Everything you ever wanted to know about IVIG, and more!

Michelle Greer RN
What exactly is IVIG?

- Intravenous Immune Globulin
  - Immune Globulin – antibody, protein, Y-shaped, protect from foreign invaders – most common is IgG
  - Found in blood plasma
    - Human donors – takes thousands to make one dose
    - Plasma is treated to deactivate any potential viral contamination
    - Plasma is purified so that contents are as much IgG as possible and minimize other plasma contents
What exactly is IVIG?

• There is no generic form – impossible to replicate an antibody in a lab
• There are several brands which have variances:
  – Manufacturer and their process for viral deactivation and purification, therefore, contents etc.
  – Form – powder or liquid
  – Labeled indications
  – Cost
## Current Brands of IVIG

<table>
<thead>
<tr>
<th>Brand</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Sugar Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carimune® NF</td>
<td>CSL Behring</td>
<td>3% or 6%</td>
<td>Sucrose</td>
</tr>
<tr>
<td>Flebogamma®</td>
<td>Grifols</td>
<td>5% and 10%</td>
<td>None</td>
</tr>
<tr>
<td>Gammagard Liquid</td>
<td>Baxter</td>
<td>10%</td>
<td>None</td>
</tr>
<tr>
<td>Gammagard SD LIGA</td>
<td>Baxter</td>
<td>5%</td>
<td>Glucose</td>
</tr>
<tr>
<td>Gammagard SD</td>
<td>Baxter</td>
<td>5%</td>
<td>Glucose</td>
</tr>
<tr>
<td>Gammaked™</td>
<td>Kedrion</td>
<td>10%</td>
<td>None</td>
</tr>
<tr>
<td>Gammaplex</td>
<td>BPL</td>
<td>5%</td>
<td>Sorbitol</td>
</tr>
<tr>
<td>Gamunex®-C</td>
<td>Grifols</td>
<td>10%</td>
<td>None</td>
</tr>
<tr>
<td>Octagam®</td>
<td>Octapharma</td>
<td>5%</td>
<td>Maltose</td>
</tr>
<tr>
<td>Privigen®</td>
<td>CSL Behring</td>
<td>10%</td>
<td>None</td>
</tr>
</tbody>
</table>
How is it administered?

- Usually through a vein in your arm
- If you have difficulty with IV access, central line in chest is an option – more long term
- Slowly – most reactions occur when it is run too quickly
  - Infusion rates are specific to each individual
  - Package insert is the maximum rates for anyone, but side effects tend to decrease the more slowly it is infused
Administration continued

• Start slowly and gradually increase as tolerated
• MD or Pharmacist will determine rates
How is the dose determined?

• By weight and diagnosis

EXAMPLE:
Someone with myositis is typically prescribed 2 grams per kilogram.
80 kg person = 160 grams
This would likely be broken up into 4 days of 40 gram each day
Dosing and Administration cont’d

40 grams each day should take about 3-5 hours depending on:

- MD orders
- Any prior treatment with IVIG and how it was tolerated
- How the individual actually tolerates IVIG when administered
- What the package insert for the brand used says
- Any rate restrictions for cardiac or renal issues
Dosing and Administration cont’d

Example – Privigen Prescribing Information

Intravenous Administration Only: ITP and CIDP;
*no brand is labeled for myoitis

<table>
<thead>
<tr>
<th>Indication*</th>
<th>Dose</th>
<th>Initial Infusion Rate</th>
<th>Maintenance Infusion Rate (if tolerated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>200-800 mg/kg (2-8 mL/kg) every 3-4 weeks</td>
<td>0.5 mg/kg/min (0.005 mL/kg/min)</td>
<td>Increase to 8 mg/kg/min (0.08 mL/kg/min)</td>
</tr>
<tr>
<td>ITP</td>
<td>1 g/kg (10 mL/kg) for 2 consecutive days</td>
<td>0.5 mg/kg/min (0.005 mL/kg/min)</td>
<td>Increase to 4 mg/kg/min (0.04 mL/kg/min)</td>
</tr>
</tbody>
</table>
What are the side effects of IVIG?

Severe adverse reactions

- Anaphylaxis
- Renal Failure
- Thrombotic Event
- Aseptic Meningitis Syndrome
- Hemolytic Anemia

Infusion-related reactions

- Headache
- Blood pressure changes
- Nausea
- Vomiting
- Dizziness
- Fever
- Fatigue
- Chills
What should be done before the infusion?

• Take any prescribed premedications
• Make sure the IVIG is room temperature before it is infused
• Unless it’s contraindicated, hydrate!
• Nurse should take baseline vital signs
What should be done during the infusion?

- Vital signs should be taken prior to any rate changes/increases and at least every 30 minutes
- If you have any side effects tell the nurse
Where is the IVIG administered?

- Hospital outpatient infusion center
- Hospital
- Physician’s office infusion suite
- Home
  - Place of employment

*Wherever you receive it, the nurse administering it should have experience and knowledge with IVIG!*
Why and when is it used for myositis?

• PM and DM
  – When other therapies are not controlling the condition
  – When other medications are causing intolerable side effects
    • Prednisone
    • immunosuppressants
• IBM
  – To improve swallowing
    • Some small studies done
How does it work?

• Not completely understood, many theories
• Myositis thought to be autoimmune disease
  – Autoimmune disease is where the immune systems perceives part of the body as foreign and attempts to destroy it
  – IVIG suppresses the immune response
  – IVIG has anti-inflammatory properties
How is IVIG covered by my insurance?

- Almost every insurance requires prior authorization for IVIG
- Almost every insurance has a medical policy outlining how IVIG is approved.
- You must prove you have myositis
- You must demonstrate lack of response or toleration of other medications
From TMA’s website:

For a diagnosis of dermatomyositis, patients must present with at least one of the skin symptoms listed in "skin lesions" and four of the remaining symptoms.

For a diagnosis of polymyositis, patients present with no skin symptoms and four of the remaining criteria.

- Proximal muscle weakness (upper or lower extremity and trunk)
- Elevated serum CK (creatinine kinase) or aldolase level
- Muscle pain on grasping or spontaneous pain
- Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
- Positive anti-Jo-1 (histadyl tRNA synthetase) antibody
- Nondestructive arthritis or arthralgias
- Systemic inflammatory signs (fever: more than 37° C at axilla, elevated serum CRP level or accelerated ESR [erythrocyte sedimentation rate] of more than 20 mm/h by the Westergren method)
- Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen)
From TMA’s website

Skin lesions

- Heliotrope rash (red purple edematous erythema on the upper palpebra)
- Gottron's sign (red purple keratotic, atrophic erythema, or macules on the extensor surface of finger joints)
- Erythema on the extensor surface of extremity joints: slightly raised red purple erythema over elbows or knees

Coverage

• Most insurances have some form of these criteria in their coverage policy (Aetna is exact wording)

• For IBM, it is typically excluded from criteria as not covered
  – Small studies done don’t carry a lot of weight with insurances as evidence it is effective
  – Some will allow one or two courses to see if there is benefit
So what do I need to know about IVIG?

- Decide with your physician if it’s a therapy for you as well as
  - Where you want to receive it
  - Confirmation that it’s covered and how by your insurance
  - The nurse administering it has experience with IVIG administration
  - Know the side effects and how you can minimize and manage them