# A Single-center Experience in Treating Young Children at High Risk For Severe COVID-19 With Sotrovimab

***To the Editors:***

In Italy, the B.1.1.529 (Omicron) variant of concern (VOC) of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is now dominant[1] and sotrovimab is thought to retain activity against it.[2,3]

To the best of our knowledge, there are few data on its use in children less than 12 years old and weighing less than 40 kg.[4] European Medicine Agency (EMA) and Italian Medicine Agency (AIFA) both authorized sotrovimab for treating COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

We describe a series of 5 children less than 12 years old, treated with sotrovimab in the Department of Pediatric and Public Health Sciences, Infectious Diseases Unit, Regina Margherita Children's Hospital, Turin. All 5 patients were admitted for reasons other than COVID-19 and tested positive for SARS-CoV-2 infection. They were hospitalized to ensure clinical observation because they all fulfilled the criteria for high risk of progression to severe COVID-19 (Table 1) and they all met AIFA's indications for treatment with sotrovimab, with the exception of age and weight.[5] None of them had received vaccination for SARS-CoV-2 (4 out 5 were less than 5 years old). As required by the hospital's policy, off-label monoclonal antibodies (mAb) use for age and weight was prescribed after Hospital Drug Committee approval and once we obtained the informed parental consent.

Since pediatric clinical trials on SARS-CoV-2 treatment with sotrovimab are lacking in children, there are no formal guidelines and recommendations about the dosage in patients younger than 12 years of age and weighing less than 40 kg. Considering that the recommended dose in adults and adolescents (weighing at least 40 kg) is a single 500 mg intravenous administration,[3] we established a dose based on anthropometric values of 12.5 mg/kg for our patients.

There were no significant adverse events and reactions that required the cessation of infusion. None of the treated patients required either intensive care admission or oxygen supplementation, except for 1, who presented pulmonary worsening the day after Sotrovimab infusion and recovered with a short course of steroids.

Among the first 2 patients treated, none was readmitted for reasons related to COVID-19 or Multisystem Inflammatory Syndrome in children (MIS-C) within 30 days of follow-up. Of the other 3, 1 was discharged the day after sotrovimab infusion and another 5 days later; the last is still hospitalized for reasons other than COVID-19. These 3 children did not develop COVID-19 related symptoms at the 7-day follow-up.

In conclusion, the administration of sotrovimab in the initial phase of SARS-CoV-2 infection might be considered also in young children with risk factors for severe COVID-19.

Although our data are limited, this report provides preliminary information on the use, weight-based dosage and tolerability of sotrovimab in young children at high risk for unfavourable and complicated COVID-19 evolution.

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**TABLE 1.** Demographic and COVID-19 Related Symptoms in Our Pediatric Patients

| Subjects | Age | Weight | Sex | Ethnicity | Comorbidity | First positive test for SARS-CoV-2 | COVID-19 related symptoms | Sotrovimab infusion |
|---|---|---|---|---|---|---|---|---|
| Patient 1 | 2 months | 5.5 kg | F | Caucasian | ALL at onset | 27 January 2022 | Fatigue | 29 January 2022 |
| Patient 2 | 1 year | 12.5 kg | M | African | Mucopolysaccharidosis type I, sleep apnea syndrome with nocturnal NIV, AHSCT complicated with reactivation of CMV and EBV infection, immunosuppressive treatment with anti–B lymphocyte monoclonal antibodies (rituximab) | 2 January 2022 | Rhinitis, sore throat | 8 January 2022 |
| Patient 3 | 1 year | 10 kg | F | African | Embryonal rhabdomyosarcoma and neutropenia (ongoing chemotherapeutic agents) | 27 January 2022 | Fever | 29 January 2022 |
| Patient 4 | 2 years | 14 kg | M | Caucasian | ALL (ongoing chemotherapeutic agents) | 27 January 2022 | Fever | 29 January 2022 |
| Patient 5 | 8 years | 18 kg | M | Hispanic | Chronic pulmonary graft versus host disease after AHSCT in ALL | 1 January 2022 | Headache, rhinitis | 8 January 2022 |

AHSCT indicates allogeneic hematopoietic stem cell transplant; ALL, acute lymphoblastic leukemia; CMV, cytomegalovirus; EBV, epstein barr virus; F, female; M, male; NIV, noninvasive ventilation.

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# Letter Regarding "Delayed-onset Anaphylaxis After COVID-19 Vaccination"

***To the Editors:***

We would like to share ideas on the publication "Delayed-onset Anaphylaxis After mRNA-Based COVID-19 Vaccination in an Adolescent Male."[1] According to Shrestha et al, this instance underlines the significance of creating good AEFI surveillance mechanisms, as well as prolonging patient monitoring after COVID-19 vaccination with proper AEFI counseling.[1] We agree that the COVID-19 vaccine could induce a variety of clinical issues, including anaphylaxis. The patient in this case suffered anaphylaxis, however concluding that there is a definite causal with vaccination is problematic. Because there is no information on the patient's health or immunologic condition before immunization, the correlation may be ambiguous. In this situation, there is also the possibility of a concurrent medical condition that could lead to anaphylaxis. A vaccination recipient's clinical problems after vaccination are not always caused by the immunization. For example, dengue is a possible clinical problem that can occur in a vaccine recipient.[2] Delayed type hypersensitivity is also a known clinical problem in the pathophysiologic process of dengue.[3]


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# Refusal to Walk and Ptosis as an Atypical Presentation of Kawasaki Disease

***To the Editors***:

Kawasaki disease (KD) can present with a multitude of symptoms in addition to those that are part of the diagnostic criteria, which may delay diagnosis and therefore the establishment of treatment.

A 3-year-old girl was admitted due to 5 days of persistent high fever and refusal to walk, without joint involvement. Physical examination was normal except for decay. Blood tests show leukocytosis with neutrophilia and elevation of acute-phase reactants. Admission was decided for treatment with cefotaxime and cloxacillin due to suspicion of osteoarticular infection.

In the following days, fever persisted, associating both hands arthralgias, nonsecreting bilateral conjunctival hyperemia, and fissured lips.

Body magnetic resonance imaging was requested with a myositis focus in the right quadriceps, and multiple inflammatory foci in the upper limbs. An electromyogram was compatible with a focal muscular inflammatory process. Immunological study with complement factors, antinuclear antibody, muscle-specific antibody panel and viral and bacterial serology was negative. Lumbar puncture was performed, observing lymphocytic pleocytosis, sterile culture and negative reverse transcription polymerase chain reaction for *Brucella*, *Rickettsia*, *Coxiella burnetti* and *Borrelia sp*. An active or past infection by SARS-CoV-2 was ruled out.

From the 11th day of fever, she associated bilateral fluctuating palpebral ptosis, without the involvement of other cranial nerves (Fig. 1). Screening of myastheniform symptoms was carried out with positive anti-Acetyl-Choline receptor antibodies (ACRA) obtained at 0.79 nmol/L (≥0.45 nmol/L).

Due to meeting criteria for incomplete KD[1] [fever lasting >5 days, bilateral conjunctival hyperemia, fissured lips, C-reactive protein >3 mg/dl, erythrocyte sedimentation rate >40mm/h, anemia (Hb 9.3 g/dL), platelets >450 × 1000/L, Leukocytes >15.000 × 1000/L] intravenous immunoglobulin (2 g/kg) was administered.

The patient remained afebrile with the recovery of gait, although bilateral ptosis persisted. Days later, she presented desquamation of the fingertips as well as chromonychia (Fig. 2). Progressive improvement of ptosis was observed until it disappeared 22 days after the onset of symptoms.

Cardiological controls were normal, and 6 months after admission patient remains asymptomatic. Laboratory findings show the persistence of positive ACRA antibodies 0.69 nmol/L.

Neurological symptoms may appear throughout the course of KD, ptosis is very rare, as only 5 cases have been published previously.[2–5] It seems to be a late complication that appears between the second and fourth week from the onset of symptoms. In none of the cases, ptosis was remitted after immunoglobulins administration. All the cases had a complete resolution in a period between 5 days and 4 weeks. There is no association between this symptom and cardiac complications.


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