Management of Acute Exacerbations and Crisis in Myasthenia Gravis

For Healthcare Providers

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Disclosures

• Argenx
  – Patient Education Speaker

• Johnson & Johnson/Janssen
  – Contributor
Outline

• Introduction
• Definitions, Symptoms, & Risk Factors
• Outpatient Management
• Navigating the Emergency Room
• Inpatient Management
• Prevention
INTRODUCTION
HISTORY

- Officially Named in 1895
  - Myasthenia: muscle and weakness
  - Gravis: heavy or grievous

'At this time I had under my charge a prudent and honest Woman, who for many years hath been obnoxious to this sort of spurious Palsie, not only in the members, but also in her tongue: she for some time can speak freely and readily enough, but after she has spoken long, or hastily, or eagerly, she is not able to speak a word but becomes mute as a Fish, nor can she recover the use of her voice under an hour or two'.

Two Discourses Concerning the Soul of Brutes (1685)

Photos courtesy of: https://neuromuscular.wustl.edu/mtime/mgddx.htm
EPIDEMIOLOGY

- A rare autoimmune neurological disorder
  - 10-20 cases per 100,000 cases

- Age distribution
  - Peak around 30 years old, another peak at 50 years old
  - Younger patients more commonly female


EPIDEMIOLOGY

• Ocular vs Generalized
  – 66% of patients will have purely ocular symptoms at onset
  – 50-70% of patients with ocular symptoms at onset will generalize, typically in the first 2-3 years

• Antibody Positive vs Seronegative
  – AchR Abs: 80-85%
  – MuSK Ab: 5-7%
  – LRP4 Ab: 1-2%

• Early vs Late Onset
  – Early: <50yrs old at time of diagnosis
  – Late: >50yrs old at time of diagnosis
  – Early onset: may have more aggressive disease
  – Late onset: medical comorbidities may have more impact on disease course and treatment

DEFINITIONS, SYMPTOMS, & RISK FACTORS
EXACERBATION VS CRISIS

• Myasthenia Gravis Exacerbation
  – A worsening of any MG symptom/symptoms
  – Range in severity

• Myasthenia Gravis Crisis
  – A severe exacerbation resulting in respiratory failure requiring ventilatory support
EPIDEMIOLOGY OF MG EXACERBATION & CRISIS

- At least 70% of patients will experience an exacerbation
- A myasthenia gravis crisis occurs in about 15% of patients
  - Typically, in the first 2 years after symptom onset
  - May be the initial presentation for some patients
- Majority of patients who suffer a crisis will make a full recovery
  - Complications: Intubation, Infection, Cardiac
WHO IS AT RISK?

Patients were more likely to experience a crisis if:

- Older age
- Late onset MG
- Higher MGFA class
- Other medical comorbidities including other autoimmune conditions

Subgroups

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Count</th>
<th>Risk Ratio (95% CI)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>EOMG &amp; AID −</td>
<td>50</td>
<td>3 (6)</td>
<td>1</td>
</tr>
<tr>
<td>EOMG &amp; AID +</td>
<td>12</td>
<td>2 (16)</td>
<td>3.13 (0.46–21.27)</td>
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<tr>
<td>LOMG &amp; AID −</td>
<td>26</td>
<td>10 (39)</td>
<td>9.79 (2.39–40.08)</td>
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<tr>
<td>LOMG &amp; AID +</td>
<td>8</td>
<td>6 (75)</td>
<td>47.00 (6.49–340.65)</td>
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</table>

<table>
<thead>
<tr>
<th>Class</th>
<th>Clinical symptoms</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>Any ocular weakness</td>
</tr>
<tr>
<td>II</td>
<td>Mild Weakness. May also have ocular muscle weakness of any severity</td>
</tr>
<tr>
<td>II A</td>
<td>Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both</td>
</tr>
<tr>
<td>II B</td>
<td>Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both</td>
</tr>
<tr>
<td>III</td>
<td>Moderate weakness affecting other than ocular muscles. May also have ocular muscle weakness of any severity</td>
</tr>
<tr>
<td>III A</td>
<td>Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both</td>
</tr>
<tr>
<td>III B</td>
<td>Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both</td>
</tr>
<tr>
<td>IV</td>
<td>Severe weakness affecting other than ocular muscles. May also have ocular muscle weakness of any severity</td>
</tr>
<tr>
<td>IV A</td>
<td>Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both</td>
</tr>
<tr>
<td>IV B</td>
<td>Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both</td>
</tr>
<tr>
<td>V</td>
<td>Defined by intubation, with or without mechanical ventilation, except when employed during routine postoperative management</td>
</tr>
</tbody>
</table>
### Provoking Factors/Triggers

**Table 2** Comparison of patients with and without exacerbation

<table>
<thead>
<tr>
<th></th>
<th>Patients with exacerbation</th>
<th>Patients with no exacerbations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total MAUC-MG</td>
<td>119</td>
<td>67</td>
</tr>
<tr>
<td>Seropositive</td>
<td>53 (69%)</td>
<td>27 (54%)</td>
</tr>
<tr>
<td>Thymectomy</td>
<td>16 (21%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td><strong>MG treatment at time of exacerbation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steroids</td>
<td>98 (46%)</td>
<td></td>
</tr>
<tr>
<td>Plasma exchange</td>
<td>20 (9%)</td>
<td></td>
</tr>
<tr>
<td>IVIG</td>
<td>73 (34%)</td>
<td></td>
</tr>
<tr>
<td>Mycophenolate mofetil</td>
<td>32 (15%)</td>
<td></td>
</tr>
<tr>
<td>Azathioprine</td>
<td>95 (45%)</td>
<td></td>
</tr>
<tr>
<td>Pyridostigmine (&lt;120 mg/day)</td>
<td>32 (15%)</td>
<td></td>
</tr>
<tr>
<td>Pyridostigmine (≥120 mg/day)</td>
<td>136 (61%)</td>
<td></td>
</tr>
<tr>
<td>Zithromax</td>
<td>21 (18%)</td>
<td>10 (15%)</td>
</tr>
<tr>
<td>Fluoroquinolones</td>
<td>29 (24%)</td>
<td>20 (30%)</td>
</tr>
<tr>
<td>Gentamycin</td>
<td>1 (1%)</td>
<td>7 (10%)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>15 (13%)</td>
<td>13 (19%)</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>45 (38%)</td>
<td>16 (24%)</td>
</tr>
<tr>
<td>Prednisone</td>
<td>8 (7%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

Abbreviation: IVIG, intravenous Immunoglobulin.
70% of cases are provoked by an identifiable cause
- Infection
- Surgery
- Medications

Cautionary Drugs in Myasthenia Gravis

Drugs with US Food and Drug Administration (FDA) boxed warnings for use in myasthenia gravis
- Telithromycin (no longer available in the United States)
- Fluoroquinolones (ciprofloxacin, moxifloxacin, levofloxacin)

Drugs to use with caution, if at all, in myasthenia gravis
- Botulinum toxin
- D-penicillamine
- Chloroquine
- Hydroxychloroquine
- Quinine
- Magnesium
- Macrolide antibiotics (erythromycin, azithromycin, clarithromycin)
- Aminoglycoside antibiotics (gentamicin, neomycin, tobramycin)
- Corticosteroids
- Procainamide
- Desferrioxamine
- Beta-blockers
- Statins
- Immune checkpoint inhibitors (pembrolizumab, nivolumab, atezolizumab, avelumab, durvalumab, ipilimumab)

Data from Myasthenia Gravis Foundation of America.

Corticosteroids may cause transient worsening of symptoms in the first 2 weeks but are part of the standard treatment for myasthenia gravis. Close monitoring should be in place when initiating steroids.
• **Drooping Eyelids (Ptosis)**
  – Can be unilateral or bilateral

• **Neck Weakness**
  – Head drop

• **Facial Weakness**
  – Decreased facial expressions
  – Jaw Fatigue
  – Impaired eye/lip closure

• **Blurry Vision/Double Vision** (diplopia)

• **Limb Weakness/Fatigability**
  – Difficulty with walking/rising from seated position/using stairs
  – Difficulty raising arms

SIGNS & SYMPTOMS

• Speech Changes (Dysarthria)
  – Slurred/Nasal Speech

• Difficulty Swallowing (Dysphagia)
  – Liquids and/or solids
  – Managing secretions

• Shortness of Breath (Dyspnea)
  – At rest or with activity
  – Worsening with laying flat (orthopnea)
  – Use of accessory muscles when breathing
OUTPATIENT MANAGEMENT
Management

• Minimal/Mild Exacerbations
  – Including ptosis, vision changes, mild extremity weakness
  – Obtain history
  – Schedule for virtual or in-office visit, if possible
  – Adjustments to treatment regimen
    • Pyridostigmine
    • Prednisone
    • IVIG or PLEX schedule
  – Low threshold for ED/hospital evaluation if symptom worsening
NAVIGATING THE EMERGENCY ROOM
MODERATE & SEvere EXACerbATIONS

• Symptoms: Progressive difficulty swallow and/or progressive shortness of breath, moderate or severe muscle weakness
• Called EMS or immediately present to the nearest ER
• Evaluation by ER physician & staff
  – Triage
  – History & Physical
  – Labs & Imaging
  – Neurology & pulmonology consults, if available
BEDSIDE EXAMINATION

• Neurological
  – Prolonged upgaze
  – Voice changes
  – Eye movements, facial strength, neck strength
  – Muscle strength – fatigability
  – Single Breath Count
    • Want greater than or equal to 20
BEDSIDE EXAMINATION

• Pulmonary Function Testing
  – Negative Inspiratory Force (NIF) or Maximum Inspiratory Pressure (MIP)
    • Normal NIF > -25cmH20
    • Normal MIP > -60cmH20
  – Functional Vital Capacity (FVC)
    • Normal is > 70-100%

• Important Note
  – Oxygen saturation is NOT a reliable measure of respiratory distress in patients with myasthenia gravis
ER MANAGEMENT

• Antibiotics for potential infection
  – Important physician is familiar with antibiotics which should be used with caution

• Intravenous Fluids

• Correction of electrolyte abnormalities
  – Avoid high doses of magnesium

• Nothing by mouth until formal evaluation
Checklist for a Myasthenia Gravis Emergency

☐ Take an updated list of all medications & treatments and treating physicians

☐ Keep a list of medications to be avoided or used with caution in patients with myasthenia gravis

☐ Inform the emergency room staff about your diagnosis of myasthenia gravis, your symptoms, and name of neurologist

☐ Share any recent changes (e.g. new medications) or symptoms (e.g. signs of infection, new cough)

☐ Make sure you have bedside pulmonary function testing performed including:
  o Negative Inspiratory Force (NIF) or Maximum Inspiratory Pressure (MIP)
    ▪ Normal NIF > -25cmH20
    ▪ Normal MIP >-60cmH20
  o Functional Vital Capacity (FVC)
    ▪ Normal is > 70-100 %

☐ Make sure to have swallow function evaluated
  o Do not eat or drink until cleared by the physician

☐ If admitted to hospital, treatment may include intravenous immunoglobulin (IVIG) or plasma exchange (PLEX)
  o The treatment team should include a neurologist and pulmonologist

☐ Once stable, contact your primary neurologist to inform him or her of what has occurred and your status

☐ At the time of hospital discharge, call your neurologist to make a follow-up appointment in 1-2 weeks
INPATIENT MANAGEMENT
INPATIENT MANAGEMENT

- Admit to an IMU or ICU
- Stop any contributing medications
  - Including pyridostigmine
- Regular monitoring of PFTs
- Start non-invasive ventilation, if possible
  - Can prevent/delay intubation in over 50% of patients with myasthenia
- Intubation
  - Consideration of elective intubation
- Cardiac monitoring
  - Severe arrhythmias ~20% of patients
B  Proposed Treatment for Severe Exacerbations of Generalized Myasthenia Gravis

Intensive care
IV immune globulin or plasma exchange
Treatment of infection and other precipitating events

Improvement?

Yes → Intensify long-term immunosuppression

No

Plasma exchange or IV immune globulin
Glucocorticoids in megadose
Intensive care

Improvement?

Yes → Intensify long-term immunosuppression

No

Rituximab
Intensive care
Treatment of complications
Other immunosuppressive drugs
Never give up

• Infusion of purified pooled preparations of IgG antibody from plasma

• Immunomodulation through several mechanisms

• 2g/kg of patient weight divided over 4-5 days

• Use in caution in patients with cardiac/vascular history, including DVT, and in patients with kidney disease

**IV Immunoglobulin**

- Infusion-related events
  - Headache
  - Shivering
  - Myalgia
  - Chest pain
  - Hyperviscosity (risk of thrombosis, including arterial events)
  - Aseptic meningitis
  - Acute kidney injury
  - Anaphylaxis (if IgA deficiency)
  - Transfusion reaction (including transfusion-related acute lung injury)

IgA = immunoglobulin A; IV = intravenous.
**PLASMA EXCHANGE (PLEX)**

- Directly removes immune factors such as autoantibodies, immune complexes, complement, and other non-specific inflammatory mediators
- 5 sessions scheduled every other day
- May require central venous catheter
- Use for caution in patients with infection, high bleeding risk

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**Plasma Exchange**

- Venous catheter-related events
  - Infection
  - Pneumothorax
  - Local hematoma
- Hemodynamic instability (hypotension)
- Hemoconcentration
- Coagulopathy (mild)
- Hypocalcemia
- Removal of highly protein-bound drugs
- Transfusion reaction (including transfusion related acute lung injury)
Both IVIG and PLEX have similar effectiveness in treating myasthenia gravis exacerbation/crisis.

PLEX may result in a more rapid effect.

If incomplete effect from PLEX, IVIG may be given subsequently.

Decision depends on clinical patient characteristics, safety/tolerability, previous response, other patient specific factors.

Figure 1: Treatment and outcome

Days in the intensive care unit (ICU) (A) and days of mechanical ventilation (B) of patients who were treated with immunoadsorption (IA) or plasma exchange (PE) (IA/PE, n = 56), IV immunoglobulins (IVig; n = 66), IA or PE in combination with IVig treatment (IA/PE + IVig; n = 43), or without IA, PE, or IVig (none; n = 34). Decedents (n = 30) and cases where the number of days of ventilation was not known exactly (n = 21, e.g., because of ventilation at discharge or transfers from other hospitals) were excluded. Bars show mean ± SD.

• Corticosteroids
  – Often a part of the treatment plan for MG crisis
  – Must be used with caution as rapid administration or high dose steroids may cause worsening
    • Less likely in patients being treated with IVIG or PLEX
  – For non-intubated patients, doses should be started lower (10-20mg) and increased by 5mg every 2-3 days; goal typically 60-80mg/day
  – For intubated patients, higher initial doses may be tolerated
PREVENTION
• Symptomatic Treatment
  – Pyridostigmine
    • Acetylcholine esterase inhibitor
    • Dosing variable
    • Side Effects: GI upset, increased saliva, increased tearing, runny nose, muscle cramping, muscle twitching

IgG antibodies recycle through FcRn...

efgartigimod potently blocks FcRn...

Leading to IgG elimination

THYMECTOMY

• Can be considered to improve long-term control of MG symptoms
  – Recommended for patients under 65yo and either AchR Ab+ or seronegative status
  – Usually earlier on in disease course and/or in patients with more severe and harder to control myasthenia gravis
  – Patient should be stable enough for surgery
  – Endoscopic surgery is preferred approach
  – May have preoperative use immunomodulatory therapy

• Surgery is recommended for thymoma regardless of age, disease severity, or antibody status

Randomized Trial of Thymectomy in Myasthenia Gravis

Gil I. Wolfe, M.D., Henry J. Kaminski, M.D., Inmaculada B. Aban, Ph.D., Greg Minisman, M.A., Hui-Chien Kuo, M.S., Alexander Marx, M.D., Philipp Ströbel, M.D., Claudio Mazia, M.D., Joel Oger, M.D., J. Gabriel Cea, M.D., Jeannine M. Heckmann, M.B., Ch.B., Ph.D., Amelia Evoli, M.D., et al., for the MGTX Study Group

A Quantitative Myasthenia Gravis Score

<table>
<thead>
<tr>
<th>Visit Month</th>
<th>Mean Score</th>
<th>Prednisone Alone</th>
<th>Mean Score</th>
<th>Thymectomy + Prednisone</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>12</td>
<td>9</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>9.5</td>
<td>7.5</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>8.5</td>
<td>7</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>7.5</td>
<td>6</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>6.5</td>
<td>5</td>
<td>2.5</td>
<td></td>
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<tr>
<td>30</td>
<td>5.5</td>
<td>4</td>
<td>1.5</td>
<td></td>
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<tr>
<td>36</td>
<td>4.5</td>
<td>3</td>
<td>0</td>
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</table>

B Prednisone Dose

<table>
<thead>
<tr>
<th>Visit Month</th>
<th>Mean Dose (mg)</th>
<th>Prednisone Alone</th>
<th>Mean Dose (mg)</th>
<th>Thymectomy + Prednisone</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
<td>90</td>
<td>80</td>
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<tr>
<td>6</td>
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<tr>
<td>18</td>
<td>50</td>
<td>40</td>
<td>30</td>
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<td>24</td>
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<td>30</td>
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<tr>
<td>36</td>
<td>20</td>
<td>10</td>
<td>0</td>
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Table 2. Primary and Subgroup Analyses of the Primary Outcomes.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Prednisone Alone</th>
<th>Thymectomy plus Prednisone</th>
<th>Estimated Difference (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>value</td>
<td>no. of patients</td>
<td>value</td>
<td>no. of patients</td>
</tr>
<tr>
<td>Primary analyses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time-weighted average QMG score over 3-yr period</td>
<td>8.99±4.93</td>
<td>56</td>
<td>6.15±4.09</td>
<td>62</td>
</tr>
<tr>
<td>Time-weighted average alternate-day prednisone dose over 3-yr period (mg)</td>
<td>54±29</td>
<td>56</td>
<td>32±23</td>
<td>61</td>
</tr>
<tr>
<td>Subgroup analyses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time-weighted average QMG score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisone use at enrollment</td>
<td>0.86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9.10±5.06</td>
<td>46</td>
<td>6.30±3.89</td>
<td>47</td>
</tr>
<tr>
<td>No</td>
<td>8.84±4.60</td>
<td>9</td>
<td>5.66±4.79</td>
<td>15</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9.73±5.16</td>
<td>38</td>
<td>6.47±4.13</td>
<td>46</td>
</tr>
<tr>
<td>Male</td>
<td>7.45±4.11</td>
<td>18</td>
<td>5.23±3.95</td>
<td>16</td>
</tr>
<tr>
<td>Age at disease onset</td>
<td>0.74</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40 yr</td>
<td>9.60±5.32</td>
<td>34</td>
<td>6.50±4.41</td>
<td>42</td>
</tr>
<tr>
<td>≥40 yr</td>
<td>7.85±3.50</td>
<td>18</td>
<td>5.33±2.79</td>
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<tr>
<td>Time-weighted average alternate-day prednisone dose (mg)</td>
<td>0.91</td>
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<tr>
<td>Prednisone use at enrollment</td>
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</tr>
<tr>
<td>Yes</td>
<td>56±31</td>
<td>46</td>
<td>35±25</td>
<td>46</td>
</tr>
<tr>
<td>No</td>
<td>45±22</td>
<td>9</td>
<td>25±17</td>
<td>15</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>54±27</td>
<td>37</td>
<td>33±25</td>
<td>45</td>
</tr>
<tr>
<td>Male</td>
<td>55±34</td>
<td>19</td>
<td>31±18</td>
<td>16</td>
</tr>
<tr>
<td>Age at disease onset</td>
<td>0.81</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40 yr</td>
<td>55±30</td>
<td>33</td>
<td>35±25</td>
<td>41</td>
</tr>
<tr>
<td>≥40 yr</td>
<td>49±29</td>
<td>19</td>
<td>27±18</td>
<td>18</td>
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</tbody>
</table>

* CI denotes confidence interval.
† We used 95% confidence intervals in all analyses except for analyses involving the QMG score, for which we used 99.5% confidence intervals, per protocol.
‡ P values for between-group comparisons are based on two independent sample Student’s t-tests. P values for interaction with treatment were based on fitting a general linear model separately for each variable.

Fatigue present in about 80% of patients with MG

Management can include

- Cognitive behavioral therapy
- Weight Reduction
- Pain control


• **Exercise**
  - Able to be tolerated in most patients with MG
  - Aerobic exercise performed with more rest periods
  - Balance and stretching exercises
  - Avoidance of high temperatures
  - Type and length of exercise dependent on clinical/physical status

• **Diet**
  - Low gluten, avoid processed sugars, increased fruits and vegetables
  - Plant based
  - Evaluation of the gut microbiome

ADDITIONAL RECOMMENDATIONS

• Early and accurate diagnosis

• Close outpatient monitoring
  • Especially early in disease course

• Patient and Provider Education
  – Early identification of exacerbation symptoms

• Management of Comorbidities

• Vaccinations
  – Including COVID-19 vaccination & booster
CONCLUSION

- Myasthenia gravis exacerbations are common though most are mild
- About 15% of patients with MG will experience a myasthenia gravis crisis requiring respiratory support
- Be prepared with medication list, medications to avoid, name of neurologist, and information on recent health changes
- Close monitoring of pulmonary function
  - Oxygen saturation is not a reliable measure of respiratory distress
  - May include elective intubation
- The majority of patients who experience an exacerbation or crisis will make a full recovery
CONCLUSION

• Older patients and those with another autoimmune condition are more likely to experience an exacerbation

• Prevention includes
  – Establishing care with a neurologist/neuromuscular specialist early
  – Management of comorbidities, vaccination, and education
  – Achieving effective long-term treatment

• Recommend exercise and healthy diet
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NO TWO THE SAME

MYASTHENIA GRAVIS

thank you