5PSQ-078

ANALYSIS OF CASIRIVIMAB AND IMDEVIMAB USE IN OUTPATIENTS WITH COVID-19

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1 Background and Importance

Casirivimab and imdevimab (C/I) monoclonal antibodies

- 600/600 mg intravenous infusion
- in Delta COVID-19 pandemic wave
- **postexposure prophylaxis** or **treatment** of **mild to moderate COVID-19** in **high-risk patients**not requiring hospitalisation
- beneficial for reducing SARS-CoV-2 viral load
- decreasing COVID-19-related emergency room visits and hospitalisations
- under European use authorisation (EUA)

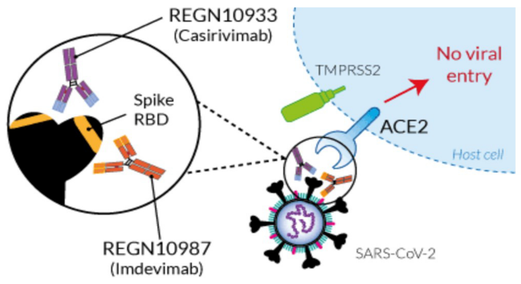


Fig. 1 Specific SARS-CoV-2 Spike-RBD recombinant human IgG1 & mouse IgG2a antibodies (https://www.invivogen.com)

2 Aim and Objectives

The study aims to describe **outpatients** with **C/I treatment of SARS-CoV-2** infection until **90 days post-infusion** in terms of:

- patient characteristics
- indications for C/I infusion
- vaccination status
- self-reported symptom burden
- C/I adverse events (AE)

3 Methodology

study design

- prospective
- multicentric in three hospitals
- included outpatients with C/I treatment
- excluded patients escalated to further COVID-19 treatment
- patient questionnaire and telephone survey

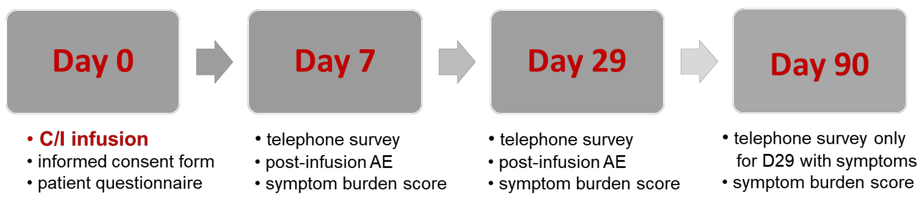
data collection

- patient medical notes
- COVID-19 adapted symptom score[1]
- SARS-CoV-2 positivity
- SARS-CoV-2 vaccination
- risk factors for severe COVID-19 (EUA)
- C/I infusion related AE
- hospitalization
- structured telephone survey

study period 09/2021–01/2022+ 90 days follow-up

data analysis
MS Excel

study survey timeline



4 Results

- n=471 patients with C/I outpatient administration, of which n=67 not met inclusion criteria (not consented, long inpatient stay, loss to follow-up, further antiviral treatment)
- n=**404 patients** (n=396; 98% the first COVID-19 episode) included in telephone survey by hospital pharmacists (Tab.1) with EUA defined risk factors (Fig.2)
- **1.2% patients** (n=5) of which 2 unvaccinated, required **short hospitalization post-C/I infusion** for hypoxia and increased respiratory difficulty (n=4) or hemoptysis (n=1) but no further antiviral treatment (more AE in Fig.3)
- Tab.2 and Fig.3 demonstrate **safety and clinical efficacy** of timely C/I infusion within a mean of **2.3±1.8 days** (range 0–11 days) since SARS–CoV-2 positivity in high-risk patients (Fig.2)
- Hospital pharmacists consulted on symptom management and **recommended medical appointment** to **60 patients (14.9%)**
- **Limitation:** unknown viral load pre- and post -C/I, no control group

Tab.1 Characteristics of outpatients with C/I infusion

Patient characteristics (n=404)	
Gender	
Female	**57.4%** (232)
Male	**42.6%** (172)
Age	
Range	**12–92 years**
Median	**66 years**
Body mass index (kg/m^2)	
Underweight < 18.5	**0.2%** (1)
Normal weight 18.5–24.9	**12.4%** (50)
Overweight 25–29.9	**17.1%** (69)
Obese ≥ 30	**30.0%** (121)
Unknown	**40.3%** (163)
Vaccination status prior C/I	
Complete vaccination	**62.6%** (253)
Unvaccinated	**35.6%** (144)
Incomplete vaccination	**1.8%** (7)

Most frequent risk factors for severe disease progression of COVID-19 in outpatients with C/I infusion (n=404 patients)

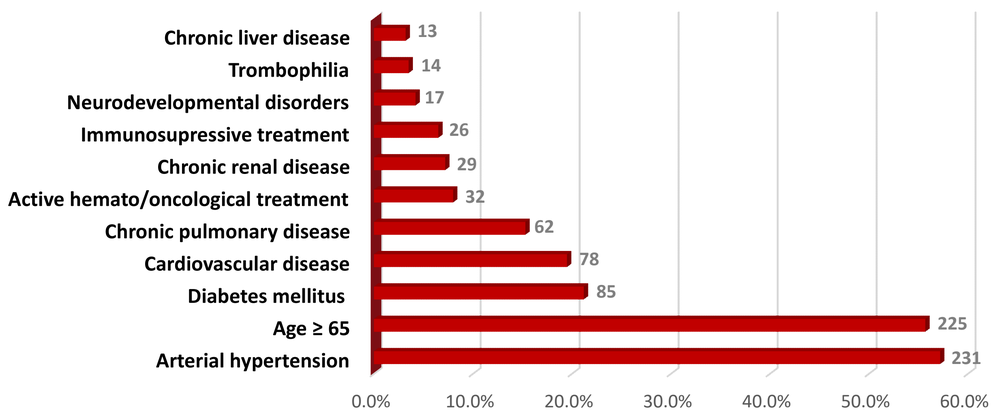
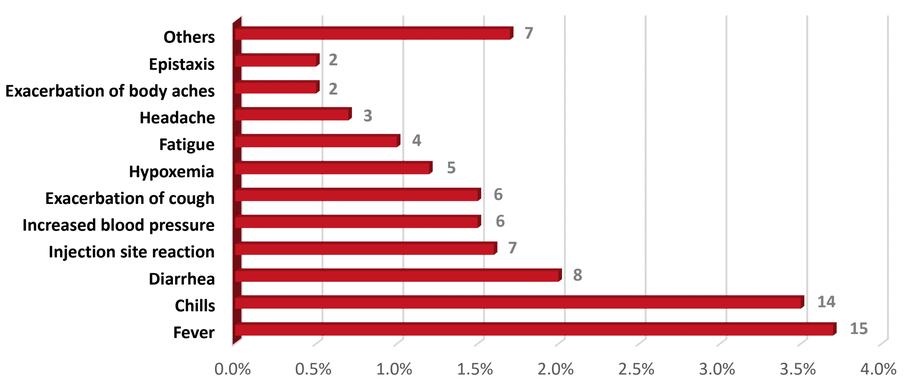


Fig. 2 Indication for C/I infusion in followed cohort of SARS-CoV2 positive outpatients

Most frequently reported adverse events after C/I infusion (n=404 patients)



Others = dizziness (n=1; 0.2%), heart palpitations, constipation, pain in varicose veins, earlier mentrual period, swellig of the neck/cheeks

Fig. 3 Most reported adverse events after C/I infusion

Tab.2 Proportion of patients with symptom score difference in set timepoints (D= days, SS= symptom score)

Timepoint intervals	D0 vs. D7 improved	D0 vs. D7 worse	D0 vs. D7=0	D0 vs. D29 improved	DO vs. D29 worse	D0 vs. D29=0	D0 vs. D90 improved	D0 vs. D90 worse	D0 vs. D90=0
% patients with SS difference n=404 (100%)	350 (**86.6%**)	14 (**3.5%**)	40 (**9.9%**)	368 (**91.1%**)	6 (**1.5%**)	30 (**7.4%**)	221 (**54.7%**)	0 (**0.0%**)	183 (**45.3%**)

5 Conclusion and Relevance

Real-life outpatient administration of C/I under provisional approval **in Delta COVID-19 pandemics** is described. **Therapeutic value** of **C/I infusion timely** administration is **evident in high-risk patients** with completed vaccination. Next generations of monoclonal antibodies with effective neutralisation capacity against circulating SARS-CoV-2 variants are needed for passive immunotherapy especially for **high-risk patients** who do not develop vaccine protection.

Disclosure of Interest:
None to declare

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References:
[1]N Engl J Med. 2021 Jan 21;384(3):229-237

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