Demographicsmuskmg

Demographics Information

Study Subject ID

_____
(Example: PYA1, or RUP2. The first letter will be either P (Prospective) or R (Retrospective). The next two letters are center codes that have been assigned to you, for example YA for Yale. The No. is the subject No. at your site. Please make a note of this No. in relationship to you patient's ID No., so you can identify the patient. Also, if your patient has multiple TPE series, please make sure that you use the same Study subject ID No.))

Center ID

◯ Cleveland Clinic (CC)
◯ CHOP (CH)
◯ CNMC (CN)
◯ Columbia (CO)
◯ Mayo (MA)
◯ New York Blood Center (NY)
◯ U Minn (UM)
◯ U Penn (UP)
◯ U Michigan (MI)
◯ Virginia Commonwealth University (VC)
◯ Yale (YA)

Gender

◯ Female
◯ Male
◯ Undifferentiated
◯ Unknown

Ethnicity

◯ Hispanic or Latino
◯ Not Hispanic or Latino

Race

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Unknown or mixed
(Study participants should self-report race, with race being asked about after ethnicity. Check all that apply.)

What is the subject's age at the first Study TPE

_____
(Record age of the subject in years. Ex: 39 or 45.)

Age (years) at initial MUSK-MG diagnosis

_____
(Record age of the subject in years. Ex: 39 or 45.)

Year of the first study TPE performed/Started

◯ 2017
◯ 2016
◯ 2015
◯ 2014
◯ 2013
◯ 2012
◯ 2011
◯ 2010
◯ 2009
◯ 2008
◯ 2007
◯ 2006
◯ 2005
◯ 2004
◯ 2003
◯ 2002
◯ 2001
◯ 2000

(Year of the first TPE procedure performed for this TPE session)

Prior non-registered TPE

◯ Yes
◯ No

(If there are prior TPE sessions that you are aware, but you do not intend to report to the registry or the TPE were performed prior to 2000, please check yes for this field, and give a brief summary of the prior TPEs such as roughly when, what for, the estimated No., outcome, and source of the information such as per chart, per patient, per family, etc..)

Notes for prior non-registered TPE

_____

(If there are prior TPE session that you are aware, but you do not intend to report to the registry or the TPE were performed prior to 2000, please give a brief summary of the prior TPEs such as roughly when, what for, the estimated No., outcome, and source of the information such as per chart, per patient, per family, etc..)

Study Enrollment Date

_____

(Please enter the date that you start to work on this case, so you can obtain a summary for IRB reporting)

What is the date of complete reporting?

_____

((Please enter the date of your completion of this case.))

Study notes

_____

((Please use this field to leave notes for your own use or notes for the registry committee)

Tpe Session Info Musk Mg

TPE Session Information Please provide summary for this TPE session

What TPE series Is this?

◯ 1
◯ 2
◯ 3
◯ 4
◯ 5
◯ 6
◯ 7
◯ 8
◯ 9
◯ 10
◯ >10, please enter No. below
(This refers to a series of TPE treatments)

Total Series No. if >10, otherwise leave it blank

_____

Date of first TPE in this TPE series/session

_____
(Date for the first TPE for this TPE series or session)

Date of last TPE in this TPE series/session

_____

Weight (Kg)

_____

Height (cm)

_____

Diagnostic Criteria

☐ Positive Acetylcholine Receptor Antibody
☐ Positive Anti-MuSK Antibody
☐ Positive Edrophonium tests
☐ Positive Electromyography
☐ Positive Single Fiber EMG

Clinical symptoms/information at Onset (before the start of first TPE of this series)

☐ None
☐ Diplopia
☐ Ptosis
☐ Dysarthria
☐ Dysphagia
☐ Limb weakness
☐ Shortness of breath
☐ intubation

Treatment summary

◯ Steroid resistant add on
◯ Steroid + TPE combination treatment de novo
◯ Maintenance
◯ Others

Treatment summary notes

_____

Clinical status assessment (from pre-TPE baseline to within 10 days post last TPE)

◯ 1-No improvement
◯ 2-Mild improvement (slight but definite change and with no impact on the daily function)
◯ 3-Moderate improvement (obvious improvement that impacts daily function)
◯ 4-Marked improvement (significant difference from Pre-first TPE baseline with major functional daily improvement)
◯ 5-full recovery from Pre-first TPE baseline

Did patient relapse after this TPE series/session?

◯ Yes
◯ No

If patient relapsed after this TPE series/session, age (yrs) at relapsed:

_____

If patient relapsed after this TPE series/session, months lapsed since last TPE:

_____

Meds/treatment tried prior to start of TPE

☐ None
☐ Mestinon (Pyridostigmine)
☐ Prednisone;
☐ Methylprednisolone
☐ Hydrocortisone
☐ IVIG
☐ Rituximab
☐ Imuran
☐ Cyclosporine
☐ Azathioprine
☐ Mycophenolate mofetil
☐ Thymectomy

Meds/treatment while on TPE

☐ None
☐ Mestinon (Pyridostigmine)
☐ Prednisone;
☐ Methylprednisolone
☐ Hydrocortisone
☐ IVIG
☐ Rituximab
☐ Imuran
☐ Cyclosporine
☐ Azathioprine
☐ Mycophenolate mofetil
☐ Thymectomy

Meds/treatment on within 10 days post TPE

☐ None
☐ Mestinon (Pyridostigmine)
☐ Prednisone;
☐ Methylprednisolone
☐ Hydrocortisone
☐ IVIG
☐ Rituximab
☐ Imuran
☐ Cyclosporine
☐ Azathioprine
☐ Mycophenolate mofetil
☐ Thymectomy

Meds/treatment on within 30 days post TPE

☐ None
☐ Mestinon (Pyridostigmine)
☐ Prednisone;
☐ Methylprednisolone
☐ Hydrocortisone
☐ IVIG
☐ Rituximab
☐ Imuran
☐ Cyclosporine
☐ Azathioprine
☐ Mycophenolate mofetil
☐ Thymectomy

Meds/treatment on within 60 days post TPE

- ☐ None
- ☐ Mestinon (Pyridostigmine)
- ☐ Prednisone;
- ☐ Methylprednisolone
- ☐ Hydrocortisone
- ☐ IVIG
- ☐ Rituximab
- ☐ Imuran
- ☐ Cyclosporine
- ☐ Azathioprine
- ☐ Mycophenolate mofetil
- ☐ Thymectomy

Meds- status assessment, please assess status from pre_TPE baseline to within 10 days post last TPE

	No change	Decreased	Stopped	Increased	Added
Mestinon (Pyridostigmine)	☐	☐	☐	☐	☐
Prednisone	☐	☐	☐	☐	☐
Methylprednisolone	☐	☐	☐	☐	☐
Hydrocortisone	☐	☐	☐	☐	☐
IVIG	☐	☐	☐	☐	☐
Rituximab	☐	☐	☐	☐	☐
Imuran	☐	☐	☐	☐	☐
Cyclosporine	☐	☐	☐	☐	☐
Azathioprine	☐	☐	☐	☐	☐
Mycophenolate mofetil	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

Meds-status assessment, please assess status from pre_TPE baseline to within 30 days post last TPE

	No Change	Decreased	Stopped	Increased	Added
Mestinon (Pyridostigmine)	○	○	○	○	○
Prednisone	○	○	○	○	○
Methylprednisolone	○	○	○	○	○
Hydrocortisone	○	○	○	○	○
IVIG	○	○	○	○	○
Rituximab	○	○	○	○	○
Imuran	○	○	○	○	○
Cyclosporine	○	○	○	○	○
Azathioprine	○	○	○	○	○
Mycophenolate mofetil	○	○	○	○	○

Meds-status assessment, please assess status from pre_TPE baseline to within 60 days post last TPE

	No Change	Decreased	Stopped	Increased	Added
Mestinon (Pyridostigmine)	◯	◯	◯	◯	◯
Prednisone	◯	◯	◯	◯	◯
Methylprednisolone	◯	◯	◯	◯	◯
Hydrocortisone	◯	◯	◯	◯	◯
IVIG	◯	◯	◯	◯	◯
Rituximab	◯	◯	◯	◯	◯
Imuran	◯	◯	◯	◯	◯
Cyclosporine	◯	◯	◯	◯	◯
Azathioprine	◯	◯	◯	◯	◯
Mycophenolate mofetil	◯	◯	◯	◯	◯

Replacement solution predominantly used

- ☐ 5% albumin
- ☐ Plasma protein fraction/plasmanate
- ☐ FFP
- ☐ Plasma >24 hrs thawed
- ☐ Normal Saline
- ☐ Hetastarch
- ☐ Others

If solution other than albumin/plasmanate was used was it because of:

- ☐ Possible coagulopathy
- ☐ It is standard protocol at my institution
- ☐ Availability of primary product
- ☐ Patient preference
- ☐ Possible transfusion reaction
- ☐ Other

If Other, please explain: _____

Volume of exchange (average):

- ◯ < 1 plasma volume
- ◯ 1.0-1.25
- ◯ 1.26 -1.50
- ◯ 1.51-1.75
- ◯ 1.76-2.00
- ◯ 2.01-3.0
- ◯ >3.0

Frequency of exchange

- ◯ Daily
- ◯ Every other day including weekends
- ◯ Every other day, not including weekends
- ◯ Once a week
- ◯ Twice a week
- ◯ Weekly
- ◯ Every other week
- ◯ Every three weeks
- ◯ Monthly
- ◯ Every two months
- ◯ Other

Others, please detail

_____

Notes for TPE session

_____

Tpe Procedure Informationmuskmg

Start date of this TPE Procedure

_____
(, please enter 1:00 am)

Global Neurological Assessment (baseline or since last TPE)

◯ Baseline-First TPE
◯ 1-No improvement
◯ 2-Mild improvement (slight but definite change and with no impact on the daily function)
◯ 3-Moderate improvement (obvious improvement that impacts daily function)
◯ 4-Marked improvement (significant difference from Pre-first TPE baseline with major functional daily improvement)
◯ 5-full recovery from Pre-first TPE baseline
(Comparing to pre-first TPE baseline)

Plasma Volume Exchanged for This TPE Procedure

◯ < 0.75 plasma volume
◯ 0.76-0.99
◯ 1.0-1.25
◯ 1.26 -1.50
◯ 1.51-1.75
◯ 1.75-2.00
◯ 2.10-2.50
◯ >2.5
◯ Others
(Plasma volume (No. exchanged), such as 1, 1.5, 2))

Notes for Volume exchanged

_____
(If you answered "others" on the above question, please specify here)

Fluid Balance

◯ 100%
◯ 105%
◯ 110%
◯ 95%
◯ Others: Please type in notes

Notes for Fluid balance

_____
(If you answered "others" on the above question, please specify here)

Replacement Fluid 1

◯ 5% albumin
◯ Plasma protein fraction/plasmanate
◯ FFP
◯ Plasma >24 hrs thawed
◯ Normal Saline
◯ Hetastarch
◯ Others
(If your fluid is not listed, please use replacement fluid 3)

Notes for Replacement Fluid 1

_____
(If you answered "others" on the above question, please specify here)

Replacement Fluid 1 Volume (ml)

_____
(mL)

Replacement Fluid 2

◯ 5% albumin
◯ Plasma protein fraction/plasmanate
◯ FFP
◯ Plasma >24 hrs thawed
◯ Normal Saline
◯ Hetastarch
◯ Others
(plasma, 5% albumin, etc.)

Notes for Replacement Fluid 2

_____
(If you answered "others" on the above question, please specify here)

Replacement Fluid 2 Volume (mL)

_____
(mL)

Replacement Fluid 3

◯ 5% albumin
◯ Plasma protein fraction/plasmanate
◯ FFP
◯ Plasma >24 hrs thawed
◯ Normal Saline
◯ Hetastarch
◯ Others
(plasma, 5% albumin, etc.)

Replacement 3 notes

_____
(If you answered "others" on the above question, please specify here)

Replacement Fluid 3 Volume (ml)

_____
(mL)

Access

◯ Peripheral access
◯ IJ central line
◯ SC central line
◯ Femoral line
◯ Permacath
◯ Fistula
◯ Others

Access notes

_____
(If access type is not listed, please specify)

Hct, point of care (may also be from non POCT instrument)

_____

Anticoagulant used for TPE

◯ ACD-A
◯ ACD/Heparin
◯ Heparin
◯ Others

Anticoagulant notes

_____
(If anticoagulant is not listed, please specify)

Calcium replacement

☐ Add Ca into replacement fluid
☐ i.v. Ca continuous infusion
☐ p.o. Ca
☐ i.v. and p.o. Ca
☐ None
☐ Others, please specify in notes

Ca replacement notes

_____
(If you answered "others" on the above question, please specify here)

Potassium Replacement

◯ Yes
◯ No

Magnesium Replacement

◯ Yes
◯ No

RBC priming performed

◯ Yes
◯ No

Rinsed performed

☐ none
☐ partial
☐ full
(also known as rinse back)

BPsystolic pre

_____

BPdiastolic, pre

_____

HR pre

_____

Temp (F), pre

_____

Temp (C), pre

_____

O2 Sat % pre

_____

Oxygen Treatment, pre

◯ RA
◯ 2L, face mask
◯ 4L, face mask
◯ Mechanic Ventilation
◯ Others

Notes for Oxygen treatment, pre

_____
(If you answered "others" on the above question, please specify here)

BPsystolic, post

_____

BPdiastolic, post

_____

HR, post

_____

Temp (F), post

_____

Temp (C), post

_____

O2 Sat %, post

_____

Oxygen, treatment post

◯ RA
◯ 2L, face mask
◯ 4L, face mask
◯ Mechanic Ventilation
◯ Others

Notes for Oxygen treatment, post

_____
(If you answered "others" on the above question, please specify here)

Apheresis Adverse event

◯ yes
◯ no
◯ others
(If answered yes or others, please fill the next two sections)

Please define the imputability and severity of the adverse reaction:

Imputability:
Definitively: The only explanation
Probable: The likelihood is high, but not absolute
Possible: The likelihood is relatively high, but it is also possible not relate to apheresis
Can't rule out: The likelihood is very small, but not impossible
Not related: not related to apheresis

Severity:
None
Mild: no or minor modification of procedure
Moderate: major modification including stopping of procedure
Severe: patient was admitted or received major medical treatment or death

Apheresis Adverse Reaction

	Definitively	Probable	Possible	Can't rule out	Not related	Mild	Moderate	Severe
Vasovagal reaction	☐	☐	☐	☐	☐	☐	☐	☐
Citrate toxicity	☐	☐	☐	☐	☐	☐	☐	☐
Hypovolemia	☐	☐	☐	☐	☐	☐	☐	☐
Blood no return	☐	☐	☐	☐	☐	☐	☐	☐
Others	☐	☐	☐	☐	☐	☐	☐	☐

If added others please note here

_____

Transfusion reaction present?

◯ No
◯ Yes, please report in detail
◯ Others, please report in detail

Please define type, imputability and severity of transfusion reaction:

Please use CDC definition

[Attachment: "BV-HV-protocol-current.pdf"]

TPE Procedure Notes

_____
(Please use this field to write note for yourself or to the registry)

TPE Labs

Labs during TPE session/series

Date of Lab _____

Time to TPE
◯ 12-24 hrs prior to starting TPE
◯ < 12 hrs prior to starting TPE
◯ During TPE
◯ Within 12 hrs after finishing TPE
◯ 12-24 hrs after finishing TPE

PT (sec) _____

INR _____

PTT (sec) _____

Fibrinogen (mg/dL) _____

Hct (%) _____

Hemoglobin (g/dL) _____

Platelet (K/microL) _____

Albumin (g/dL) _____

Total Protein (g/dL) _____

Creatinine (mg/dL) _____

Ca (mg/dL) _____

Mg (mg/dL) _____

Phos (mg/dL) _____

iCa _____

iCa units
◯ mg/dL
◯ mmol/L

Notes of Labs if necessary

_____

Clinical Assessmentmuskmg

MUSK-MG Clinical Assessment If possible please collect baseline (before current MG attack), during attack (before any treatment as well as before TPE treatment), pre-TPE baseline, during TPE (as many as you can), about 6 month post TPE

Date of MUSK_MG Clinical Assessment _____

Data Type

- ◯ Baseline (before current attack)
- ◯ During Attack (pre-medical treatment, as many as you have)
- ◯ Before first TPE for this session (closest one)
- ◯ During TPE (as many as you have)
- ◯ Post TPE within 1 month
- ◯ Post TPE between 1 and 3 months
- ◯ Post TPE between 3 and 6 months

Clinical symptoms/Information

- ☐ None
- ☐ Diplopia
- ☐ Ptosis
- ☐ Dysarthria
- ☐ Dysphagia
- ☐ Limb weakness
- ☐ Shortness of breath
- ☐ intubation

Meds/treatment on

- ☐ None
- ☐ Mestinon (Pyridostigmine)
- ☐ Prednisone;
- ☐ Methylprednisolone
- ☐ Hydrocortisone
- ☐ IVIG
- ☐ Rituximab
- ☐ Imuran
- ☐ Cyclosporine
- ☐ Azathioprine
- ☐ Mycophenolate mofetil
- ☐ Thymectomy

Prednisone dose _____

Mestinon dose _____

Initial of the person who did data extraction _____

Data Source

- ◯ Extraction from neurology notes
- ◯ Extraction from clinical notes
- ◯ Own assessment
- ◯ Others

Notes for meds/treatment

_____

MUSK-MG Lab Results

MUSK_MG Lab results If possible please collect baseline (before current MG attack), during attack (before any treatment as well as before TPE treatment), pre-TPE baseline, during TPE (as many as you can), about 6 month post TPE

Date of testing _____

Data Type
- ◯ Baseline (before current attack)
- ◯ During Attack (pre-medical treatment, as many as you have)
- ◯ Before first TPE for this session (closest one)
- ◯ During TPE (as many as you have)
- ◯ Post TPE within 1 month
- ◯ Post TPE between 1 and 3 months
- ◯ Post TPE between 3 and 6 months

Time to TPE (only during TPE session)
- ◯ 12-24 hrs prior to starting TPE
- ◯ < 12 hrs prior to starting TPE
- ◯ During TPE
- ◯ Within 12 hrs after finishing TPE
- ◯ 12-24 hrs after finishing TPE

Anti-AChR (binding, nmol/L) _____

Anti-AChR (blocking, %) _____

Anti-AChR (modulating, titer) _____

Striated Muscle antibody (titer, eg. >1:40) _____
(This is the anti-MUSK antibody results)

Reference laboratory where Achr testing was performed. _____
(Please comment on where each testing was performed)

Reference laboratory where anti-MUSK was performed _____

Reference laboratory where other Ab testing was performed _____

Note of Ab testing, including testing of other types of Ab related to MG _____