

# Real Life Experience with Monoclonal antibody -Sotrovimab in High Risk COVID-19 Patients: A Retrospective Study in a Lebanese Tertiary Care University Hospital.

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## Abstract

**Abstract:** Background: Sotrovimab, a monoclonal antibody, is among the approved therapies for coronavirus disease – 2019 (COVID-19). Sotrovimab binds to the spike protein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and inhibits virus attachment to human cells. Real-life experience about the effectiveness of Sotrovimab is limited. We aimed to evaluate the efficacy of Sotrovimab in preventing COVID-19 hospitalizations and other patient-related outcomes as well as the appropriateness of use in an academic hospital in Lebanon. Methodology: In this retrospective observational study, we included adult patients with positive test results for SARS-CoV-2 who received intravenous (IV) Sotrovimab at the American University of Beirut Medical Center (AUBMC) from November 2021 through March 2022. The data collected included patient demographics and comorbidities. Primary outcomes were hospitalization, deterioration after 24 hours, and death due to any cause up to 60 days after the Sotrovimab infusion. Secondary outcomes were progression to critical illness and adverse events. Results: A total of 62 subjects received Sotrovimab infusion at our hospital. More than 50% of the patients had a malignancy. About 77% of the cohort belonged to Tier 1 of the National Institutes of Health (NIH) criteria for Sotrovimab use, and 21% of the patients had clinical deterioration 24 hours after Sotrovimab infusion. The percentage of progression to critical disease was 9.7% and the mortality 6.5 %. Conclusion: Sotrovimab is effective against COVID-19 infection and prevents mortality in high-risk patients.

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**Keywords:** COVID-19, Sotrovimab, Monoclonal antibodies, Lebanon, Middle East, low- and middle-income countries, high risk

**Running Title:** Sotrovimab Early Use in COVID-19

## Introduction:

The COVID-19 pandemic continues to pose a significant burden on healthcare systems around the world with successive waves and an increasing death toll despite progress in antiviral therapy and vaccine development[1] . More than 6 million COVID-19-related deaths have been reported globally as of July 2022 [2]. In Lebanon, more than 1 million confirmed COVID-19 cases along with more than 10,000 deaths have been reported so far [2-3].

Several factors are associated with an increased risk of COVID-19 progression to severe disease. Older age is a strong risk factor for poor outcomes[3-4]. The number of deaths, due to COVID-19 in the United States (U.S) in patients who are older than 65 years, was around 125 times higher than those aged between 18 and 29 years [4-5]. Similarly, in Lebanon, the reported number of deaths due to COVID-19 in patients older than 60 years was around 100 times higher than those aged between 20 and 29 years [6]. Other conditions associated with hospital admission, progression to critical illness, and mortality include cerebrovascular disease, chronic kidney disease (CKD), chronic lung disease, chronic liver disease, diabetes mellitus, cardiovascular conditions, autoimmune diseases, immunocompromising conditions, mental health disorders, obesity, and male gender [7]. Vaccination and herd immunity have contributed to decreasing the mortality associated with COVID-19 despite wide variations related to pre-existing co-morbidities and other risk factors [8] .

Monoclonal antibodies for COVID-19 are recommended either as post-exposure prophylaxis (PEP) for ambulatory patients with mild to moderate COVID-19 or pre-exposure prophylaxis for those who are at high risk for progression to severe disease [9]. They bind to virus spike protein and prevent the virus attachment to human cells, and mark the virus for elimination [10]. Sotrovimab is a recombinant human immunoglobulin G-1 (IgG1-Kappa) monoclonal antibody that binds to a conserved epitope on the spike protein receptor binding domain of SARS-CoV-2 and inhibits an undefined step that occurs after virus attachment and before the fusion of the viral and cell membranes [11].

In a phase 3 clinical trial, conducted in four countries the United States, Canada, Brazil, and Spain between August 27, 2020 and March 4, 2021 [12] where the circulating COVID-19 variant was predominantly Delta variant in the US, Sotrovimab showed a significant reduction in the risk of COVID-19 progression among high-risk ambulatory patients with mild to moderate disease [12]. Patients who received Sotrovimab had 85% lower rates of hospitalization for > 24 hours for any cause or death at day 29 compared with the placebo arm [12]. Subsequently, Sotrovimab received emergency use authorization from the Food and Drug Administration (FDA) and preliminary approval from the European Medicine Agency (EMA) in May 2021 [11]. The American National Institute of Health (NIH) included IV Sotrovimab infusion as one of the therapeutic options recommended for outpatients with mild to moderate COVID-19 who are at high risk for disease progression [9]. More recently, with the rise and spread of the Omicron variant, it became obvious that Sotrovimab is not effective against it and its subvariants [13].

Real-life experience about the effectiveness of Sotrovimab is limited. In Lebanon, the COVID-19 response was particularly challenging as it happened amid an unprecedented economic crisis and political turmoil, aggravated by the catastrophic Beirut port explosion of August 4, 2020 [14]. All those factors added to the challenges of the pandemic, severely affected medical supplies and drug availability in the country, and resulted in critical shortages of various medications including essential COVID-19 therapies [14]. The American University of Beirut Medical Center (AUBMC) is a university tertiary care hospital in Beirut, Lebanon and was one of the tertiary medical centers who cared for a large number of COVID-19 patients. The hospital received donations of various drugs including 62 doses of Sotrovimab. In this study, we set to evaluate the efficacy of Sotrovimab in preventing COVID-19 hospitalizations and other patient-related outcomes, as well as its appropriateness of use at AUBMC.

## Methodology:

This is a retrospective observational study conducted at AUBMC. We included adult patients ([?] 18 years) with a positive test result for SARS-CoV-2 polymerase-chain-reaction or rapid antigen test who received IV Sotrovimab either in the Emergency Department (ED) upon presentation or during hospitalization for hospital-acquired COVID-19 from November 2021 through March 2022.

Due to the limited supply, Sotrovimab was prioritized for immunocompromised patients who were unvaccinated against COVID-19 or those who were fully or partially vaccinated but were not expected to mount an adequate immune response to the vaccine. We developed criteria for the use of Sotrovimab based on the NIH guidelines. As such, only patients with a high risk of disease progression were eligible to receive Sotrovimab after the approval of two infectious disease attending physicians. Major risk factors for clinical progression included: age ([?] 65 years), obesity (BMI [?] 30), immune suppression, cardiovascular disease (including congenital heart disease) or hypertension, and chronic lung diseases (i.e., Chronic Obstructive Pulmonary Disease (COPD), moderate to severe asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension). Other risk factors contributing to disease progression were CKD, pregnancy, sickle cell disease, and neurodevelopmental disorders.

The collected data included patient demographics such as COVID-19 vaccination status, clinical characteristics (e.g., duration of symptoms, risk factors for disease progression), history of use of other monoclonal antibodies and concurrent immunosuppressive medications, data related to the use of Sotrovimab (e.g., dosing regimen, administration, drug interactions), and outcomes. This study was approved by the Institutional Review Board of the AUBMC. The requirement for informed consent was waived because of the retrospective

nature of the study. Patient anonymity and privacy were respected by deleting all subjects' identifiers such as medical record number and full name from the data collection sheet and each subject received a unique identifier number for data collection purposes.

Primary outcomes were hospitalization, deterioration after 24 hours, and death due to any cause at day 60 after the Sotrovimab infusion. Hospitalized patients were further classified into those who were already admitted to the hospital for a reason other than COVID-19 and those who were hospitalized due to COVID-19. Patient deterioration was defined as oxygen saturation SpO<sub>2</sub> [?] 94% on room air and/or the need for supplemental oxygen. Secondary outcomes were progression to critical illness and adverse events. Critical illness was defined as patients on mechanical ventilation and/or extracorporeal mechanical oxygenation (ECMO). It also included -end-organ dysfunction as seen in sepsis/septic shock and acute respiratory distress syndrome (ARDS).

The appropriateness of Sotrovimab use was assessed as well, since the drug was recently added to the institution's formulary. The use of Sotrovimab was restricted to patients that met the above criteria. Each prescription order was reviewed by the pharmacist to verify the patients' eligibility in addition to securing the required approval of two infectious diseases (ID) physicians. The appropriateness of use was assessed by collecting data related to indication, dosing regimen, administration route, rate of infusion, and contraindications. Drug-drug interactions were screened, and any adverse drug events were reported.

Descriptive statistics were used. Continuous variables were expressed by mean values and standard deviations (SD). Categorical variables were expressed as frequencies and percentages. Data were analyzed using Statistical Package for Social Sciences (SPSS) v.25.

## Results:

Between November 2021 and March 2022, a total of 62 subjects received Sotrovimab infusion at AUBMC. Patients had a mean age of 59.7 years and an average Body Mass Index (BMI) of 26.72 Kg/m<sup>2</sup>. Most of the patients were males (66.1%), and almost half were smokers (51.6%).

More than 70% of subjects were vaccinated against COVID-19 (Pfizer AstraZeneca, Sinopharm, and other various vaccines), and 25 (43.1%) out of 62 had received two doses of any COVID-19 vaccine. The average duration of symptoms before hospital presentation was 3.97±4.5 days. The baseline characteristics are shown in **Table 1**.

Regarding patient comorbidities, hypertension was the most common and was present in 56.5% of subjects, followed by hematological malignancies with a rate of 35.5%. The prevalence rates of all comorbidities are listed in (**Figure1**) ,

The subject population was grouped according to the NIH criteria for prioritizing the use of anti-SARS-CoV-2 therapies [15] and it was found that 77% of the population belonged to Tier 1, 8.1 % to Tier 2, and 14.5 % to Tier 3 (**Table 2**) .

Concerning the ongoing chronic treatment of the subjects, 40.3% of the 62 subjects were on active chemotherapy and 17.7% of them were currently receiving or previously received rituximab within the past 12 months (**Table 3**) .

We calculated the primary and the secondary outcomes using SPSS by adding the patients with the specific outcome to generate the total number (N) and we divided them by the total number of patients to get the percentage (%). For the primary outcomes, 39 subjects received the drug in the ED and did not require hospitalization (62.9%). 23 subjects (37.1%) were hospitalized: 13 of them required hospitalization due to COVID- 19 (and received Sotrovimab subsequently), whereas the other 10 patients were already hospitalized when they acquired COVID-19 infection. Thirteen patients (21.0%) experienced clinical deterioration 24 hours after Sotrovimab infusion and only four patients (6.5%) died due to any cause at 60 days after the infusion. For the secondary outcomes, six patients (9.7%) out of the total subjects progressed to critical illness and no adverse events were reported in any of the subjects (**Table-4**).

Concerning the appropriateness of Sotrovimab use based on the institution criteria developed as mentioned above, we found that Sotrovimab administration was appropriate and in compliance with the NIH-derived institution criteria in 61 out of the 62 (98.4%) patients.

## Discussion:

This study included 62 subjects who tested positive for COVID-19 and received Sotrovimab infusion within an average of 4 days of symptoms onset between November 2021 and March 2022 at AUBMC. To our knowledge, this study is the second one from the Middle East, the first one was conducted in United Arab Emirates (UAE) [16], describing real-life experience with Sotrovimab as treatment in patients with COVID-19. And it is the first study that includes a high proportion of cancer patients.

Most of our subjects were classified as tier 1 priority as per NIH criteria as patients in this tier were at the highest risk for disease progression. As compared to other cohorts in the earlier Sotrovimab clinical trials [12, 16-17], more patients in our study had hematological malignancies and/or were receiving active chemotherapy. Moreover, more than 50% ( $63.4\% = 27.9 + 35.5$ ) of our patient population had cancer, whether hematological malignancy or solid organ malignancy and those are considered high-risk subjects and at risk for severe COVID-19 disease and death [18]. In the study from UAE only 1% of the subjects in the Sotrovimab group were immunosuppressed [16]. Whereas in the study by Aggarwal et al 24.9% of the subjects who received Sotrovimab were immunosuppressed [19].

Before the use of Sotrovimab, COVID-19 was associated with serious complications in cancer patients. In fact, the percentage of hospitalization among cancer patients who were infected with COVID-19 in the U.S varied between 25.2% and 33.7% [20]. And, in a study from China, the percentage of clinical deterioration and intensive care unit (ICU) admission in this patient population was reported as 39% [21].

In our cohort, we found that 21% of the subjects required hospitalization after receiving Sotrovimab, and 21 % had clinical deterioration within 24 hours of Sotrovimab infusion even though most of our subjects were cancer patients. Those rates were higher compared to the previously published trials [12, 19]. In the study from UAE, the overall hospitalization was 3.9%, and the percentage of critical disease progression was 0% [16]. However, patients who received Sotrovimab in the UAE study were selected based on a risk stratification criterion with at least one risk factor for disease progression, and the most prevalent risk factor for disease progression among patient who received Sotrovimab infusion was overweight 36% followed by HTN 20 % [16] and both percentages were much lower than the risk factors percentages in our cohort where 63.2 % of our subjects were obese and 56.5 % had HTN.

In a recent study from Sao Paulo Brazil the mortality rate among cancer patients who were hospitalized for COVID-19 was 49% without Sotrovimab [22]. The mortality rate in our study was much lower at 6.5% but still higher than the mortality rate among patients who received Sotrovimab in the studies that included less cancer patients such as the study from UAE [16] and that from Aggarwal et al [19].

The difference in the findings is mainly due to the overall proportion of immune suppressed subjects in the various studies and whether the NIH prioritization criteria were applied or not.

In our series, no adverse events related to Sotrovimab infusion were reported compared to 2% Sotrovimab related adverse events in the COMET ICE clinical trial and 10% in the TICO trial [12, 17].

Another point of relevance in this study is the very high compliance with the set criteria for use of Sotrovimab developed at our institution by the concerned stakeholders including ID specialists and pharmacists. Despite the chaos in Lebanon and the many challenges faced in all health care institutions [14], the Antimicrobial Stewardship Program at AUBMC has high level expertise in developing institutional policies, and guidelines for various diseases including COVID-19 with a tight control on the use of various agents including the monoclonal antibodies. The program follows patients closely to ensure adherence and compliance to various medications use.

Our study has several limitations. First, it is a retrospective study and not all the data needed was available

in the reviewed charts. Also, the sample size is small, given the limited number of available Sotrovimab doses. It included vaccinated patients, and vaccination was not homogenous among the cohort and the subjects received different types of vaccines. In addition, our study was not homogenous in terms of management and treatment options for COVID-19 infection (concomitant use of remdesivir, steroids, and tocilizumab). As a result, the generalizability of the findings of the study is limited. Another limitation is the fact that the SARS-CoV-2 variant type of each subject was not identified; this information would have been important in light of several reports of a decreased efficacy of Sotrovimab against Omicron variants of COVID-19 [13].

## Conclusion:

Research on COVID-19-related treatment can guide clinicians in their practice. This study, in addition to several others published in the literature, proves that COVID-19 monoclonal antibodies, such as Sotrovimab, are effective against COVID-19 infection when given early in the course of the disease, and may contribute to preventing mortality and complications in high-risk individuals. This study paves the way to conduct larger trials on special groups of subjects with immune-compromising conditions and, to study groups that represent the population, in order to further assess the benefit of monoclonal antibodies and identify patients who would benefit the most from their use. The availability of Sotrovimab at our hospital was made possible through a generous donation and its use generated positive outcomes. This emphasizes the need to support low-income countries so that patients around the world can benefit from the therapeutic advances made in the management of COVID-19.

## Declaration:

- **Ethics approval and consent to participate:** This study was approved by the Institutional Review Board of the AUBMC. The requirement for informed consent was waived because of the retrospective nature of the study.
- **Availability of data and material :** The data that support the findings of this study are available from the corresponding author upon reasonable request.
- **Competing interests:** No competing interest
- **Funding:** No funding
- **Acknowledgments and Author contributions:**

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