

Retrospective Cohort Analysis of Sotrovimab and Remdesivir Use in Ambulatory Patients with COVID-19 in Five Teaching Hospitals in Quebec, Canada

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P2614

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BACKGROUND

In the context of the COVID-19 pandemic, efficacy of treatment is evaluated through clinical trials with specific inclusion and exclusion criteria for commercial approval. Real-world data complements this evidence for sotrovimab and remdesivir in ambulatory adult patients with different characteristics in a rapidly evolving environment.

OBJECTIVES

We aimed to describe:

- The efficacy outcomes (hospitalization and death)
- Factors that increase risks of complications
- Quebec health authority guidelines compliance

METHODS

Retrospective descriptive analysis

Collection period : december 15, 2021 to april 30, 2022.

Inclusion criteria:

Adult COVID-19 patients (18+) who received remdesivir or sotrovimab or combination therapy:

- Ambulatory
- Hospitalized for reason other than COVID-19 were considered ambulatory (e.g. surgery)

Exclusion criteria:

- Hospitalized patients due to COVID-19 who received oxygen therapy or other treatment (including remdesivir for 5 or 10 days)
- Ambulatory patients who received other monoclonal antibody or other antiviral (e.g. casirivimab-irmdevimab, nirmatrelvir-ritonavir)

Study outcomes:

- Hospitalization or death within 30 days of treatment
- Patient characteristics: age, sex, BMI, vaccination status, immunosuppression status/reasons, comorbidities, treatment choice

Analyses

Collected data were evaluated using descriptive statistics (mean, median, standard deviation, and proportions) for each treatment group. Strength of association of risk factors with hospitalization was evaluated using multinomial logistic regression.

RESULTS

- 710/857 screened patients met the inclusion criteria
- A total of 712 treatment courses included

Sotrovimab and remdesivir are not comparable groups due to patient selection as treatment choice was at the discretion of the clinician according to the Quebec health authority guidelines.

Patient characteristics

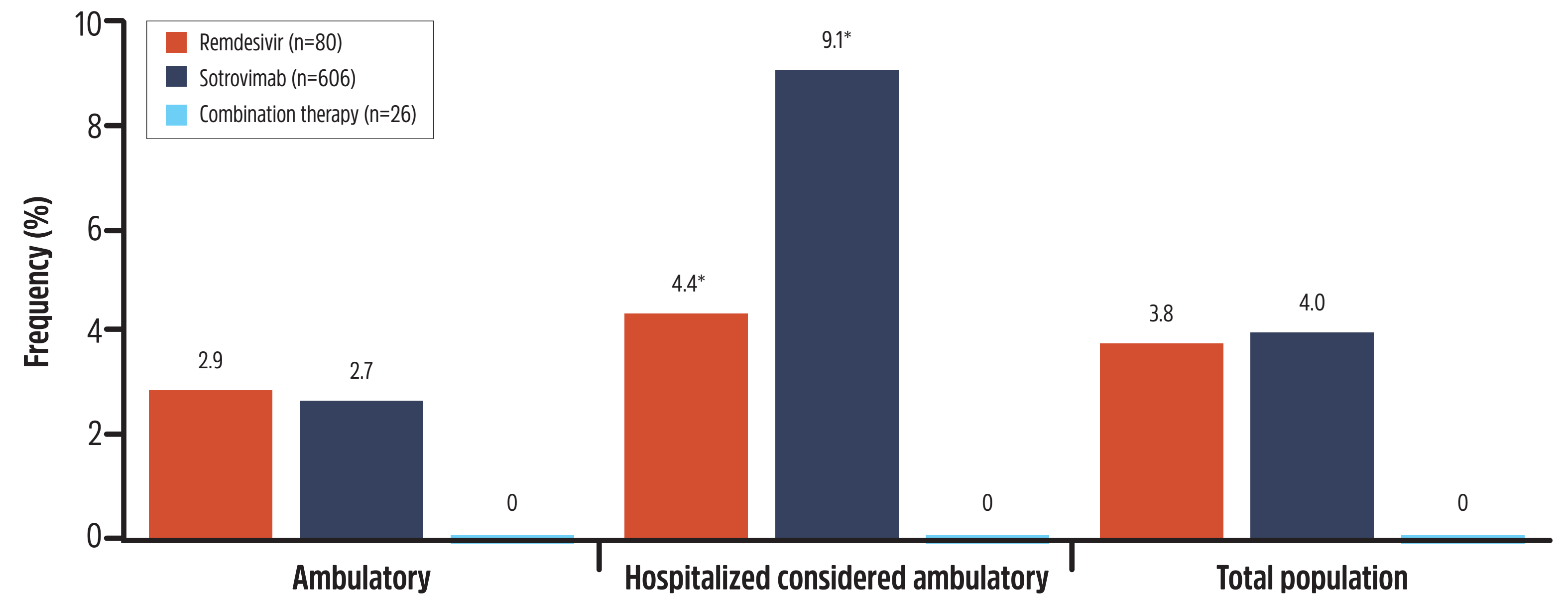
Remdesivir	Ambulatory (n=35)	Hospitalized considered ambulatory (n=45)	Total population (n=80)
Age (mean-years)	59.4	65.1	62.6
Male	18 (51.4%)	25 (55.6%)	43 (53.8%)
Female	17 (48.6%)	20 (44.4%)	37 (46.3%)
Body mass index (mean-kg/m ²)	27.2	24.3	25.6
Vaccination status			
• Adequately vaccinated	29 (82.9%)	31 (68.9%)	60 (75%)
• Inadequately vaccinated	4 (11.4%)	11 (24.4%)	15 (18.8%)
• Unknown	2 (5.7%)	3 (6.7%)	5 (6.2%)
Immunocompromised	32 (91.4%)	26 (57.8%)	58 (72.5%)
Comorbidities	26 (74.3%)	37 (82.2%)	63 (78.3%)
Mean delay symptoms-treatment (days)	3.7	3.8	3.7

Sotrovimab	Ambulatory (n=485)	Hospitalized considered ambulatory (n=121)	Total population (n=606)
Age (mean-years)	52.1	59.6	53.6
Male	243 (50.1%)	60 (49.6%)	303 (50%)
Female	242 (49.9%)	61 (50.4%)	303 (50%)
Body mass index (mean-kg/m ²)	27.6	27.2	27.5
Vaccination status			
• Adequately vaccinated	358 (73.8%)	63 (52%)	421 (69.5%)
• Inadequately vaccinated	94 (19.4%)	52 (43%)	146 (24.1%)
• Unknown	33 (6.8%)	6 (5%)	39 (6.4%)
Immunocompromised	452 (93.2%)	102 (84.3%)	554 (91.4%)
Comorbidities	321 (66.2%)	91 (75.2%)	412 (68%)
Dose administered			
• 500 mg	460 (94.8%)	113 (93.4%)	573 (94.6%)
• 1000 mg	25 (5.2%)	8 (6.6%)	33 (5.4%)
Mean delay symptoms-treatment (days)	4.2	4	4.1

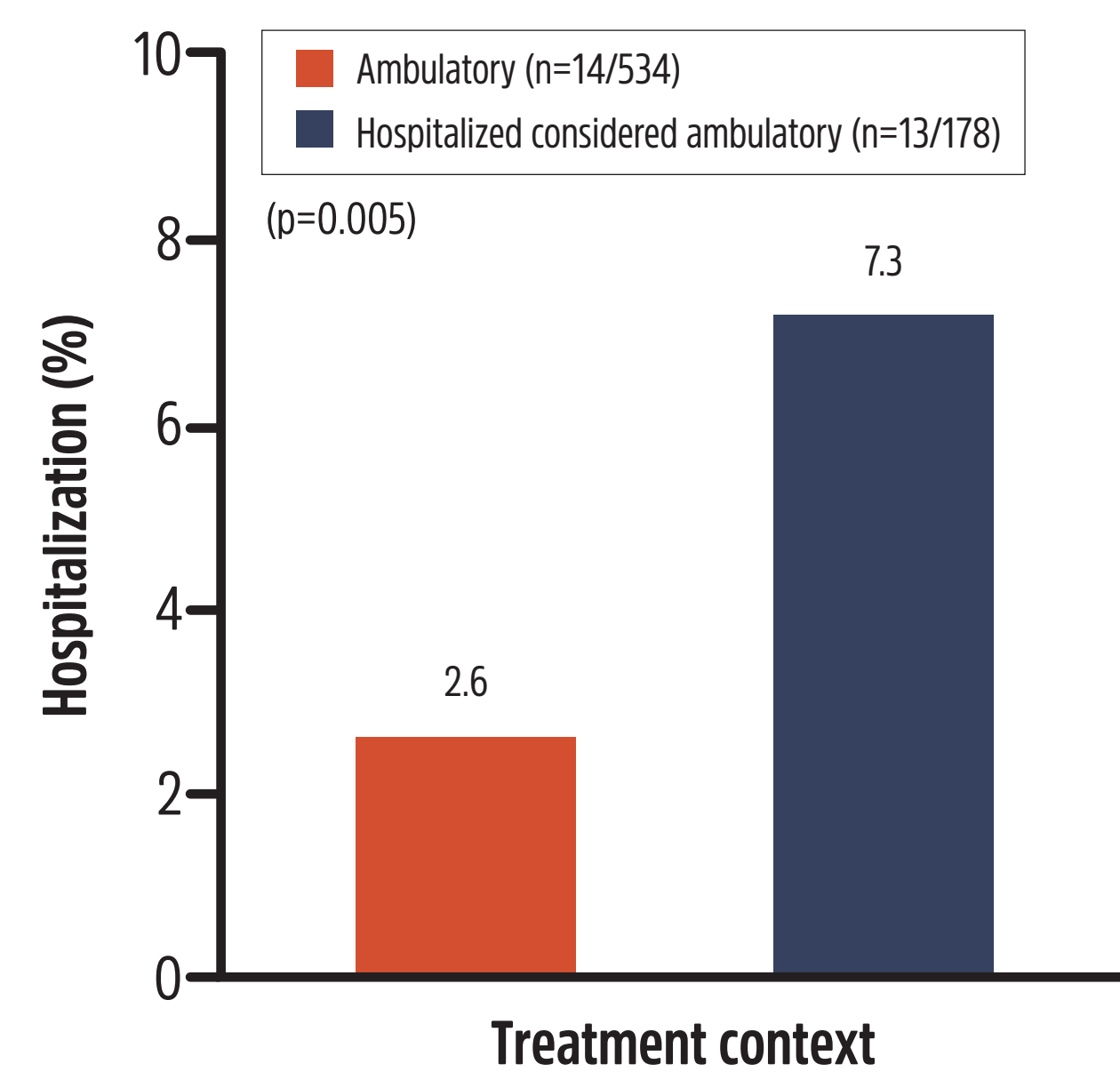
Combination therapy (n=26)

- Mean age was 50.9 years
- 100% were immunocompromised
- 73% were adequately vaccinated
- 69% with comorbidities

Hospitalization rate



Hospitalizations in ambulatory patients vs patients hospitalized but considered ambulatory



Risk factors for hospitalization or death in total population (N=712)

Factors	Odds Ratio	CI 95%		P
		Lower	Upper	
Age 65 years +	3.312	1.401	7.830	0.006
Adequately vaccinated*	0.305	0.134	0.696	0.05
Immunocompromised	2.021	0.547	7.467	0.291
Number of comorbidities				
1	0.945	0.153	5.817	0.951
2	2.912	0.715	11.851	0.136
3+	6.253	1.661	23.538	0.007

*Unknown patients are considered non adequately vaccinated
 Multicollinearity was evaluated by the variation inflation factor. No correlations were observed.

Death rate

- Remdesivir: 1 (2.2%) in hospitalized but considered ambulatory group
- Sotrovimab: 2 (0.3%): one in each group
- Combination therapy: 0%

Sub-analysis of all immunocompromised patients

Immunocompromised patient characteristics

	Total (n=638)	Hospitalized for COVID (n=24)
Age (mean-years)	53.88	65.58
Vaccination status		
• Adequately vaccinated	458 (71.8%)	14 (58.3%)
• Inadequately vaccinated	140 (21.9%)	9 (37.5%)
• Unknown	40 (6.3%)	1 (4.2%)
Immunocompromised conditions		
• Solid organ transplant	314 (49.2%)	12 (50%)
• Active cancer	176 (27.6%)	5 (20.8%)
• Autoimmune disease	118 (18.5%)	5 (20.8%)
Comorbidities		
• High blood pressure	300 (47%)	14 (58.3%)
• Diabetes	193 (30.3%)	10 (41.7%)
• Renal insufficiency	123 (19.3%)	12 (50%)

Risk factors for hospitalization or death in sub-group of immunocompromised patients (n=638)

Factors	Odds Ratio	CI 95%		P
		Lower	Upper	
Age 65 years +	2.747	1.141	6.611	0.024
Adequately vaccinated*	0.360	0.149	0.870	0.023
Number of comorbidities				
1	1.476	0.203	10.757	0.701
2	3.997	0.771	20.712	0.099
3+	10.349	2.197	48.745	0.003

*Unknown patients are considered non adequately vaccinated
 Multicollinearity was evaluated by the variation inflation factor. No correlations were observed.

Quebec health authority guidelines non-compliance:

- 19% didn't received medication in the recommended therapeutic window
- 6% were adequately vaccinated and not immunocompromised
- 3.7% received a combination therapy
- 3% were asymptomatic

DISCUSSION

Hospitalization and death rates were low:

- Hospitalization rate of ambulatory patients (2.6%) was significantly lower when compared to hospitalized patients but considered ambulatory (7.3%) (p=0.005)

90% of the population was immunocompromised and 69% had at least one comorbidity.

- 89% of the hospitalized population was immunocompromised

Age 65 or older significantly increases the probability of hospitalization by a factor of 3.3 (p=0.006).

Being adequately vaccinated significantly decreases the probability of hospitalization by 70% (p=0.05).

Having three comorbidities or more significantly increases the probability of hospitalization by a factor of 6.3 (p=0.007).

The same risk factors (age 65 or older, vaccination status, comorbidities) were significant in the immunocompromised population and have been observed in previous studies with similar populations.

CONCLUSION

This retrospective cohort analysis complements our understanding of treatment efficacy for patients at high risk of complications as defined by Quebec health authority guidelines.

Hospitalization and death rates in all treatment groups were low when compared to other studies with similar populations. Some risk factors, also noted in other studies, had a greater impact on the likelihood of hospitalization.

Our data confirm that treatments prescribed mostly conformed with Quebec health authority guidelines.

