

Data Set for CARE-MG

COVID-19 Associated Risks and Effects in Myasthenia Gravis (CARE-MG)

This is an effort by an international group of physicians with special interest in myasthenia gravis. We are interested in assessing outcomes in MG patients who develop COVID-19.

We ask you to register any appropriate patient, regardless of severity (including asymptomatic patients detected through screening). **Please report only after a minimum of 7 days and sufficient time has passed to observe the disease course through resolution of acute illness or death.** Reporting a case to this database should take approximately 10 minutes.

We hope to capture outcomes of COVID-19 in all types of Myasthenia (AChR, MuSK, LRP4, Seronegative) irrespective of current treatment status.

Definitions:

- Laboratory Confirmed COVID-19 - Positive viral RNA tests or positive serology for SARS-CoV-2
- Suspected COVID-19 but not confirmed - Fever with Dry cough, +/- anorexia, myalgias, dyspnea, anosmia/ageusia, potential exposure, Chest imaging suggestive of COVID
- Myasthenia Gravis: As defined by treating physician based on antibody status and if seronegative (based on standard testing such as repetitive testing, single fiber EMG, response to acetylcholine esterase inhibitors)

Name of the physician reporter: _____

Email ID of the reporter: _____

Name of the physician caring for the patient with MG: _____

Has this case has been reported in another registry or been published/presented in a scientific forum (e.g. abstract or manuscript)? : Yes No

If Yes, please specify _____

DEMOGRAPHICS

Patient age in years	Patient sex (M or F)	Height in centimeters	Weight in kilograms	Country at time of COVID-19 onset

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If female, **Pregnant?**: Yes No Unknown Not applicable

If Yes, Gestation weeks _____

What's the **Race** of the patient? :

- Asian
- Black or African American
- Middle Eastern or North African
- Native American or Alaska Native
- Native Hawaiian or Pacific Islander
- White or Caucasian
- More than one race
- Other
- Unknown or Not Reported

What's the **Ethnicity** of the patient? :

- Hispanic or Latino
- Not Hispanic or Latino
- Unknown or Not Reported

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MG SPECIFIC DATA

Antibody Status (check all that apply)

- AChR MuSK LRP4 Seronegative
 Unknown

MG subtype: (If the patient ever had MG related weakness outside of the eye muscles, select generalized)

- Ocular MG Generalized MG

Age of onset of MG symptoms in years: _____

Thymectomy: Yes No Unknown

If Yes, > 1 year ago, or <1 year ago

Thymoma: Yes No Unknown

Last clinical evaluation for MG before COVID-19:

- <3 months 3-6 months 6-12 months > 12 months

MGFA Clinical Classification at last clinical visit:

- 0: No Signs of Active Disease
- 1: Ocular Only
- 2A: Mild Generalized, Predominantly Limb/Axial Muscle Weakness
- 2B: Mild Generalized, Predominantly Bulbar Muscle Weakness
- 3A: Moderate Generalized, Predominantly Limb/Axial Muscle Weakness
- 3B: Moderate Generalized, Predominantly Bulbar Muscle Weakness
- 4A: Severe Generalized, Predominantly Limb/Axial Muscle Weakness
- 4B: Severe Generalized, Predominantly Bulbar Muscle Weakness
- 5: Crisis Requires Ventilatory Support
- Unknown

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Was the MGFA status at last visit prior to COVID-19 infection minimal manifestations or better?

- Yes No Unknown

POTENTIAL RISK FACTORS

Is the patient a current smoker (cigar, cigarette, vaping)?

- Yes If yes, Enter pack-years of smoking: _____
- No If no, are they a former smoker? Yes No Unknown
- Unknown

Does the patient have any of the following comorbidities (check all that apply)

- Cardiovascular disease (coronary artery disease, heart failure, arrhythmia, etc.)
- Diabetes
- Asthma
- COPD
- Other Chronic Lung Disease (NOT asthma/COPD)
- Hypertension
- Cancer
- History of stroke
- Chronic neurological and/or neuromuscular disease
- Chronic renal disease (CKD, etc.)
- Chronic liver disease (PSC, NADLD, cirrhosis, etc.)
- Immunodeficiency disease (not related to immunotherapy for MG)
- Morbid obesity
- Other (relevant comorbidity not listed above) _____
- None

MG treatment at time of COVID-19 Infection (check all that apply)

- Plasma Exchange in last 90 days
- IVIg in last 90 days
- Rituximab in past 12 months (If yes, < 6 months or > 6 months ago)
- Pyridostigmine (Mestinon) or other ChEI

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- Corticosteroids
- Azathioprine
- Cyclosporine
- Mycophenolate
- Tacrolimus
- Methotrexate
- 3, 4 - Diaminopyridine
- Cyclophosphamide
- Eculizumab. (If yes, last dose within the last 2 weeks, within 2-4 weeks, or >4 weeks)
- Other MG treatment (please specify) _____
- No current treatment
- Unknown
- Interventional clinical trial participant? (Please do not provide actual trial info)

COVID-19 DIAGNOSIS AND MANAGEMENT

Year of COVID-19 diagnosis:

- 2019
- 2020
- 2021
- 2022

Was COVID-19 testing performed?

- Yes If yes, select result: Positive Negative Indeterminate Unknown
- No
- Unknown

If COVID-19 testing was performed, select testing assay for COVID-19 virus

- RNA-based assays (rRT-PCR, sequencing)
- Serological testing (virus specific IgM or IgG)
- Unknown

If no COVID-19 testing or unknown result, is it a suspected COVID-19 case?

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Yes

No

If chest imaging was performed, was there COVID-19 characteristic lung findings?

(e.g.: ground-glass opacities or patchy shadowing, fine reticular opacities, abnormalities mainly bilateral, with a peripheral distribution, and involving the lower lobes)

Yes

No

Was the patient evaluated in a following setting? (circle all that apply)

Emergency Room: Yes No Unknown

Clinic evaluation (face to face): Yes No Unknown

Telemedicine: Yes No Unknown

Was the patient hospitalized? Yes No Unknown

If yes, number of days of hospitalization _____

Did the patient have an ICU stay? Yes No Unknown

If yes, number of days in ICU stay _____

Was the patient intubated? Yes No Unknown

If yes, numbers of days of intubation _____

Specific ICU/Respiratory scores (see notes below)

If patient developed pneumonia, CURB-65 score for pneumonia severity at time of pneumonia diagnosis _____

If patient developed sepsis, qSOFA score for organ failure at time of sepsis diagnosis _____

Treatments administered for COVID-19 other than supportive care (select all that apply)

<input type="checkbox"/> Remdesivir	<input type="checkbox"/> Chloroquine	<input type="checkbox"/> Hydroxychloroquine
<input type="checkbox"/> Azithromycin	<input type="checkbox"/> Oseltamivir	<input type="checkbox"/> Lopinavir/ritonavir

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<input type="checkbox"/> Tocilizumab or other anti-IL6 or anti-IL6 receptor therapy	<input type="checkbox"/> Corticosteroids (check box only if started specifically for COVID-19 treatment, not for MG care)	<input type="checkbox"/> Convalescent serum or plasma
<input type="checkbox"/> IVIg (check this box only if started specifically for COVID-19 treatment, not for MG care)	<input type="checkbox"/> Favipiravir	<input type="checkbox"/> Baricitinib
<input type="checkbox"/> Other _____	<input type="checkbox"/> No medications and/or investigational therapies were used	<input type="checkbox"/> Unknown

MG STATUS DURING COVID-19 INFECTION

MG exacerbation? Yes No Unknown

If yes, how many days after viral infection symptoms _____

If Yes, **Specify the MG exacerbation treatment** (check all that apply)

- PLEX IVIg Corticosteroids
 Other _____ No treatment Unknown

Were there any other changes to the patient's MG treatment (during or within 14 days of infection)? (check all that apply)

<input type="checkbox"/> Start oral steroids	<input type="checkbox"/> Increase oral steroids	<input type="checkbox"/> Decrease oral steroids
<input type="checkbox"/> Stop oral steroids	<input type="checkbox"/> Start IV steroids	
<input type="checkbox"/> Increase steroid sparing immunosuppressive treatment (e.g., mycophenolate or azathioprine)	<input type="checkbox"/> Decrease steroid sparing immunosuppressive treatment (e.g., mycophenolate or azathioprine)	<input type="checkbox"/> Stop steroid sparing immunosuppressive treatment (e.g., mycophenolate or azathioprine)
<input type="checkbox"/> Start chronic PLEX	<input type="checkbox"/> Start chronic IVIG	<input type="checkbox"/> Start Eculizumab
<input type="checkbox"/> Stop Eculizumab	<input type="checkbox"/> Start rituximab	<input type="checkbox"/> Hold scheduled rituximab

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<input type="checkbox"/> Stop all immunosuppressive treatments	<input type="checkbox"/> Other _____	<input type="checkbox"/> None (no changes)
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MGFA severity classification at time of COVID-19 diagnosis:

- 0: No Signs of Active Disease
- 1: Ocular Only
- 2A: Mild Generalized, Predominantly Limb/Axial Muscle Weakness
- 2B: Mild Generalized, Predominantly Bulbar Muscle Weakness
- 3A: Moderate Generalized, Predominantly Limb/Axial Muscle Weakness
- 3B: Moderate Generalized, Predominantly Bulbar Muscle Weakness
- 4A: Severe Generalized, Predominantly Limb/Axial Muscle Weakness
- 4B: Severe Generalized, Predominantly Bulbar Muscle Weakness
- 5: Crisis Requires Ventilatory Support
- Unknown

Worst MGFA severity classification during COVID-19 illness (within 1 month of infection if different from above):

- 0: No Signs of Active Disease
- 1: Ocular Only
- 2A: Mild Generalized, Predominantly Limb/Axial Muscle Weakness
- 2B: Mild Generalized, Predominantly Bulbar Muscle Weakness
- 3A: Moderate Generalized, Predominantly Limb/Axial Muscle Weakness
- 3B: Moderate Generalized, Predominantly Bulbar Muscle Weakness
- 4A: Severe Generalized, Predominantly Limb/Axial Muscle Weakness
- 4B: Severe Generalized, Predominantly Bulbar Muscle Weakness
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- Unknown

OUTCOMES

Discharge Disposition for hospitalized patients

- Home
- Rehab

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- Skilled nursing
- Died from COVID-19 or other complications caused by or contributed to by COVID-19
- Died from MG exacerbation
- Unknown

If Died, number of days between onset of COVID-19 symptoms and death_____

For non-hospitalized patients, was there improvement in MG symptoms?

- Yes
- No
- Unknown

Disposition for non-hospitalized patients

- Recovered
- Not recovered
- Died from COVID-19 or other complications caused by or contributed to by COVID-19
- Died from MG exacerbation
- Unknown

If Died, number of days between onset of COVID-19 symptoms and death_____

Please enter any additional data not included on the case report form that you feel may be relevant/important for this particular case.

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Notes on ICU scores:

qSOFA and CURB-65 are simple questionnaires and have been used in most analysis of outcomes with COVID-19.

qSOFA: (Quick Sequential Organ Failure Assessment)

Parameter	0 points	1 point
Altered mental status GCS <15	No	Yes
Respiratory rate ≥ 22	No	Yes
Systolic blood pressure ≤ 100	No	Yes

CURB-65- Score for severity of Pneumonia

Parameter	No (0)	Yes (1)
Confusion		
BUN >19 mg/dl (>7 mmol/L)		
Respiratory Rate ≥ 30		
Systolic BP < 90 mmHg or Diastolic BP ≤ 60 mmHg		
Age ≥ 65		