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Vaccination and anti-SARS-CoV-2 treatment reduce disease progression: a real-life experience

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❖ Background

After the identification of the first SARS-CoV-2-infected patient, several drugs have been prescribed, mainly in patients with risk factors increasing the probability of disease progression. Three antivirals (molnupiravir, nirmaltrevir/r, remdesivir) and two monoclonal antibodies (casirivimab/imdevimab and sotrovimab) are currently available in Italy. Identify people at risk of disease progression is fundamental to optimize drug prescription. The aim of the present study was to evaluate the association between risk factors and COVID-10 disease progression in a real-life cohort.

❖ Materials and Methods

- ✓ A single-centre retrospective cohort study was performed. Patients with a confirmed diagnosis of SARS-CoV-2 infection between the 1st of January, 2022 and the 10th of May, 2022 were recruited.
- ✓ Demographical and clinical data were collected. Disease progression was defined by the prescription of oxygen therapy, not attributable to other conditions. Preventive treatment was prescribed in patients with recent symptom onset (≤5/7 days), no need of oxygen supplementation, and who had risk factors for disease progression.
- ✓ Student t-test, chi-square, or Fisher exact tests were used to assess differences for quantitative and qualitative variables. In addition, a logistic regression analysis was performed to test the association between the collected variable and the outcome (disease progression). A two-tailed *p*-value<0.05 was considered statistically significant. All statistical analyses were performed with STATA version 17 (StataCorp, Texas, USA).

Table 1. Characteristics of 1,118 patients infected by SARS-CoV-2 with and without disease progression

	No Disease Progression (n=755)	Disease Progression (n=363)	Overall (n= 1,118)	p-value
Age, mean (±SD)	67.9±17.1	74.8±13.1	70.1±16.2	<0.0001
Male gender, n (%)	387 (51.2)	195 (53.7)	582 (52.1)	0.441
BMI >30Kg/m²	175 (23.2)	99 (27.3)	274 (24.5)	0.136
CKD, n (%)	102 (13.5)	59 (16.2)	161 (14.4)	0.221
Dialysis, n (%)	11 (1.5)	6 (1.6)	17 (1.5)	0.802
Immunodeficiency, n (%)	130 (17.2)	57 (15.7)	187 (16.7)	0.525
Decompensated diabetes, n (%)	77 (10.2)	56 (15.4)	133 (11.9)	0.011
Chronic Liver Disease, n (%)	44 (5.8)	29 (8.0)	73 (6.5)	0.171
Chronic Lung disease, n (%)	125 (16.6)	91 (25.1)	216 (19.3)	0.001
Neurological disorder, n (%)	138 (18.3)	92 (25.3)	230 (20.6)	0.006
Solid tumour, n (%)	140 (18.5)	51 (14.1)	191 (17.1)	0.062
Haematological cancer, n (%)	40 (5.3)	30 (8.3)	70 (6.3)	0.055
Cardiovascular disease, n (%)	284 (37.6)	154 (42.4)	438 (39.2)	0.123
Comorbidities, mean ± SD	1.76 ±1.26	2.08±1.41	1.87±1.32	0.0002
CCI, mean ± SD	4.92±2.65	5.51±2.65	5.11±2.67	0.0005
4C-score, mean ± SD	7.97±3.60	11.53±3.26	9.35±3.88	<0.0001
Vaccination with at least 2 doses, n (%)	665 (88.0)	205 (56.5)	870 (77.8)	<0.0001
Last vaccination between 14-120 days, n (%)	390 (51.7)	103 (28.4)	493 (44.1)	<0.0001
Fever, n (%)	319 (42.5)	212 (58.4)	531 (47.5)	<0.0001
Cough, n (%)	366 (48.5)	181 (49.9)	547 (48.9)	0.664
Sore throat, n (%)	201 (26.6)	32 (8.8)	233 (20.8)	<0.0001
Asthenia, n (%)	289 (38.3)	113 (31.1)	402 (36.0)	0.020
Headache, n (%)	137 (18.1)	41 (11.3)	178 (15.9)	0.003
Myalgia, n (%)	162 (21.5)	58 (16.0)	220 (19.7)	0.031
Gastrointestinal symptoms, n (%)	95 (12.6)	48 (13.2)	143 (12.8)	0.764
Dyspnoea, n (%)	74 (9.8)	233 (64.2)	307 (27.5)	<0.0001
Molnupiravir, n (%)	303 (40.1)	31 (8.5)	334 (29.9)	<0.0001
Nirmatrelvir/r, n (%)	48 (6.4)	0	48 (4.3)	<0.0001
Remdesivir (3 days), n (%)	34 (4.5)	6 (1.6)	40 (3.6)	<0.0001
Casirivimab/Imdevimab, n (%)	102 (13.5)	26 (7.2)	128 (11.4)	0.002
Sotrovimab, n (%)	73 (9.7)	10 (2.8)	83 (7.4)	<0.0001

BMI: body-mass index; CKD: chronic kidney disease; CCI: charlson comorbity index.

❖ Results

- ✓ 1,118 patients were enrolled. Disease progression was recorded in 363 (32.5%).
- ✓ Advanced age, a higher burden of comorbidities, lower vaccination coverage, and having fever and/or dyspnoea at hospital admission were associated with higher risk of progression. Patients exposed to antivirals or monoclonal antibodies had a lower risk of disease progression (Table 1).
- ✓ The regression analysis showed an increased risk of clinical severity with age increasing, chronic respiratory disease, hematologic malignancies, fever and dyspnoea. Preventive therapy for SARS-CoV-2 was confirmed to be associated with a lower risk of progression (Table 2).
- ✓ None of the patients treated with Nirmatrelvir/r underwent disease progression. However, these patients were significantly younger (59.1 VS. 70.6 years; *p*-value <0.0001).

Table 2. Logistic regression analysis to assess the relationship between sociodemographic, clinical and therapeutic variables and disease progression in 1,118 patients infected by SARS-CoV-2 (only variables included in the multivariate analysis are reported).

Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Age	1.03 (1.02-1.04)	<0.0001	1.04 (1.02-1.05)	<0.0001
Decompensated diabetes	1.61 (1.11-2.33)	0.01	1.03 (0.59-1.81)	0.91
Chronic respiratory disease	1.69 (1.24-2.28)	0.001	1.73 (1.11-2.69)	0.02
Neurological disorder	1.52 (1.12-2.05)	0.006	1.42 (0.93-2.16)	0.10
Hematological cancer	1.61 (0.99-2.63)	0.06	2.82 (1.41-5.65)	0.003
Vaccination completed	0.18 (0.13-0.24)	<0.0001	0.22 (0.15-0.33)	<0.0001
Fever	1.92 (1.49-2.47)	<0.0001	2.20 (1.53-3.15)	<0.0001
Dyspnea	16.49 (11.95-22.76)	<0.0001	13.24 (8.99-19.50)	<0.0001
Molnupiravir	0.14 (0.09-0.21)	<0.0001	0.13 (0.08-0.21)	<0.0001
Remdesivir	0.36 (0.15-0.86)	0.02	0.18 (0.06-0.52)	0.002
Casirivimab/imdevimab	0.49 (0.32-0.75)	0.0002	0.50 (0.28-0.89)	0.02
Sotrovimab	0.27 (0.14-0.52)	<0.0001	0.37 (0.16-0.84)	0.02

OR: odds ratio.

Conclusions

Vaccination, antivirals and monoclonal antibodies reduce the risk of disease progression in SARS-CoV-2 infected patients. Of note, patients enrolled in our study were older and had a higher comorbidity burden when compared with those enrolled in clinical trials.