

SARS-CoV-2 in Paraguay: Immune Response Characteristics

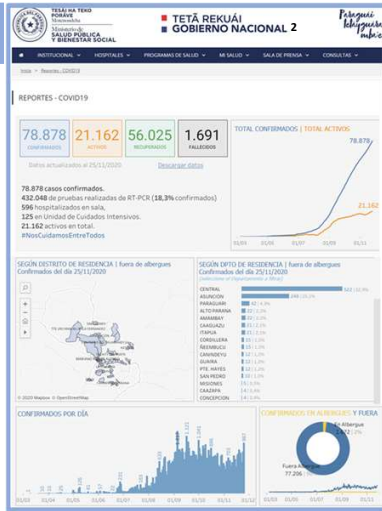
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BACKGROUND

CNN Health - COVID-19 in Latin America including Paraguay¹



- The Latin America region has been severely affected by the SARS-CoV-2 pandemic, including Paraguay.
- Paraguay, with population of around 7-million, has about 80,000 cases, and 2,000 deaths, with increasing cases affecting healthcare resources acutely.
- A national response to mitigate the effects of the pandemic has been conducting therapeutic studies, including an open label therapeutic effectiveness study of the administration of convalescent plasma transfusion (CPT).

OBJECTIVE

The main objective of the CPT study is to evaluate the effectiveness of CPT in reducing mortality in hospitalized patients diagnosed with COVID-19.

METHODS

Design: Open-label, prospective, not randomized, CPT treatment and standard care for COVID-19 patients and compared to a group receiving only standard care.

Setting: Multicenter (13 acute care facilities), public and private services throughout Paraguay.

Participants. Recipients of CPT were 18 years or older, male or female, non-pregnant, hospitalized and diagnosed with COVID-19 by RTqPCR, with mild to severe illness, within 15 days of symptoms onset, with any risk factor for deterioration, who signed an informed consent. Donors of CPT were 18 years or older, male, diagnosed with COVID-19 by RTqPCR, 14 days with no COVID-19 symptoms, or 30 days after symptoms onset, completely recovered and asymptomatic from COVID-19, and signed an informed consent for study participation.

Intervention. Transfusion of two units of CPT, obtained from different donors using standard transfusion guidelines, during hospitalization within 15 days of COVID-19 symptom onset. The intervention cohort were compared to a individuals who received the standard of care but not CPT at the participating healthcare facilities.

Outcomes. 30-day hospital mortality and requiring higher level of care in a critical care unit.

Plasma evaluation of recipients and donors. Neutralizing antibodies in serum will be done to assess the immune response to the viral illness.

Statistics. Descriptive statistics with rates and percentages; and test statistics when appropriate.

RESULTS

Summary of the trial. 338 hospitalized participants meeting the inclusion criteria were included in the study. Each recipient had two doses of a CPT collected from different donors. There were 280 donors, also meeting the inclusion criteria. Serum collected from both donors and recipients will undergo further studies.

Recipients characteristics. This group was treated within 3 days of hospitalization. Clinical characteristics are listed in Table 1. Most of the recipients required regular acute care (85.9%) only, few (14,1%) required admission to the ICU, and 7.1% died.

Table 1. Demographic Characteristics of Participants by Risk Factors Types

	Received CPT, N=338
Sex (male)	202 (59.4%)
Average age in years (SD)	55.4 (± 14.9)
Severity	
Mild	41 (13.5%)
Moderate	235 (77%)
Severe	29 (9.5%)
Risk factors	
Cardiovascular Diseases	193 (57.1%)
Pulmonary Diseases	42 (12.4%)
Diabetes and Morbid Obesity	156 (46.1%)
Immunosuppression	7 (2.1%)
Chronic Diseases (Renal, Hepatic, Neurologic, Endocrine)	33 (9.6%)
Age > 65 Years (Only Factor)	96 (28.4%)
Healthcare Worker	56 (16.5%)

NOTE. Values are presented as n (%) or means ± Standard Deviation (SD).
Abbreviations: CPT, convalescent plasma transfusion

Effect of CPT on mortality. Recipients of CPT were compared to individuals hospitalized at participating acute care facilities but did not receive CPT. The 30-day mortality rate was 7.1 %, vs. 25 %, ($p < 0.01$); the ICU mortality were 43.9 %, vs. 49 %, ($p = 0.442$).

Plasma evaluation, recipients and donors. Plasma from recipients was collected at day 1, 7 and 14 of receiving the CPT. Plasma from donors was collected only once and used in recipients. Neutralizing antibodies (IgM, and IgG) present in the serum will be characterized to assess the immune response to the viral illness in recipients and donors.

CONCLUSIONS

- Recipients of CPT had a mortality of 7.1% during hospitalization compared to the control which had a mortality of 25%. This difference were not seen once they were admitted to the ICU.
- The ultimate purpose of the proposed study is to gather critical information that will be relevant in better understanding the immune response and the designing of preventive and therapeutic interventions.

References

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