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Sotrovimab in solid organ transplant recipients with COVID-19: a systematic review and meta-analysis

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Background: Despite widespread implementation of vaccination against coronavirus disease 2019 (COVID-19), solid organ transplant recipients (SOTRs) can remain particularly vulnerable to this disease. The present study was conducted to investigate the efficacy and safety of sotrovimab in the treatment of SOTRs with COVID-19.
Methods: A search was performed of PubMed, Cochrane Library, Web of Science, medRxiv, and Google Scholar to gather relevant evidence through July 25, 2023. The quality of the included studies was assessed using the risk of bias tool. Comprehensive Meta-Analysis software (ver. 3.0, Biostat) was employed for data analysis.
Results: Ten studies, involving a total of 1,569 patients, were included. The meta-analysis revealed significant differences between the patients administered sotrovimab and those treated with the standard of care. These differences were observed in mortality rate (odds ratio [OR], 0.15; 95% confidence interval [CI], 0.03–0.67), hospitalization rate (OR, 0.35; 95% CI, 0.21–0.57), intensive care unit (ICU) admission rate (OR, 0.16; 95% CI, 0.04–0.62), the need for supplemental oxygen therapy (OR, 0.22; 95% CI, 0.09–0.51), and the need for mechanical ventilation (OR, 0.09; 95% CI, 0.01–0.70). However, no significant difference was observed between sotrovimab and other treatments regarding the rates of hospitalization or ICU admission (P>0.05). Regarding safety, sotrovimab was associated with a lower rate of adverse events compared to the absence of sotrovimab (OR, 0.15; 95% CI, 0.02–0.86).
Conclusions: These results suggest that sotrovimab may improve efficacy outcomes among SOTRs with COVID-19. Nevertheless, additional high-quality trials are necessary to confirm these findings.

Keywords: COVID-19; SARS-CoV-2; Organ transplantation

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INTRODUCTION

Background

Solid organ transplant recipients (SOTRs) with coronavirus disease 2019 (COVID-19) have demonstrated a heightened risk of hospitalization and mortality compared to the general population [1]. Even when these patients have been vaccinated against severe acute respirato-

HIGHLIGHTS

- Sotrovimab could reduce risk of death in solid organ transplant recipients with coronavirus disease 2019 (COVID-19).
- Solid organ transplant recipients treated with sotrovimab were less likely to be hospitalized.
- Sotrovimab was not superior to other monoclonal antibodies for improving clinical outcomes.
- Further research is needed to examine sotrovimab effectiveness against current COVID-19 variants.

ry syndrome coronavirus 2 (SARS-CoV-2), the primary cause of COVID-19, it is recommended that they receive antibody treatments [2]. Various monoclonal antibodies (mAbs) have been proposed and evaluated for the treatment of SARS-CoV-2–infected SOTRs, and they appear to be promising therapeutic options for these patients [3,4]. The US Food and Drug Administration (FDA) has authorized the emergency use of anti-spike mAb therapies in the treatment of high-risk patients with mild-to-moderate COVID-19, including SOTRs [5,6]. Current evidence supports the therapeutic benefits of mAbs such as bamlanivimab [3], bamlanivimab/etesevimab [7], casirivimab/imdevimab [7], and sotrovimab [4,8,9] in the treatment of SOTRs with COVID-19.

Importance

Several studies [9-11] have demonstrated that the administration of sotrovimab may effectively reduce mortality and hospitalization rates in SOTRs with COVID-19. However, some concerns exist regarding the emergence of mutations conferring resistance following the use of sotrovimab in high-risk patients infected with the Omicron variant of SARS-CoV-2 [12].

General Objectives

This study was conducted to investigate the efficacy and safety of sotrovimab in SOTRs infected with COVID-19.

Research Question

The research question posed was "Is sotrovimab infusion effective and safe in treating SOTRs with COVID-19?"

METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were utilized for this research [13].

Literature Search

Two researchers (RS and KR) conducted independent searches of PubMed, Cochrane Library, Web of Science, medRxiv, and Google Scholar through July 25, 2023 to identify relevant studies. They also reviewed the reference lists of the final studies to discover additional relevant records. No language restrictions were applied. The search terms used included 2019-novel coronavirus, SARS-CoV-2, COVID-19, SOTRs, sotrovimab, and mAb. The following search strategy was employed to locate relevant citations in PubMed: (((((((((Coronavirus[Title/Abstract]) OR (Coronavirus[MeSH Terms])) OR (COVID-19[Title/Abstract])) OR (COVID-19[MeSH Terms])) OR (SARS-CoV-2[MeSH Terms])) OR (SARS-CoV-2[Title/Abstract])) OR (2019 novel coronavirus infection[Title/Abstract])) OR (2019-nCoV infection[Title/Abstract])) AND ((Sotrovimab[Title/Abstract]) OR (monoclonal antibod*[Title/Abstract]))) AND (Transplant Recipients[Title/Abstract]).

Study Selection

The inclusion criteria were as follows: (1) the population consisted of SOTRs with COVID-19 confirmed by polymerase chain reaction testing; (2) the intervention was sotrovimab; (3) the control groups received placebos, the standard of care (SOC), or other treatments; and (4) the outcomes of interest were mortality and hospitalization rates. Studies involving animal models, case reports, case series, and commentaries were excluded.

Data Extraction and Quality Assessment

Two researchers (BA and RS) independently extracted the following data: (1) general study information, including the first author, year of publication, country, and design; (2) characteristics of the patients, namely sample size, sex, and mean age; (3) details of the interventions, including sample size, treatment dose, and treatment duration; and (4) efficacy and safety outcomes, specifically mortality rate, hospitalization rate, intensive care unit (ICU) admission rate, need for supplemental oxygen therapy, need for mechanical ventilation, and incidence of adverse events. The risk of bias of the included studies was evaluated using the Risk of Bias in Non-randomized Studies

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of Interventions (ROBINS-I) tool [14]. This instrument is used to assess bias due to confounding, participant selection, classification of interventions, departures from intended interventions, missing data, measurement of outcomes, and selection of reported results. Additionally, two researchers (BA and KR) separately assessed the domains of bias using a series of questions with five possible responses: yes, probably yes, no, probably no, or no information. Each domain was then classified as low-risk, moderate-risk, serious-risk, critical-risk, or no information. In the event of any disagreement between the authors, the issue was discussed and resolved through consultation with a third author (BA).

Statistical Analysis

Comprehensive Meta-Analysis software (ver. 3.0, Biostat) was utilized to evaluate the efficacy and safety of sotrovimab in comparison to controls. Odds ratios (ORs) with 95% confidence intervals (CIs) were used to analyze the dichotomous data. Substantial heterogeneity was considered significant when I^2 exceeded 50% or the P-value was less than 0.10. For studies exhibiting heterogeneity, a random-effects model was applied, while a fixed-effects model was used in other cases. Subgroup analyses were performed for outcomes with a sufficient number of studies, considering factors such as the SARS-CoV-2 variant, type of transplant, and COVID-19 vaccination rate. Additionally, a sensitivity analysis was carried out by excluding studies that presented a high risk of bias.

RESULTS

Literature Search and Included Studies

Fig. 1 presents the flow diagram of the study selection process, which was based on the title, abstract, and full text of each study. After eliminating duplicates from the initial 182 records, a total of 10 studies [4,8-11,15-19], including 1,569 patients, were included in the meta-analysis. All incorporated studies were retrospective in design. Most of these studies were conducted while the SARS-CoV-2 Omicron variant predominated, and kidney transplants were the most frequently reported type of transplant. Sotrovimab was administered as a single-dose infusion, with a dose of either 500 or 1,000 mg. The primary characteristics of the included studies are detailed in Table 1.

Risk of Bias Assessment

The results of the risk of bias assessment, conducted using the ROBINS-I tool, are presented in Supplementary Table 1. The quality of the included studies was deemed acceptable.

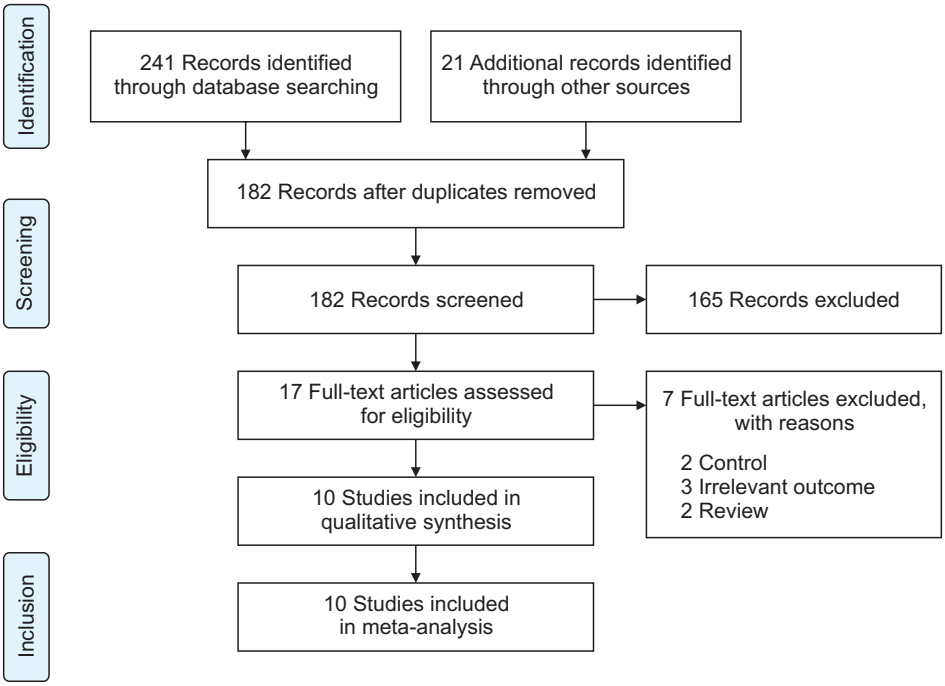

Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart.

Table 1. Characteristics of studies included in the meta-analysis

Study	Country	Design	SARS-COV-2 variant	Transplant type	No. of patients	No. of male	Intervention	Control	COVID-19 severity	COVID-19 vaccination rate (%)
Casutt et al. (2023) [15]	Switzerland	RS	Delta, Omicron	Lung	60	31	SOT	C/I, T/C	Mild or moderate	72[a)]
Chavarot et al. (2022) [8]	France	RS	Omicron	Kidney	125	75	SOT	SOC	Mild or moderate	SOT, 96; SOC, 96.2
Fernandes et al. (2022) [16]	Belgium	RS	Omicron, Delta	Kidney	47	26	SOT	C/I	Mild or moderate	SOT, 84; C/I, 81
Gleeson et al. (2022) [17]	United Kingdom	RS	Omicron	Kidney	116	63	SOT	SOC, MOL	NR	SOT, 87; SOC, 81; MOL, 100
Hedvat et al. (2022) [4]	United States	RS	Omicron	Heart, kidney, liver, pancreas, lung	154	NR	SOT	SOC, N/R	Mild or moderate	SOT, 84.3; SOC, 81; N/R: 85.8
Papadimitriou-Olivgeris et al. (2022) [18]	Switzerland	RS	Omicron	Kidney	243	157	SOT	CI	NR	37[a)]
Radcliffe et al. (2022) [10]	United States	RS	Omicron	Heart, kidney, liver, pancreas	122	70	SOT	MOL, N/R, SOC	Mild or moderate	SOT, 88; SOC, 81; MOL, 92; N/R, 100
Solera et al. (2022) [11]	Canada	RS	Omicron	Heart, kidney, liver, pancreas, lung	300	171	SOT	SOC	NR	63.6[a)]
Wong et al. (2022) [19]	Australia	RS	Omicron	Kidney, pancreas	41	21	SOT	SOC	NR	97.6[a)]
Yetmar et al. (2022) [9]	United States	RS	Omicron	Heart, kidney, liver, pancreas, lung	361	229	SOT	BEB	Mild or moderate	SOT, 87; BEB, 85.9

SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; COVID-19, coronavirus disease 2019; RS, retrospective study; SOT, sotrovimab; C/I, casirivimab/imdevimab; T/C, tixagevimab/cilgavimab; SOC, standard of care; MOL, molnupiravir; NR, not reported; N/R, nirmatrelvir/ritonavir; BEB, bebtelovimab.

[a)]Total COVID-19 vaccination rate.

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Data and Analyses

Mortality rate

The meta-analysis incorporated four studies [4,10,11,17] with a total of 586 patients. The pooled estimate revealed a significant disparity in the mortality rate between patients who received sotrovimab and those who were administered SOC treatment (OR, 0.15; 95% CI, 0.03–0.67; P=0.01; I^2=0%) (Fig. 2).

Hospitalization rate

The pooled estimate of five studies [8,10,11,17,19] indicated a significant difference between patients who were administered sotrovimab and those who underwent SOC treatment (OR, 0.35; 95% CI, 0.21–0.57; P<0.001; I^2=39%) (Fig. 3). However, the pooled analysis did not indicate a significant difference between patients who received sotrovimab and those who were given mAbs (OR, 1.10; 95% CI, 0.43–2.82; P=0.83; I^2=0%) or molnupiravir (OR, 0.30; 95% CI, 0.08–1.16; P=0.09; I^2=0%) (Supplementary Figs. 1 and 2).

Intensive care unit admission

Four studies [8,10,11,17] involving a total of 460 patients reported on ICU admissions in sotrovimab and SOC treatment groups. The pooled estimate from these studies revealed a significant difference in ICU admissions between the two groups (OR, 0.16; 95% CI, 0.04–0.62; P=0.008; I^2=0%) (Fig. 4). However, no significant difference was observed between the sotrovimab and molnupiravir groups in terms of ICU admission (OR, 0.30; 95% CI, 0.03–3.04; P=0.31; I^2=0%) (Supplementary Fig. 3).

Need for supplemental oxygen therapy

Two studies [4,11], including 419 patients, reported the need for supplemental oxygen therapy among SOTRs. These studies revealed a significant disparity between the sotrovimab and SOC groups regarding the necessity for supplemental oxygen (OR, 0.22; 95% CI, 0.09–0.51;

Study name	Odds ratio	Lower limit	Upper limit	P-value
Solera 2022	0.061	0.004	1.031	0.053
Radcliffe 2022	0.265	0.013	5.348	0.387
Hedvat 2022	0.201	0.010	3.978	0.292
Gleeson 2022	0.196	0.009	4.189	0.297
	0.154	0.035	0.679	0.013

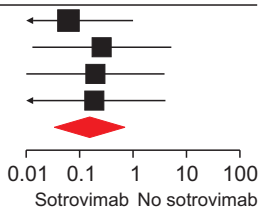

Fig. 2. Forest plot of sotrovimab versus standard of care for mortality rate. CI, confidence interval.

Study name	Odds ratio	Lower limit	Upper limit	P-value
Gleeson 2022	0.083	0.010	0.675	0.020
Radcliffe 2022	0.245	0.050	1.190	0.081
Solera 2022	0.496	0.270	0.912	0.024
Chavarot 2022	0.354	0.113	1.112	0.075
Wong 2022	0.045	0.005	0.400	0.005
	0.354	0.218	0.573	0.000

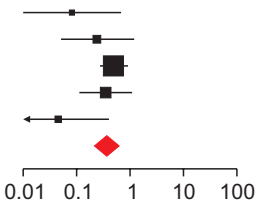

Fig. 3. Forest plot of sotrovimab versus standard of care for hospitalization rate. CI, confidence interval.

Study name	Odds ratio	Lower limit	Upper limit	P-value
Gleeson 2022	0.333	0.013	8.391	0.504
Radcliffe 2022	0.265	0.013	5.348	0.387
Solera 2022	0.043	0.003	0.721	0.029
Chavarot 2022	0.203	0.026	1.608	0.131
	0.165	0.044	0.623	0.008

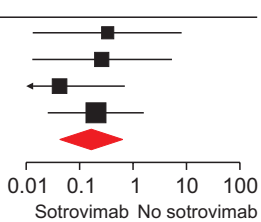

Fig. 4. Forest plot of sotrovimab versus standard of care for intensive care unit admission. CI, confidence interval.

P<0.001; I^2=0%) (Supplementary Fig. 4).

Need for mechanical ventilation

The meta-analysis incorporated two studies [4,11] that involved a total of 419 patients. The pooled estimate indicated a significant difference between the sotrovimab and SOC groups with respect to the need for mechanical ventilation (OR, 0.09; 95% CI, 0.01–0.70; P=0.02; I^2=0%) (Supplementary Fig. 5).

Adverse events

Three studies [10,16,17], encompassing 236 patients, documented the occurrence of any adverse events and were incorporated into the meta-analysis. The pooled estimate suggested a significant difference in the incidence of adverse events between the patients who were and were not treated with sotrovimab (OR, 0.15; 95% CI, 0.02–0.89; P=0.03; I^2=0%) (Fig. 5).

Sensitivity and subgroup analyses

The results of the subgroup analyses, which were based on SARS-CoV-2 variant, COVID-19 vaccination rate, and transplant type, are presented in Table 2. Regarding the hospitalization rate by SARS-CoV-2 variant, the findings remained consistent across subgroups for studies involving only the SARS-CoV-2 Omicron variant (OR, 0.85; 95% CI, 0.30–2.41; P=0.76; I^2=0%) and for those involving the Delta and Omicron variants (OR, 3.35; 95% CI, 0.39–28.83; P=0.27; I^2=0%). In the subgroup analysis by transplant type in relation to the hospitalization rate, sotrovimab was effective in reducing the hospitalization rate in patients with both kidney and other types of transplants (P<0.05). However, in the subgroup analysis by COVID-19 vaccination rate, sotrovimab did not demonstrate effectiveness in improving the hospitalization rate (Table 2). The sensitivity analysis revealed no significant difference in hospitalization rate after the exclusion of one study with high risk of bias (OR, 0.20; 95%

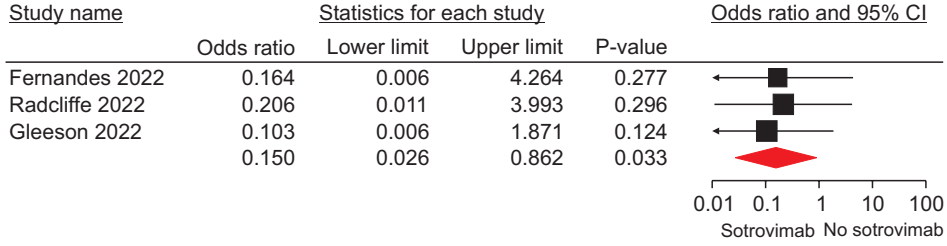

Fig. 5. Forest plot of sotrovimab versus absence of sotrovimab for adverse events. CI, confidence interval.

Table 2. Results of subgroup and sensitivity analyses

Analysis	No. of studies	Sample size	Point estimate (95% CI)	P-value	Heterogeneity		
					Q-value	P-value	I^2
Subgroup analysis							
Hospitalization rate by SARS-CoV-2 variant (SOT vs. mAbs)	4	546					
Omicron	2	462	0.85 (0.30–2.41)	0.760	0.02	0.88	0
Omicron and Delta	2	84	3.35 (0.39–28.83)	0.270	0.02	0.87	0
Hospitalization rate by transplant type (SOT vs. SOC)	5	626					
Kidney	3	261	0.18 (0.07–0.46)	0	3.40	0.18	41.18
Other	2	365	0.45 (0.25–0.79)	0.006	0.66	0.41	0
Hospitalization rate by transplant type (SOT vs. mAbs)	4	546					
Kidney	2	148	1.03 (0.24–4.37)	0.960	0.51	0.47	0
Other	2	398	1.16 (0.34–3.99)	0.800	0.77	0.37	0
Hospitalization rate by COVID-19 vaccination rate	4	546					
<75%	2	138	1.13 (0.27–4.76)	0.860	0.87	0.34	0
≥75%	2	408	1.08 (0.31–3.74)	0.890	0.42	0.51	0
Sensitivity analysis							
Hospitalization rate (SOT vs. SOC)	4	501	0.20 (0.06–0.62)	0.005	6.65	0.08	54.90

CI, confidence interval; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SOT, sotrovimab; mAbs, monoclonal antibodies; SOC, standard of care; COVID-19, coronavirus disease 2019.

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CI, 0.06–0.62; P=0.005; I^2=54.9%) (Table 2).

DISCUSSION

The objective of this study was to assess the efficacy and safety of sotrovimab in SOTRs with COVID-19, who are at an elevated risk of mortality and hospitalization compared to the general population. While current clinical research indicates that sotrovimab may be a promising treatment option for SOTRs with COVID-19 [4,9], the emergence of sotrovimab-resistant spike mutations presents a potential challenge [20]. The US FDA has restricted the use of sotrovimab in COVID-19 patients infected with the BA.2 Omicron subvariant [21]. Nonetheless, sotrovimab may still be effective against this subvariant.

The meta-analysis revealed that sotrovimab was associated with a significantly lower mortality rate in SOTRs with COVID-19 compared to similar patients who received SOC treatment. This finding aligns with the results of a meta-analysis conducted by Farhadian et al. [22], who found that sotrovimab treatment decreased the mortality rate in SOTRs with COVID-19. Our prior meta-analysis of 27,429 cases also suggested that sotrovimab could effectively lower the mortality rate in patients with COVID-19 [23]. Generally, mAbs have been demonstrated effective in reducing COVID-19–associated deaths [24]. This decrease in mortality rate could be attributed to the role of sotrovimab in counteracting the progression to severe disease. Anti-SARS-CoV-2 mAbs target the SARS-CoV-2 spike protein, neutralize the infection, and inhibit viral load [25]. However, the present meta-analysis indicated that sotrovimab was not significantly superior to molnupiravir in reducing the hospitalization rate among patients with COVID-19.

The meta-analysis also revealed that SOTRs who received sotrovimab were significantly less likely to require hospitalization due to COVID-19 compared to those who received SOC treatment. A similar result was reported by Farhadian et al. [22], who found that sotrovimab reduced the rate of hospitalization in SOTRs with COVID-19. Subgroup analysis further revealed that sotrovimab was associated with a significantly lower rate of hospitalization in SOTRs infected with the SARS-CoV-2 Omicron variant. A meta-analysis of 13 studies indicated that sotrovimab can significantly and effectively reduce the rate of hospitalization in patients infected with the Delta and Omicron variants of SARS-CoV-2 [23]. However, the pooled estimate of the included studies showed that sotrovimab had no significant effect on hospitalization rate relative to mAbs and molnupiravir treatments. Gleeson et al. [17] found that patients treated with sotrovimab were less likely to require hospitalization compared to those who received molnupiravir (2% vs. 14%, respectively).

The findings of the present meta-analysis indicate that SOTRs infected with SARS-CoV-2 who received sotrovimab were statistically less likely to require admission to an ICU compared to those who received SOC treatment. This is consistent with the results of Farhadian et al. [22], who found that the ICU admission rate was lower for SOTRs treated with sotrovimab compared to those who did not receive this treatment. This observation aligns with our previous meta-analysis, which demonstrated that sotrovimab significantly reduced the rate of ICU admission in patients with COVID-19 [23]. Data from real-world studies have also suggested that mAb therapies may effectively lower the rate of ICU admission among patients with this disease [26,27]. However, the present meta-analysis did not reveal a significant difference in ICU admission rates between SOTRs receiving sotrovimab and those administered molnupiravir. According to Radcliffe et al. [10] and Gleeson et al. [17] , 2% of SOTRs with COVID-19 who received molnupiravir were admitted to the ICU, while none of the SOTRs treated with sotrovimab required ICU hospitalization.

In the present meta-analysis, treatment with sotrovimab was significantly associated with reduced rates of required supplemental oxygen therapy and mechanical ventilation in SOTR patients with COVID-19, compared to those treated with SOC. This finding is consistent with the pooled estimate of six studies, which demonstrated the effectiveness of sotrovimab in decreasing the need for mechanical ventilation due to COVID-19 [23]. The existing literature also suggests that other mAb therapies, such as regdanvimab [28] and casirivimab/imdevimab, may be effective in reducing the need for supplemental oxygen therapy and mechanical ventilation in patients with COVID-19, compared to control participants.

Regarding safety, the present meta-analysis demonstrated that compared to the group not administered sotrovimab, sotrovimab treatment was statistically associated with a lower rate of adverse events in SOTRs with COVID-19. However, our previous meta-analysis showed statistically similar incidence rates of adverse events among COVID-19 patients receiving and not receiving

sotrovimab [23]. One potential explanation could be the difference in patient population. Generally, data from real-world studies have shown that sotrovimab is safe and well-tolerated in SOTRs with COVID-19 [10,16,17].

The present study had some notable limitations. First, all studies included in the meta-analysis were retrospective, potentially subjecting the results to bias and confounding. Second, it was not possible to conduct subgroup analyses based on variables such as COVID-19 vaccination status and the degree of comorbidities, due to insufficient information provided in the articles. However, we were able to perform a subgroup analysis based on the COVID-19 vaccination rate. Third, the use of different treatment protocols in the SOC group had the potential to introduce bias. Finally, the inclusion of relatively few studies in the meta-analysis for certain outcomes of interest could have diminished the statistical significance of the results.

The findings of this meta-analysis suggest that treatment with sotrovimab may be effective for SOTRs infected with the SARS-CoV-2 Omicron variant. This effectiveness is demonstrated by reductions in mortality rate, hospitalization rate, ICU admission, the need for supplemental oxygen therapy, and the need for mechanical ventilation. Furthermore, treatment with sotrovimab was associated with a lower incidence of adverse events. These results could provide valuable insights for healthcare system managers and policymakers when considering effective treatment strategies for SOTRs with COVID-19, who are at elevated risk of developing severe COVID-19. However, additional studies are necessary to confirm the efficacy and safety of sotrovimab in this patient population.

ARTICLE INFORMATION

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Supplementary Materials

Supplementary materials can be found via https://doi.org/10.4285/kjt.23.0038.

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