Infectious Diseases Clinic, 301, Sankalp Square 2, Near Kalgi Cross Road, Ellisbridge, Ahmedabad 380006, India*
[m] *405, AXIS Business Space, Nanpura, Surat 395001, India*
[n] *Community Medicine Department, GMERS Medical College, Sola, Ahmedabad, Gujarat 380060, India*

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ABSTRACT

Purpose: To understand the benefits of COVID-19 vaccination (Covishield, Covaxin) on clinical features and outcome of COVID-19 during the third wave in India.

Materials and methods: The primary study aim was to describe the clinical profile and outcome of COVID-19 regarding their vaccination and to identify risk factors for disease progression in vaccinated patients. This was a prospective observational multicentric study of COVID-19 attended by Infectious Disease physicians during January 15, 2022 to February 15, 2022. Adult patients with positive RT-PCR or rapid antigen test for COVID-19 were enrolled. Patient received treatment as per local institutional protocol. Chi square test for categorical and Mann Whitney test for continuous variables were applied for the analysis. Logistic regression was used to calculate adjusted odds ratios.

Results: A total of 788 patients were included in analysis out of 883 enrolled patients from 13 centers across Gujarat. By the end of two weeks' follow up, 22 patients (2.8%) had expired. The Median age of subjects was 54 years, with a (55.8%) male. 90% of the subjects were vaccinated, majority (77%) of them had received 2 doses of vaccine with Covishield (659, 93%). Mortality among the non-vaccinated was significantly (11.4%) higher than vaccinated (1.8%). Logistic regression analysis showed numbers of comorbidities ($p = 0.027$), baseline higher WBC count ($p = 0.02$), higher NLR ($p = 0.016$), and Ct value ($p = 0.046$) were associated with mortality while vaccination was associated with survival ($p = 0.001$). The factors associated with mortality among vaccinated were age, comorbidities, baseline higher WBC, NLR, and CRP.

Conclusions: Omicron variant was associated with mild symptoms. Clinical and laboratory risk factors for getting severe disease with Omicron variant were the same with previous SARS CoV-2 strain. Two doses of vaccine protect people against severe disease and death. Age, comorbidities, baseline leucocytosis, high NLR, elevated CRP are the risk factors for poor outcome in vaccinated patients.

* Corresponding author.
E-mail address: atulpatel65@gmail.com (A.K. Patel).

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1. Introduction

The COVID-19 pandemic has infected 3.54 crore persons in India till January 7, 2022 with 4.83 lacs deaths. During the first (beginning of the pandemic in March 2020 till the end of 2020) and second wave (March–June 2021), supportive treatment was the main stay of therapy. All repurposed drugs with potential antiviral activities (hydroxychloroquine, ivermectin, lopinavir/ritonavir, azithromycin, doxycycline) were used without clinical benefits [1,2]. Dexamethasone was found to be a lifesaving intervention in hypoxic patients with COVID-19 [3]. Important pillars for containing the outbreak include 1. Surveillance and Detection, 2. Vaccination 3. Prophylaxis (both pre-exposure and post exposure) and 4. Clinical management of active cases. We don't have an effective pharmacological preventive therapy for a COVID-19 outbreak even though it has been more than a two years since the pandemic begun. Hydroxychloroquine was recommended by the Indian Council of Medical Research (ICMR) as a pre-exposure prophylaxis without substantial clinical studies and was found to be ineffective [4,5]. Remdesivir has shown benefit in reduction of disease progression by 87% in high risk patients if given within 3–5 days of symptom onset [6]. Non-pharmacological measures like wearing a mask, social distancing and hand hygiene proved to be useful in controlling the spread of infection [5]. COVID-19 vaccination has proved beneficial in reducing hospitalization and mortality from COVID-19 across various countries [7,8]. India has launched COVID-19 vaccination drive in January 2021 and has done a tremendous job in vaccinating its citizens using ChAdOx1 (Covishield) or indigenous inactivated whole virus vaccine (Covaxin). By January 2022, 95% of the 18+ population of the state of Gujarat had been fully vaccinated [9]. The third wave of COVID-19 in India was seen between December 2021–March 2022. This wave was predominantly driven by the Omicron variant which contains more than 30 mutations in the spike protein and was responsible for the third wave in India. These mutations were associated with a higher replication rate, increased transmissibility and immune evasion of vaccine induced, natural infection induced and hybrid immunity [10,11]. The Omicron variant tends to escapes neutralisation from commercially available therapeutic monoclonal antibodies [12–14]. Several published studies reported asymptomatic to mild symptomatic illness with Omicron variant as compared to other variants [15–18]. The current study was undertaken during this third wave to understand the influence of vaccination on clinical presentation and severity of COVID-19.

2. Materials and Methods

2.1. Objectives of this study

1. Describe the clinical profile and outcome of patients diagnosed with COVID-19.
2. Assess the effect of COVID-19 vaccination on clinical presentation and outcome of patients with COVID-19.
3. Identify risk factors for disease progressions in vaccinated patients with COVID-19.

This was a prospective observational study of COVID-19 patients (outpatient and inpatient) attended by Infectious Disease physicians at thirteen participating centers across the state of Gujarat from January 15, 2022 to February 15, 2022.

2.2. Study patients

Symptomatic and asymptomatic adult patients (age >18 years) with positive RT-PCR or rapid antigen test for COVID-19 were included in this study and followed up to two weeks after presentation. Patients received COVID-19 treatment as per local hospital protocol and treating physician's discretion.

Patients' demographic details, presenting symptoms, comorbidities, laboratory parameters, history of prior COVID-19 infection, COVID-19 vaccination, treatment received, outcome details and other relevant data were collected in predefined case report forms. COVID -19 severity was defined as per government of India, MoH&FW critera [19].

2.3. Ethical statement

The study protocol received the Institute Ethics Committee approval from all participating centers (SHAEC/AP/Covid study-India/011-2022).

2.4. Statistical analysis

IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA) was used for undertaking appropriate bivariate and multivariate analysis. Chi square test for Categorical and Mann Whitney test for Continuous variables were used. Backward Elimination (Likelihood Ratio) Logistic regression was used to calculate adjusted odds ratios. P values of 0·05 or less were considered statistically significant.

3. Results

Total 788 patients were included in analysis out of 883 enrolled patients from 13 centers across Gujarat during study period. Patients with key missing information (n = 82) and patients lost to follow up (n = 13) after first consultation were excluded from the analysis. Majority of the cases were mild and subsequently recovered. By the end of two week follow up, 22 patients (2.8%) had expired. The Median age of subjects was 54 years with a slight (55.8%) male preponderance. 23 (2.9%) cases were asymptomatic. Fever and upper Respiratory tract infection symptoms were present in more than half of the subjects. 9 cases presented with only abdominal symptoms. Loss of taste or smell was the least common symptom (1.5%). History of past COVID-19 infection was present in 126 (16.3%, n = 773). 90% of the subjects were vaccinated, majority (77%) of them had received 2 doses of vaccine with Covishield (659, 93%) being the most common. 13 of the 22 expired cases had received Covishield and the others were unvaccinated. 13 were recipients of other vaccines (Moderna, Pfizer, Sputnik). Baseline white blood cell (WBC) count, neutrophil-lymphocyte ration (NLR), baseline C- reactive protein (CRP) and D-dimer were significantly higher among the deceased group. Majority cases (62%) were managed at home. All the deceased patients had been hospitalized. The use of anti-viral medications (Remdesivir, Favipiravir and Molnupiravir) and Immunomodulators (Corticosteroids, Tocilizumab) was required only in a few cases, and was found to be much higher in the deceased group as compared to those who survived. The demographic details, Clinical presentations, and baseline characteristics of the subjects, segregated according to outcome, are described in Table 1. Age, non-vaccination and number of comorbidities were significant risk factors for mortality. In the presenting symptoms, breathlessness (68.2%) was significantly higher among the deceased while upper respiratory infections were higher among those who survived. Higher WBC count, higher NLR, lower cycle threshold (Ct) value, higher CRP & D-dimer, and severe COVID disease were associated with mortality. Hospitalization, average hospital stay, use of anti-viral and immunomodulators were significantly higher among the deceased [Table 1].

Age, COVID-19 vaccination, number of comorbidities, WBC count, NLR, CRP, Ct value, COVID-19 Severity, Antiviral, Immunosuppressant were modelled using Logistic regression. Number of Comorbidities, WBC count, CRP, COVID-19 Severity, Antiviral use, and Immunomodulator use were significantly associated (positively) with mortality whereas COVID-19 vaccination and Ct value were found to be negatively associated [Table 2]. NLR showed strong positive association in univariate analysis, however, in modelling it showed negative association.

Mortality among the non-vaccinated was significantly (11.4%) higher than vaccinated (1.8%). The mortality decreased with number of vaccine doses (1 dose – 3.3%, 2 doses – 1.8%, 3 doses – 1.4%). Severe COVID disease (15.2%) and hospitalization (70.9%) were significantly higher in

unvaccinated as compared to vaccinated (5.9%, 34% respectively). Both of these decreased with vaccine doses (1 dose – 10%, 36.7%; 2 doses – 6.3%, 35.2%; 3 doses – 1.4%, 23% respectively). Vaccinated patients had mild clinical features, lower baseline CRP, WBC counts, NLR, and D-dimer as compared to unvaccinated, while unvaccinated has lower Ct value as compared to vaccinated suggesting higher viral load in the respiratory sample. All these clinical and laboratory markers favours poor prognosis. Other significantly associated factors are as described in Table 3.

Subgroup analysis to identify risk factors associated with mortality among the vaccinated group (n = 709) is described in Table 4. The factors significantly associated with mortality among vaccinated included: Age, Comorbidities, baseline higher WBC, NLR, CRP, and COVID-19 severity.

Patients who were lost to follow (n = 13) up were elderly [median age 67 (57-77) years], 5 were females, 6 (46.2%) didn't receive vaccine, none had history of COVID-19 in the past, all of them had comorbidities and 6 patients each had moderate and severe COVID-19.

Study cohort had 70 patients with special medical condition, including 19 (18 improved, 1 died) HIV patients, 12 [11 improved, 1 left against medical advice (LAMA)] with haematological malignancies, 12 (11 improved, 1 LAMA) with solid tumours, 11 (9 improved, 1 died, 1 LAMA) with autoimmune diseases receiving immunosuppression, 9 who had received solid organ transplant and 7 pregnant females all of whom had improved.

4. Discussion

After the first report in November 2021 from South Africa, Omicron variant rapidly spread to many other countries. India reported it's first Omicron case in December 2021. Predominant circulating SARS CoV-2 variant in our region during study period was Omicron (BA.1 and BA. 2) [20]. During the study period, Gujarat Biotech Research Centre, Gandhinagar conducted total 1654 genomic sequences from samples across the Gujarat, 1420 were BA.2, 211 were BA.1 and 2 were B.1.617.2. (personal communication) Majority of people infected with Omicron variants had milder clinical illness, mainly running nose, upper respiratory symptoms, itchy throat and fever [15,16,21]. This is consistent with the clinical features of our study participants. In current study, 90% had received at least one dose of vaccine and 86.2% had received two or more dose of vaccine, while 16.4% participants had past history of COVID-19. Omicron infection occurred in 74.2% patients with vaccine induced immunity, 15.7% patients with hybrid immunity (natural infection plus vaccine), 0.5% with natural immunity and 10% of unvaccinated patients.

Table 2
Logistic regression analysis of risk factors for mortality.

Covariate	Adjusted OR (95% CI)	p =
Age	1.062 (0.989–1.141)	0.096
COVID-19 Vaccination		0.014
Non Vaccinated	Ref	–
Single Dose	0 (0-.)	0.998
Two Doses	0.015 (0.001–0.191)	0.001
Three Doses	0.052 (0.002–1.228)	0.067
Number of Comorbidities	3.026 (1.137–8.058)	0.027
WBC	1 (1–1.001)	0.02
NLR	0.625 (0.426–0.916)	0.016
COVID-19 Severity		0.049
Mild	Ref	
Moderate	24.431 (1.106–539.788)	0.043
Severe	41.698 (2.106–825.729)	0.014
Antiviral (Yes)	9.307 (0.683–126.838)	0.094
Ct value	0.812 (0.662–0.996)	0.046

Variable(s) entered on step 1: Age, COVID-19 Vaccination, Number of Comorbidities, WBC, NLR, COVID-19 severity, Antiviral, CRP, Immunosuppressant, Ct value.

Table 1
Baseline characteristics of Study Subjects.

Characteristic	Total 788 (100%)	Alive 766 (97.2%)	Expired 22 (2.8%)	p	OR (95% CI)
Age (IQR)	54 (37–67)	53 (37–67)	72 (65.75–82.25)	0	–
Female	348 (44.2%)	341 (44.5%)	7 (31.8%)	0.28	1.72 (0.69–4.26)
Male	440 (55.8%)	425 (55.5%)	15 (68.2%)		
Symptoms					
Fever	615 (78%)	602 (78.6%)	13 (59.1%)	0.04	0.39 (0.16–0.94)
URI	445 (56.5%)	441 (57.6%)	4 (18.2%)	0	0.16 (0.05–0.49)
Breathlessness	136 (17.3%)	121 (15.8%)	15 (68.2%)	0	11.42 (4.56–28.6)
Abdominal symptoms	63 (8%)	61 (8%)	2 (9.1%)	0.69	1.16 (0.26–5.06)
Clinical History					
Number of Comorbidities	1 (0–2)	0 (0–1)	2.5 (2–3)	0	–
Past COVID-19	126 (16.4%)	123 (16.4%)	3 (13.6%)		
No past COVID-19	647 (83.7%)	628 (83.6%)	19 (86.4%)	0.4	
Non Vaccinated	79 (10%)	70 (9.1%)	9 (40.9%)	0.001	Ref
1 Dose	30 (3.8%)	29 (3.8%)	1 (4.5%)		0.27 (0.03–2.21)
2 Dose	605 (76.8%)	594 (77.5%)	11 (50%)		0.14 (0.06–0.36)
3 Dose	74 (9.4%)	73 (9.5%)	1 (4.5%)		0.11 (0.01–0.86)
Laboratory Parameters					
WBC (/cmm) n = 609	6400 (5200–8392.5)	6400 (5200–8300)	8600 (5600–12,020)	0.01	–
Neutrophils (%) n = 609	68 (55–78)	67 (54–77)	83 (77–89.75)	0	–
Lymphocytes (%) n = 609	25 (16–34.5)	24 (15–34.5)	12 (8–18)	0	–
NLR, n = 609	2.8 (1.62–5.27)	2.74 (1.6–5)	6.92 (4.24–11.06)	0	–
Ct value, n = 583	23 (20–26 0	23.2 (20–26)	18.5 (16–25.75)	0.04	–
CRP (mg/dL) n = 621	7.95 (3.43–19.98)	7.7 (3.36–19)	37 (7.65–87)	0.001	7.95 (3.43–19.98)
D-dimer (ng/ml) n = 510	400 (205.79–740)	381.5 (199.45–716.25)	1616.5 (376.25–3070)	0.001	400 (205.79–740)
COVID-19 severity					
Mild	610 (77.4%)	124 (79.4%)	2 (9.1%)	0.001	Ref
Moderate	124 (15.7%)	119 (15.5%)	5 (22.7%)		12.77 (2.45–66.6)
Severe	54 (6.9%)	39 (5.1%)	15 (68.2%)		116.92 (25.82–529.55)
Treatment					
Home Isolation	491 (62.3%)	491 (64.1%)	0 (0%)	0	–
Hospitalization	297 (37.7%)	275 (35.9%)	22 (100%)		
Duration of hospitalization (days)	4 (3–6)	4 (3–5)	6 (3.5–7.25)	0.07	–
Antiviral drugs	267 (33.9%)	252 (32.9%)	15 (68.2%)	0	4.37 (1.76 10.85)
Immunomodulators	181 (23%)	164 (21.4%)	17 (77.3%)	0	12.48 (4.54–34.33)

Table 3
Baseline characteristics of patients according to their vaccination status.

Characteristics	Unvaccinated 79 (100%)	Vaccinated 709 (100%)	P	OR (95% CI)
Age	61 (35–75)	53 (37–66.5)	0.024	
Symptomatology				
Fever	54 (68.4%)	561 (79.1%)	0.032	1.755 (1.056–2.915)
URI	30 (38%)	415 (58.5%)	0.001	2.119 (1429–3.72)
Breathlessness	25 (31.6%)	111 (15.7%)	0.001	0.401 (0.239–0.671)
Abdominal Complaints	12 (15.2%)	51 (7.2%)	0.025	0.433 (0.22–0.852)
Comorbidities	1 (0–2)	0 (0–1)		
Previous COVID	4 (5%)	122 (17.6%)	0.004	4 (1.44–11.14)
Laboratory Findings				
NLR	4.278 (1.83–7.62)	2.76 (1.66–4.92)	0.003	–
Ct value	22 (17–26)	23.5 (20–26.1)	0.039	–
CRP	12.4 (3.9–52)	7.35 (3.4–180	0.002	–
D-dimer	634 (300–1371)	374 (197–676)	0	–
COVID-19 Severity				
Mild	46 (58.2%)	564 (79.5%)	0	Ref
Moderate	21 (26.6%)	103 (14.5%)		0.4 (0.229–0.698)
Severe	12 (15.2%)	42 (5.9%)		0.285 (0.141–0.58)
Treatment				
Home Isolation	23 (29.1%)	468 (66%)	0	0.212 (0.127–0.352)
Hospitalization	56 (70.9%)	241 (34%)		
Antiviral	42 (53.2%)	225 (31.7%)	0	0.410 (0.256–0.655)
Immunomodulators	30 (38%)	151 (21.3%)	0.002	0.442 (0.271–0.720)
Outcome				
Alive	70 (88.6%)	696 (98.2%)	0	0.145 (0.06–0.352)
Expired	9 (11.4%)	13 (1.8%)		

Table 4
Risk factors for mortality in vaccinated COVID-19 patients.

Characteristic	Vaccinated 709 (100%)	Alive 696 (98.2%)	Expired 13 (1.8%)	p
Age (IQR)	53 (37–66.5)	57 (37–66)	72 (66–78)	0
Number of Comorbidities	0 (0–1)	0 (0–1)	2 (2–3)	0
Past COVID N = 694	122 (17.6%)	120 (17.6%)	2 (15.4%)	1
Vaccine Doses				
1	30 (4.2%)	29 (4.2%)	1 (7.7%)	0.79
2	605 (85.3%)	594 (85.3%)	11 (84.6%)	
3	74 (10.4%)	73 (10.5%)	1 (7.7%)	
WBC (/cmm) n = 548	6400 (5200–8300)	6370 (5200–8205)	9000 (7700–13,000)	0.003
NLR, n = 548	2.76 (1.66–4.92)	2.7 (1.63–4.9)	6.9 (4.2–15)	0
Ct value,n = 533	23.5 (20–26.1)	24 (20–26.1)	18.5 (15–25.75)	0.135
CRP (mg/dL) n = 554	7.35 (3.4–180	7 (3.33–17)	37 (8.25–47.7)	0.001
D-dimer (ng/ml) n = 455	374 (197–676)	363.5 (195.5–670.75)	940 (270–2444)	0.058
Mild	564 (79.5%)	563 (80.9%)	1 (7.7%)	0
Moderate	103 (14.5%)	99 (14.2%)	4 (30.8%)	
Severe	42 (5.9%)	34 (4.9%)	8 (61.5%)	
Antiviral	225 (31.7%)	215 (30.9%)	10 (76.9%)	0.001
Immunomodulators	151 (21.3%)	140 (20.1%)	11 (84.6%)	0

Omicron variant is also known to evade immunity following vaccination and natural infections [7,8,10,11,22]. Even though Omicron is associated with milder disease, the poor prognostic markers (Univariate, logistic regression analysis) e.g. Older age [p= <0.0001, aOR 1.06 (0.99–1.14)], co-morbidities [p= <0.0001, aOR 3.03 (1.14–8.06)], lymphopenia with higher NLR [p= <0.0001, aOR 0.62 (0.43–0.92)] remain the same as described with infection with previous SARS CoV-2 strain [23,24]. Multiple studies conducted in India, UK and USA reported increases risk of mortality in patients with higher viral load as marked by lower cycle threshold value (Ct value) in RTPCR tests [25–27]. In our study, both univariate analysis ($p = 0.04$) and adjusted logistic regression [aOR 0.81 (0.66–0.99)] showed increased mortality in patients with low Ct value. Our study supports the existing evidence that COVID-19 vaccination provides protection against severe illness, hospitalization and death due to COVID-19 [8,10,22]. Natural immunity following past COVID-19 illness was not associated with any difference in survival while vaccine induced immunity has shown striking survival benefit in this study. 92.9% of study patient had received Covishield (ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant). We have several publications reporting effectiveness of mRNA (Moderna and Pfizer) vaccinations in reducing hospitalization and mortality in multiple countries. Publications on similar benefit following Oxford vaccine (ChAdOx-1s) is sparce. India rolled out COVID-19 vaccination program in January 2021 with Oxford vaccine, manufactured by Serum Institute of India, Pune with the name of Covishield and a second indigenous vaccine manufactured by Bharat Biotech, inactivated whole virus vaccine. Majority of citizens of Gujarat received Covishield vaccine as allocated by Government of India. Current study reported significant reduction in mortality [aOR 0.015 (0.001–0.19)] in patients who had received two doses of the vaccine. Omicron escapes in-vitro live virus antibody neutralisation study from BNT162b2 [28]. A study from South Africa reported reduced effectiveness of BNT162b2 against Omicron variant [11]. Breakthrough infections with Omicron have been described in people who have received mRNA booster dose with high anti spike antibody titers [29]. Study conducted during early vaccination drive in the UK December 2020 to February 2021 reported significant reduction in symptomatic COVID-19 in older adults, with further protection against severe disease from single dose vaccination with either ChAdOx-1s or BNT162b2. Both the vaccines were found equal in protection. Patients who had received a second dose had higher protection against symptomatic disease. Predominant variant circulating during study period was B.1.1.7 [30]. Study from Qatar, reported no benefit in preventing symptomatic COVID-19 illness following mRNA vaccines (Pfizer and Moderna) with Omicron BA.1 and BA.2 infections. This study also finds the highest protection in patients with previous infection who had undergone three doses of the vaccine while no difference was found in patients with previous infection alone and previous infection with two doses of the vaccine [22]. These finding are similar to the current study.

5. Conclusions

Our study supports evidence that infection with Omicron variant was associated with mild symptoms in majority of the patients. Clinical and laboratory risk factors for getting severe disease with Omicron variant are the same as those with previous SARS CoV-2 strains. Two doses of Covishield vaccine protect people against severe disease and death. Amongst vaccinated persons, age, comorbidities, baseline leucocytosis, high NLR, elevated CRP are the risk factors for poor outcome.

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Declaration of competing interest

All the authors have no conflicts of interest to disclose.

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