

# Safety and Tolerability of SARS-CoV-2 Vaccination and Natural History of Infection Among Patients with Castleman Disease

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## INTRODUCTION

- Castleman Disease (CD) represents a group of rare and heterogeneous hematologic disorders that have common lymph node histopathology.
- The most severe CD cases experience a cytokine storm disorder, a life-threatening exacerbation of cytokines and immune-cell hyperactivation.
- SARS-CoV-2 progresses to a severe cytokine storm in the most severe COVID-19 cases; Interleukin-6 (IL-6) is central to CD pathogenesis and often accompanies severe COVID-19 cases; inhibition of IL-6 has been shown to be effective therapy for both CD and severe COVID-19 cases.

## AIMS

To understand the impact of COVID-19 infection on the natural history of CD and examine the safety and tolerability of COVID-19 vaccines in this vulnerable patient population.

## METHODS

- Survey Distribution:** Patients who were enrolled in a longitudinal natural history study of CD (N=298) were invited to participate in a survey to characterize their experience with COVID-19 disease and vaccination.
- Statistical Analyses:** After survey distribution to all eligible patients, up to 3 separate reminders were sent to the target population. All data is self-reported, and descriptive analyses of the data are reported herein.

## RESULTS

Table 1. Symptom Characteristics.

	UCD (N=11)	iMCD (N=5)	HHV8+ MCD (N=1)
Fevers/chills (N=12)	6 (55)	5 (100)	1 (100)
Loss of taste/smell (N=11)	6 (55)	4 (80)	1 (100)
Fatigue (N=12)	8 (73)	3 (60)	1 (100)
Headaches (N=9)	7 (64)	2 (40)	0 (0)
Cough (N=8)	4 (36)	3 (60)	1 (100)
Shortness of breath (N=7)	5 (45)	2 (40)	0 (0)
Muscle and body aches (N=10)	5 (45)	5(100)	0 (0)
Congestion (N=7)	3 (27)	4 (80)	0 (0)
Persistent pain (N=4)	2 (18)	2 (40)	0 (0)
Diarrhea (N=6)	1 (9)	4 (80)	1 (100)
Sore throat (N=3)	2 (18)	1 (20)	0 (0)
Nausea/vomiting (N=7)	4 (36)	3 (60)	0 (0)
Trouble breathing (N=3)	2 (18)	1 (20)	0 (0)
New confusion (N=3)	1 (9)	2 (40)	0 (0)
Inability to wake or stay awake (N=2)	0 (0)	2 (40)	0 (0)
Pale, gray, or blue skin, lips, or nail beds (N=2)	1 (9)	1 (20)	0 (0)
"Other" symptoms (N=2)	2 (18)	0 (0)	0 (0)

Figure 1. Diagnosis and testing of survey participants

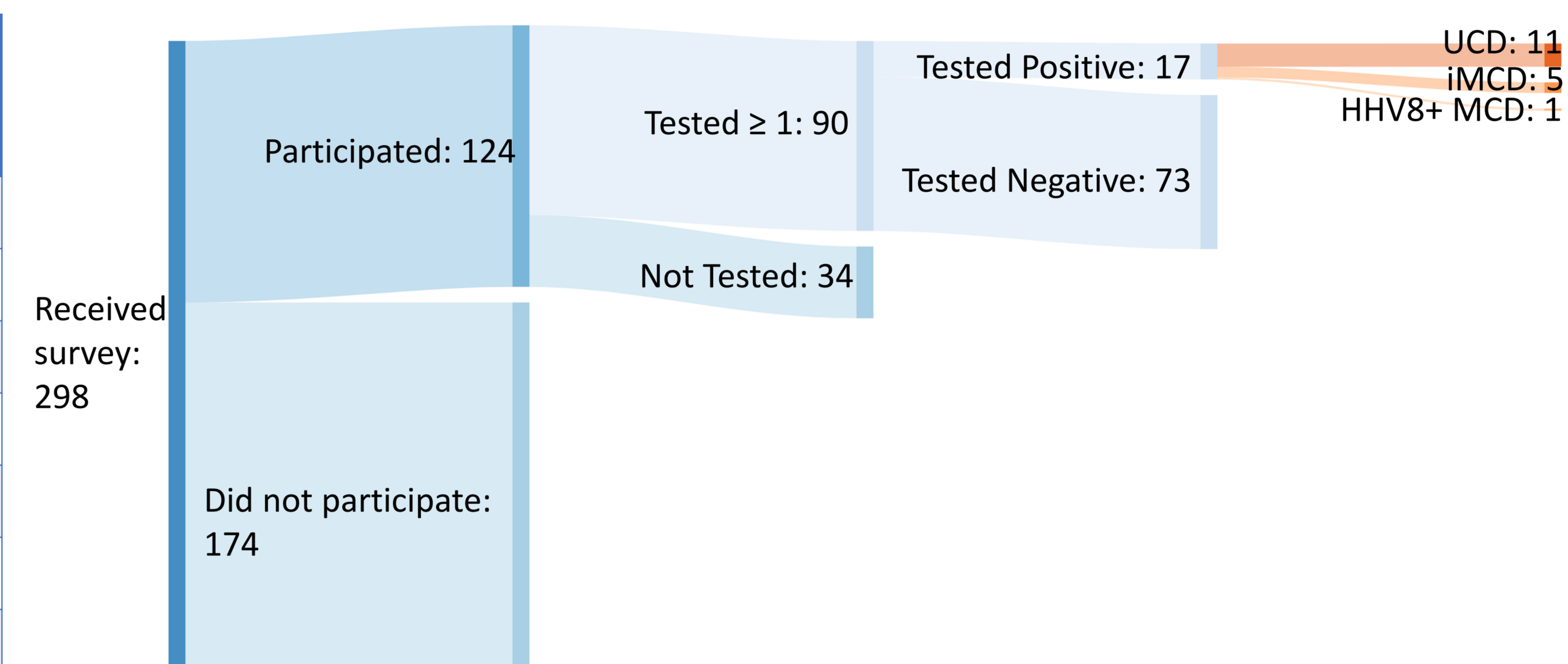


Figure 2. COVID-19 Diagnosis and Breakdown of Disease Severity among CD patients

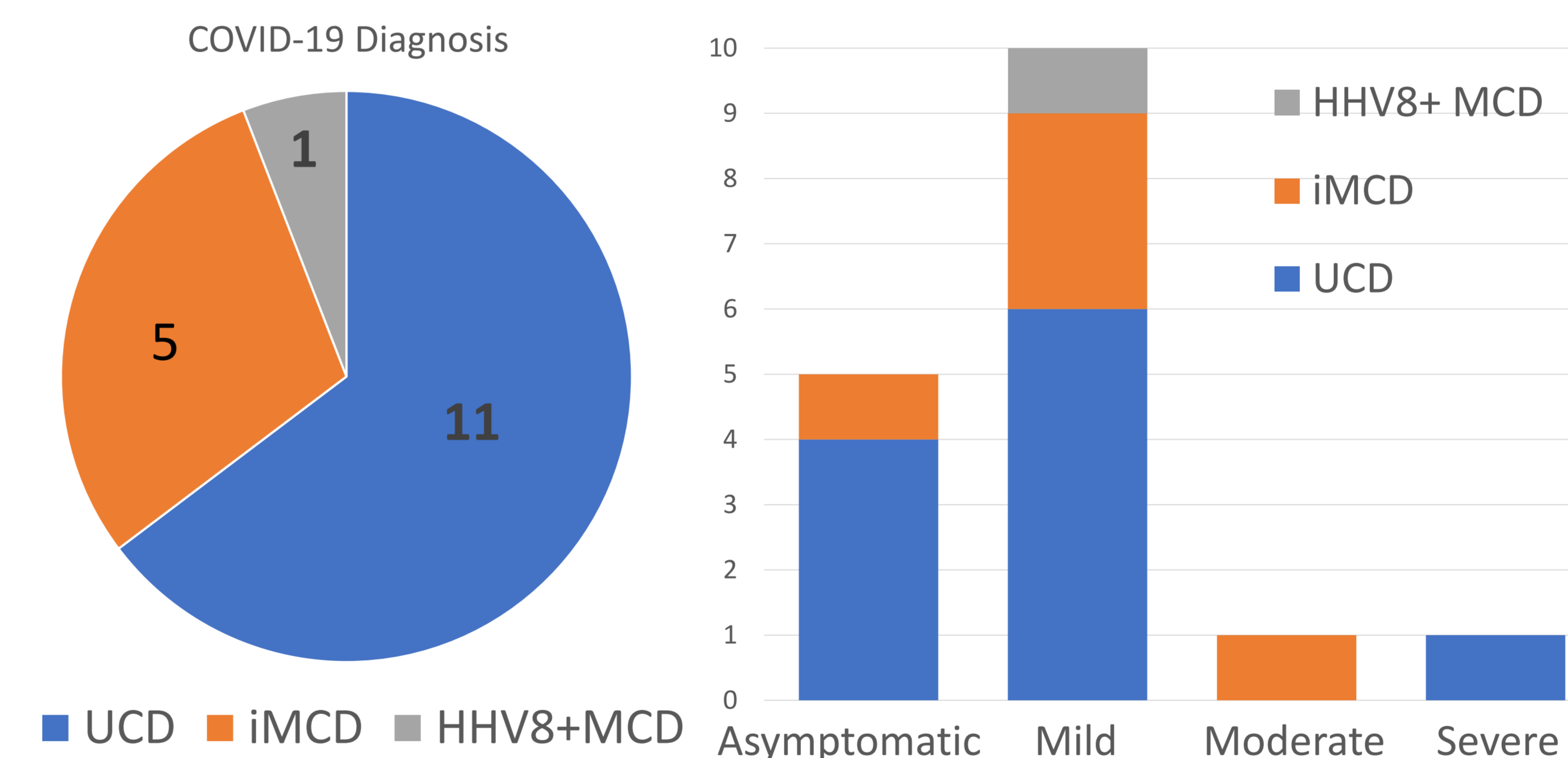


Table 2. Side effect after doses of vaccine.

	All Survey Respondents (N=124)
Received 1 at least one vaccine dose	Yes: 108 (87) No: 16 (13)
Paused treatments during vaccination period	Yes: 11 (8) No: 113 (92)
Side effects to dose 1 or dose 2	Yes: 58 (47) No: 48 (39)
Side effects after dose 2	Arm pain: 43 (35) Fatigue: 39 (31) Headache: 34 (27)

Table 3. Future vaccination plans and concerns.

	Unvaccinated Respondents (N=16)
Future vaccination plans	Will receive: 2 (13) Unsure: 6 (38) Will not receive: 8 (50)
Vaccine concerns	Potential CD interaction: 10 (63) Limited safety data: 9 (56)

## SUMMARY

- We did not observe a markedly increased inflammatory response to SARS-CoV-2 infection, and vaccination was well-tolerated; self-selection bias is a limitation.
- Further, only one report of severe disease was recorded in this sample; the distribution of symptoms and vaccine-related side effects were comparable to the general population.

## CONCLUSIONS

The prevalence of confirmed SARS-CoV-2 infection in this cohort (18.9%) is higher than reported in the US population (10.5%), with one report of severe disease in which the patient was hospitalized for >2 weeks. Additional follow-up is planned in the future to gain a better understanding of the interaction between SARS-CoV-2 and CD.