Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Letter to the Editor

Sotrovimab to prevent severe COVID-19 in high-risk patients infected with Omicron BA.2

Before the Omicron era, the neutralizing antibody targeting the SARS-CoV2 Spike protein Sotrovimab has been shown to reduce the risk of COVID-19-related hospitalization in patients who are at high risk for progression (1, 2). We recently showed that early administration of Sotrovimab in Omicron-infected patients with very high-risk for progression was associated with a low rate of COVID-19-related hospitalization within one month after treatment administration (3%), and with no death (1). However, the dominance of the Omicron sublineage BA.2 led health agencies to suspend Sotrovimab emergency use authorizations because of its lower neutralizing ability *in vitro* compared to BA.1 sublineage (3, 4). Clinical efficiency of Sotrovimab to prevent COVID-19 related complications in high-risk patients with mild-to-moderate COVID-19 Omicron BA.2 remains unknown. Our aim was to compare the clinical and virological outcomes of Omicron BA.1 and BA.2-infected patients with mild-to-moderate COVID-19 who received 500 mg of Sotrovimab IV to prevent COVID-19-related complications.

Our study is based on the ANRS 0003S CoCoPrev study (NCT04885452 (1)), an ongoing multicentric prospective cohort study that includes patients considered to be at high-risk for progression to severe COVID-19, having PCR-proven mild-to-moderate COVID-19 in the first five days of symptoms, and who are treated under an emergency use authorization (EUA) in one of the 32 participating centers. Treatment initiation, based on French Health Authorities recommendation, was left at the treating physician discretion. In this study we have included Omicron-infected patients with either the BA.1 or the BA.2 sublineages that have received 500 mg of Sotrovimab IV. The primary outcome was the proportion of patients with COVID-19-related hospitalization or death within one month of treatment administration. Secondary outcome was the slope of the change over time in the cycle threshold (Ct) value assessed by nasopharyngeal PCR, predictive factors related to the virological response (viral genotypes, emergence of resistant strains), and genotypic and phenotypic characterization of resistance variants (supplementary methods). Mixed effect models were used to estimate the temporal dynamics of the Ct value. Written informed consent was obtained from each patient before enrolment. The protocol has been approved by the "CPP Sud-Est IV" Ethics Committee (Paris, France) and the French Regulatory Authority (ANSM).

Among 190 consecutive patients who received Sotrovimab a median of 3 days (Q1-Q3 2–4) after first symptoms, 47 (25%) were BA.2-infected, 136 (72%) were immunocompromised, 143 (77%) received $\geq$ 3 vaccines doses (Table 1). There was no significant difference between BA.1 and BA.2 groups with respect to comorbidities and anti-Spike IgG positivity. At the 28th day visit after treatment administration, respectively 3/125 (2.4% - 95% Confidence Interval (CI): 1–7%) and 1/42 (2.4% - 95% CI: 0–13%) BA.1 and BA.2-infected patients were hospitalized due to COVID-19, and none died. All of them were immunocompromised. The slope of Ct values did not differ between groups ($p = 0.87$, Fig. 1). Among the 86 patients who had extended nasopharyngeal virological follow-up due to persistent PCR positivity, 15/68 BA.1-infected patients (22%, 95%CI 13–34%) developed mutations in the Spike protein *vs* none of the 18 BA.2 infected patients (0%, 95%CI 0–19%, $P = 0.033$) (Supplementary Table 1). Emergence of these mutations was not associated with baseline characteristics, did not occur among patients who experienced COVID-19-related hospitalization, and did not significantly affect the slope of Ct values (Supplementary Tables 2 and 3 and supplementary figure 1). Plasma collected at day 7 from 60 patients with negative IgG anti-Spike serology at Sotrovimab administration showed a four-fold reduction of neutralizing titers on BA.1 compared to BA.2 (Supplementary Table 4). No major side effects have been reported.

In this prospective real-life cohort study that included mostly severely immunocompromised patients, administration of Sotrovimab in BA.2-infected patients was associated with a similarly low rate of COVID-19-related hospitalization, and decline of the nasopharyngeal viral load, as in BA.1-infected patients.

Our results suggest that, although the neutralizing power of patients' sera seven days after administration of 500 mg of Sotrovimab against the Omicron sublineage BA.2 is reduced *in vitro* compared to BA.1, Sotrovimab may still be valuable in preventing COVID-19 progression in BA.2-infected patients. A recent modelization study suggested that for current monoclonal antibody regimens, doses between 7- and >1000-fold lower than currently used could still achieve around 90% of the current effectiveness (depending on the variant) (5). In that regard, the dose administered of Sotrovimab might have potentially overcome its decreased neutralizing activity on the BA.2 sublineage. The fragment crystallizable (Fc) of some monoclonal antibodies targeting the SARS-CoV2 Spike protein, such as Casirivimab and Imdevimab, is engineered in order to reduce Fc-dependent activation of immune effector cells and of the complement system, limiting the theoretical risk of antibody dependent-enhancement (6). On the contrary, although modified to enhance its half-life, the preserved ability of Sotrovimab to recruit and engage Fcγ receptor–bearing cells and complement system activator C1q may participate through Antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) to the antiviral effect of Sotrovimab *in vivo*.

Targeting a single epitope, and used as a monotherapy, the risk of developing resistance mutations of SARS-CoV-2 in Sotrovimab-treated patients is of major concern. Mutations in the spike protein at positions 337 or 340 were shown in patients infected with the Delta (7) and the Omicron lineages (8). A recent report demonstrated across a routine genomic surveillance that these mutations occurred in 24 (0.13%) of 18,882 omicron BA.1 lineages and in one

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Table 1
Baseline characteristics of patients and outcomes at the 28th day visit.

Baseline characteristics	All $N = 190$	BA.1-infected patients $N = 143$ (75%)	BA.2-infected patients $N = 47$ (25%)	p-value
Median age (years, Q1-Q3)*	59 (45–70)	59 (44–70)	55 (50–72)	0.75
≥ 80 years old (%)	17 (9)	14 (10)	3 (6)	0.57
Median BMI (Q1-Q3)*	25 (22–29)	24 (22–29)	26 (22–30)	0.42
Male sex (%)**	98 (52)	71 (50)	27 (57)	0.38
Immunocompromised patients (%), including:	136 (72)	101 (71)	35 (75)	0.61
Solid organ transplantation	55 (40)	39 (39)	16 (46)	0.46
Immunosuppressive therapy including rituximab	53 (39)	44 (44)	9 (26)	0.06
Ongoing chemotherapy	29 (21)	20 (20)	9 (26)	0.46
Corticosteroids >10 mg/day for > 2 weeks	13 (10)	10 (10)	3 (9)	1
Allogeneic hematopoietic stem cell transplantation	7 (5)	6 (6)	1 (3)	0.68
Systemic lupus or vasculitis with immunosuppressive medications	7 (5)	5 (5)	2 (6)	1
Cancer	3 (2)	1 (1)	2 (6)	0.16
Other risk factors for severe COVID-19 (%), including:	98 (52)	75 (53%)	23 (49%)	0.68
Diabetes (type 1 and type 2)	30 (31)	22 (29)	8 (35)	0.62
High blood pressure	28 (29)	21 (28)	7 (30)	0.82
Obesity BMI>30	25 (26)	19 (25)	6 (26)	0.94
Other chronic pathologies	25 (26)	20 (27)	5 (22)	0.64
Chronic kidney disease	20 (20)	16 (21)	4 (17)	0.78
Congestive heart failure	7 (7)	7 (9)	0	0.19
COPD and chronic respiratory failure	6 (6)	3 (4)	3 (13)	0.14
Having received ≥ 3 doses of vaccine (%)***	143 (77)	102 (73)	41 (89)	0.08
Positive IgG anti-Spike serology at d0 (%)****	118 (63)	85 (61)	33 (70)	0.26
Median IgG anti-spike level at d0 (BAU/mL, Q1-Q3)	531 (120–2383)	807 (126–2500)	395 (91–1574)	0.26
Day 28 outcome (% of patients with available data)	167/190 (88)	125/143 (87)	42/47 (89)	
COVID-19–related hospitalization at d28 (%)	4 (2)	3 (2)	1 (2)	1
COVID-19-related death (%)	0	0	0	

* Age and BMI were missing in 6 BA.1-infected patients and 3 BA.2-infected patients.
** Sex was missing in 1 BA.1-infected patients.
*** Vaccination status was missing in 4 BA.1-infected patients and 1 BA.2-infected patients.
**** IgG anti-Spike serology was missing in 4 BA.1-infected patients.

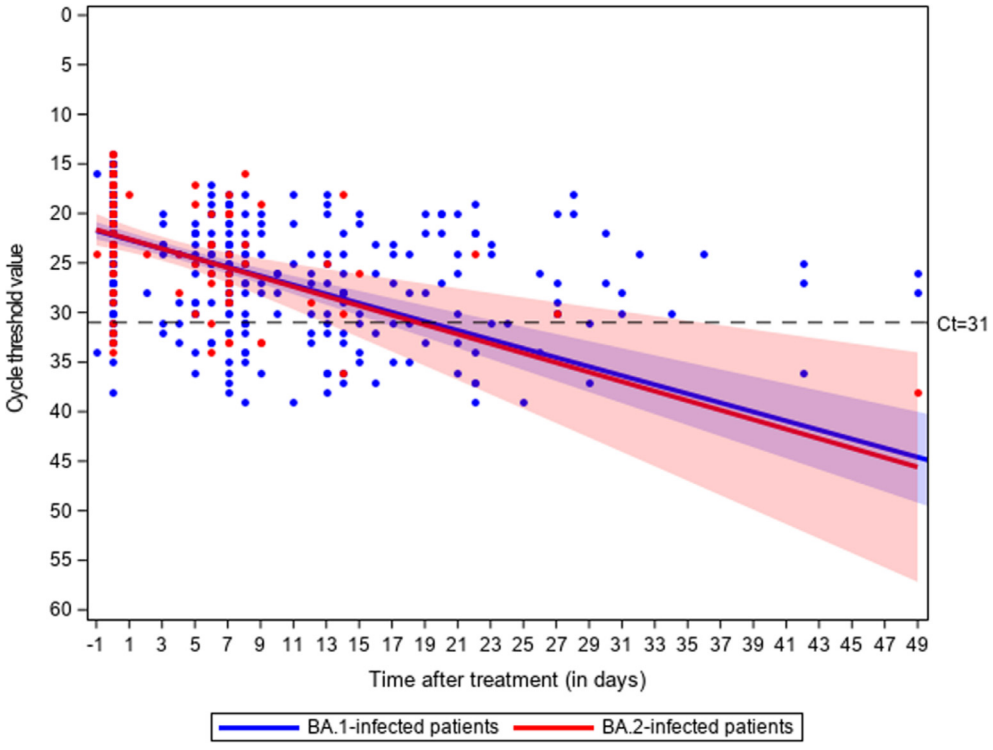

Fig. 1. Change in Ct value of gene N in 143 BA.1 and 47 BA.2-infected patients treated with Sotrovimab. The p-value for the slope difference is 0.87.

(0.02%) of 4025 omicron BA.2 lineages, affecting mostly immunocompromised patients with persistent SARS-CoV-2 excretion (9). In this work both mutations occurred in a sizeable proportion of BA.1-infected patients but did not occur among patients who experienced COVID-19-related hospitalization, and did not significantly affect the slope of Ct values. None of them were demonstrated among BA.2-infected patients.

Although our work is limited by the relatively small number of BA.2-infected patients, Sotrovimab was associated with a low incidence of COVID-19 related hospitalization or death among very high-risk patients with mild-to-moderate COVID-19 related to the BA.2 sublineage, and with no emergence of mutations.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organization for the submitted work; no financial relationships with any organization that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Contributions

GM (guarantor) was involved in the study conception, data extraction, data analysis, interpretation of results and drafting the manuscript. AGM was involved in the study conception, data extraction, data analysis, interpretation of results and drafting the manuscript. CS was involved in the study conception, data extraction, data analysis, interpretation of results and drafting the manuscript. SK was involved in data extraction, data analysis, interpretation of results and drafting the manuscript. CLN was involved in data extraction, data analysis, interpretation of results and drafting the manuscript. CD was involved in the study conception, data extraction, data analysis, interpretation of results and revising the manuscript. LN was involved in the study conception, data extraction, data analysis, interpretation of results and revising the manuscript. AB was involved in the study conception, data extraction, data analysis, interpretation of results and revising the manuscript. CM was involved in patients inclusion and revising the manuscript. AC was involved in patients inclusion and revising the manuscript. CC was involved in patients inclusion and revising the manuscript. FC was involved in patients inclusion and revising the manuscript. JPM was involved in patients inclusion and revising the manuscript. GG was involved in patients inclusion and revising the manuscript. ATD was involved in patients inclusion and revising the manuscript. AMR was involved in patients inclusion and revising the manuscript. VPM was involved in patients inclusion and revising the manuscript. FR was involved in patients inclusion and revising the manuscript. KL was involved in patients inclusion and revising the manuscript. NPS was involved in patients inclusion and revising the manuscript. pH was involved in patients inclusion and revising the manuscript. AP was involved in patients inclusion and revising the manuscript. GP was involved in patients inclusion and revising the manuscript. AM was involved in patients inclusion and revising the manuscript. VD was involved in patients inclusion and revising the manuscript. MD was involved in patients inclusion and revising the manuscript. JF was involved in patients inclusion and revising the manuscript. CC was involved in patients inclusion and revising the manuscript. RL was involved in the study conception, interpretation of results and revising the manuscript. FC was involved in the study conception, data extraction, data analysis, interpretation of results and drafting the manuscript. YY. (guarantor) was involved in the study conception, data extraction, data analysis, interpretation of results and drafting the manuscript.

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Ethical approval

This study received the ethical approval of the Comité de Protection des Personnes SUD-EST IV.

Transparency declaration

GM and YY (the manuscript's guarantors) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing

Data available upon request for academic researchers.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jinf.2022.06.033.

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