Challenges in Diagnosis and Management of Typical CIDP

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Clinical Neurological Society of America

Disclosures

- Johnson & Johnson Speaker Bureau member, UCB Pharma Company Speaker Bureau member, Amgen Biotechnology Company Advisory Board member, France Foundation Speaker.

OBJECTIVES

- Review clinical features of typical CIDP
- Learn diagnostic criteria for typical CIDP
- Review updated evidence-based treatments for CIDP
- Discuss tapering IVIg treatment regimen

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Typical CIDP Clinical Features

- **Slow onset progressive "8-10 weeks to months" weakness and sensory deficit**
  - **occasionally acute/subacute onset in relapsing form (<10%)**
- **Patients present with motor > sensory symptoms**
  - **weakness proximal & distal is most disabling feature**
  - **usually symmetric (except in CIDP variants)**
- **Weakness can be more prominent than muscle atrophy**
- **Sensory deficit usually mild distal large > small fibers, legs > arms. Pain ± 20%, especially in sensory variant**
- **Cranial nerves dysfunction in ≤ 15% (ophthalmoplegia, facial or bulbar weakness)**
- **Tendon reflexes reduced or absent early in 90%**
- **Occasional manifestations autonomic dysfunction & CNS features, papilledema, tremor**
- **Sphincters are typically spared**

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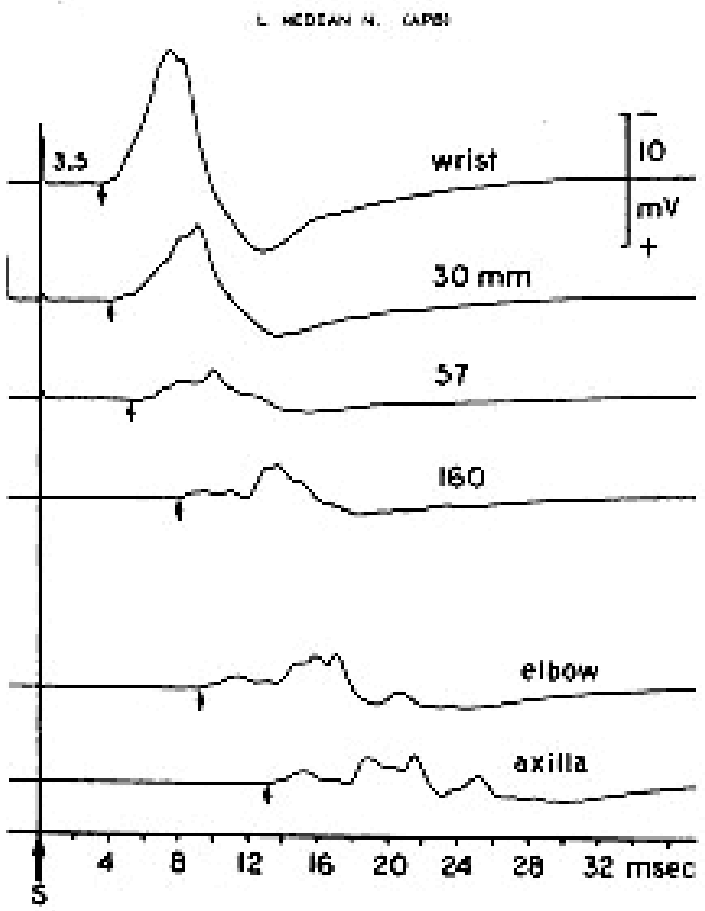
Electrophysiology Features of Demyelination;

- Variable slow motor & sensory conduction velocity (≥30% below lower limit of normal).
- Motor distal latency ≥50% of ULN (excluding median at wrist)
- Conduction block, segmental slowing, dispersion, prolonged DL
- Prolonged F- waves latency (≥20% ULN) and non-persistence
- Reduced amplitude of CMAP and SNAP correlates degree of axonal degree of axonal loss
- Source of errors;
  - interpreting conduction changes in nerves with low amplitude
  - over dependence on changes in distal lower extremities
  - not aware of various conduction changes in diabetes
- **Testing of multiple limbs is more sensitive than only unilateral or lower limbs to optimize EDXs diagnosis.**



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Electrodiagnostic Criteria and Certainty for CIDP Diagnosis (as used in the 2010 EFNS/PNS guideline)

- ***Definite;*** at least one of the following in **2 nerves;**
  - ≥ 50% prolongation of DL
  - ≥ 30% reduced MCV
  - ≥ 20% prolongation, or absent F-wave, (excluding tibial)
  - ≥ 50% reduced proximal CMAP amplitude, or ≥ 30% proximal dispersion (excluding tibial nerve)
- ***Probable:***
  - ≥ 30% reduced proximal CMAP amplitude in **2 nerves**
  - or in one nerve plus at least one other nerve with demyelinating parameter (excluding tibial nerve)
- ***Possible;***
  - As in "Definite CIDP" but in only **one nerve**

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- ***Possible;***
  - As in "Definite CIDP" but in only **one nerve**

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The 2021 EFNS/PNS Guidelines - Update

Major changes;

- Simplified certainty levels: CIDP and possible CIDP only
- Eliminated “Definite or Probable CIDP” – no gold standard exists
- No significant evidence-based difference between “probable” and “definite” criteria.

Performance Metrics:

- Sensitivity for “CIDP” 83.3%
- Sensitivity for “CIDP” or “Possible CIDP” is 93.3%
- Specificity for “CIDP” is 94%
- Specificity for “Possible CIDP” is 79%

European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of CIDP – European Journal of Neurology 2022 Jan;29(4):1288

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Typical CIDP Diagnostic Criteria

Clinical Criteria “all required”:

- Progressive or relapsing symmetric proximal and distal weakness
- Sensory involvement of at least two limbs
- Developing symptoms over ≥ 8 weeks
- Absent or reduced tendon reflexes in all limbs

Electrodiagnostic Criteria:

- Motor: Abnormalities in ≥2 nerves = CIDP diagnosis
- Abnormalities in 1 nerve = possible CIDP
- Sensory: Abnormalities in ≥2 nerves required

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To support diagnosis of CIDP in patients who fulfill clinical criteria for CIDP, but whose electrodiagnostic criteria only allow for possible CIDP

CSF

Imaging

Response to Treatment

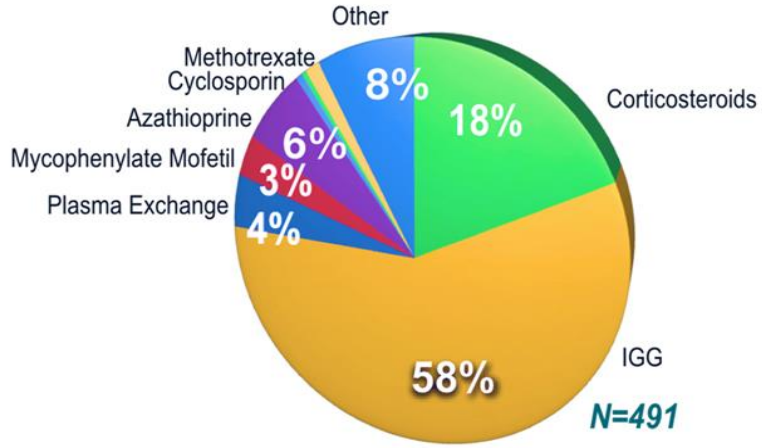
- CSF protein elevation should be interpreted cautiously in diabetics and be aware of higher normative in elderly.
- CSF protein is significantly more common in typical CIDP than in multifocal CIDP.
- MRI T2 to show enlargement and/or increased signal intensity of nerve roots
- Ultrasound to show nerve enlargement of at least two sites in proximal median nerve segments and/or brachial plexus, but not in pediatric patients.
- Objective clinical response to 4 IVIg courses.

CIDP Therapy with RCT Efficacy ;

First Line Therapy

- **Corticosteroids**
- **Immunoglobulin**
- **Plasma Exchange**

- **Other** Treatments



60 t0 70% of Patients responds to one of the 1st line therapy.

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Corticosteroids in CIDP

- 40-95% response rate with high dose prednisone, onset at 2 M, peak at 3-6 M.
- Prednisone 60-100 mg/d x 2-4 wks, then 100 mg qod then re-evaluate at 3 months, Maintenance dose of 5 – 15 mg is often necessary
- Or pulsed oral Dexamethasone 40 mg/d for 4 days monthly
- Or IV pulse methylprednisolone 1g x 4 days/week for 4 weeks, then 1g on day 1 each week/4 weeks, then 1g/month for 2 months, then tapering frequency and dose
- Motor CIDP is less responsive to corticosteroids or may deteriorates

Jama Neurology 2005;62(2):249-254
Dalakas & Engel Ann Neurol 1981, Dyck et al Ann Neurol 1982
Molenaar et al JNNP 1997, Lopate at al Arch N 2005 ,Muley et al Arch N 2008

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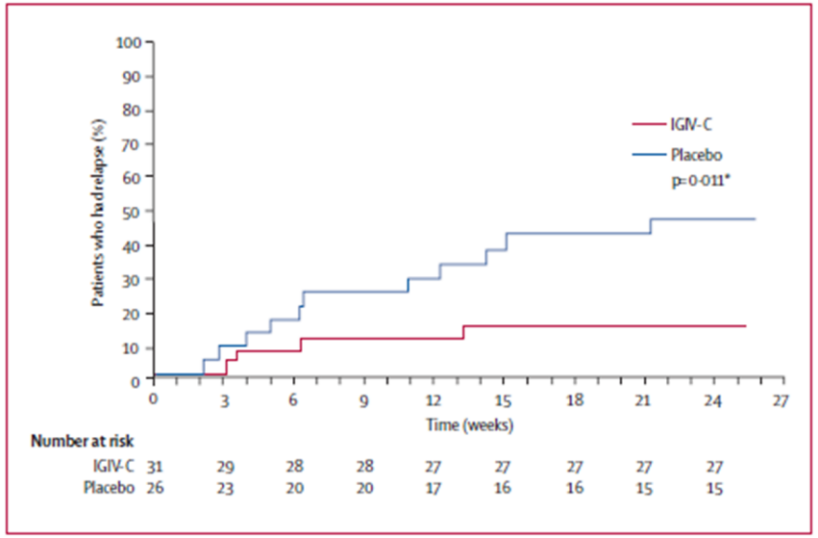
IVIg in CIDP

- **Equivalent to prednisone – though no head-to-head comparison**
- **Initial dose 2g/kg over 2-4 days, followed by 1g/kg every 3 – 4 weeks**

  (Serum IgG declines by 50% at 3 days, back to baseline in 3 to 4 weeks
- **3 to 5 courses may be required to determine response .**
- **63-76% response rate, up to 90% in selected cases**
- **Often requires chronic maintenance.**
- **Upon maximal sustained improvement lower doses and longer**

  intervals should be considered (e.g. 0.4-1g/kg every 2-6 weeks).
- **Remission rate 37% (PATH), 50% ICE trial .**



Hahn et al Brain 1996:1067-77, Mendell et al Neurology 2001;56:445-9, Hughes et al. Ann N 2001;50:195-2001
Lancet Neurol. 2008 Feb;7(2):136-44, Lancet Neurol. 2018 Jan;17(1):35-46

CIDP: Plasma Exchange (PLEX)

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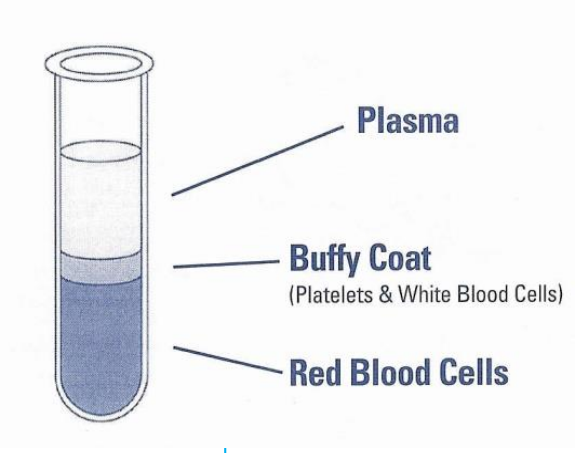
- Each PLEX reduces IgG by 45%; 3-5 PLEX removes 90%
- 2 RCTs demonstrated transient clinical & NCS improvement, however most responders relapsed in 3 weeks
- Efficacy equivalent to that of IVIG – no head-to-head study
- Induction therapy 5 - 10 exchanges of 50 mL/kg plasma volume on alternate days within 2 – 4 weeks, followed by 1 – 2 sessions every 3 -4 weeks
- Due to logistic challenges and AE's it is considered for patients with CIDP ref to IVIg and corticosteroids
- AEs venous catheter placement, hypotension, allergy, cardiac arrhythmia, va hypocalcemia, anemia, thrombocytopenia and citrate toxicity



Dyck PJ et al NEJM. 1986:461-5 . Hahn AF et al Brain 1996:1055-66
Dyck PJ et al Ann N 1994:838-45

Subcutaneous IG in CIDP Treatment (PATH study)

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- PATH Trial RC parallel-group 3-arm study to investigate 2 different doses of SC Ig compared with placebo over 24 weeks
- CIDP patients with active disease who are responsive to IVIg therapy
- Approved in 2018 for CIDP maintenance therapy
- Calculated weekly/biweekly equivalent to IV dose is 0.2 – 0.4 g/kg/w self administer
- 1 or 2 infusion pumps each about 20 cc/hr/port
- Stable IG trough levels and avoid wear-off effects
- Comparable efficacy and lower systemic AEs
- Dose 1 : 1 as IVIg divided over weekly/biweekly (0.33 g/kg/W versus 1 g/kg/3 Ws)

(Lancet Neurl. 2018 Jan; 17 (1): 35-46)

(Beydoun SR, Sharma KR, Bassam BA et al. Frontier in Neu 2021)

frontiers in Neurology

MINI REVIEW
published: 06 March 2021
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Individualizing Therapy in CIDP: A Mini-Review Comparing the Pharmacokinetics of Ig With SCIg and IVIg

Said R. Beydoun[1], Khema R. Sharma[2], Bassam A. Bassam[3], Michael T. Pulley[4], Jeffrey Z. Shije[4] and Ayman Kafal[5]*

Treatment Importance of Patient Perspective

IVIg and/or SCIg benefits vary among patients based on their lifestyle & priorities

Patient who is more suitable for IVIg	Patient who is more suitable for SCIg
• Lacking skill, confidence, dexterity or support network • At risk for non-treatment compliance • Preferring less frequent infusions • At risk for excessive bruising and/or subcutaneous bleeding tendency	• Poor venous access • Experiencing intractable side effects with IVIg infusion • Treatment-related fluctuations between IVIg infusion cycles • Wanting more autonomy • Preferring shorter, more frequent infusions

HCP Healthcare provider

Beydoun SR, et al. Front Neuro 2021;12

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CIDP Pathogenesis	IVIg Immunomodulation therapy
• B & T cells activation	• Regulates B & T cells activation
• FC receptors activation	• Blocks & modulates FcRN receptors
• Proinflammatory cytokines and adhesion molecules	• Reduces proinflammatory cytokines & adhesion molecules
• Complement activation	• Inhibits complement activation
• Autoantibodies	• Neutralize pathogenic antibodies
	• Inhibits macrophages via Fc-gamma receptors

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Dalakas M. Mechanism of action of IVIg .. Neurology (2002) 24;59 (12 Suppl 6) 513-21.

Tapering Regimen of IVIg

- The primary goal is to find the lowest effective dose or to discontinue IVIg.
- EAN/PNS recommends considering stepwise reduction once every year in stable pts., however, no standardized tapering regimen.
- Common Tapering Methods;
  - Dose reduction every 6 -12 weeks to 75%, then 50%, then 25% then 0%.
  - Or interval extension from 3 – 4 weeks to 6 weeks, then 8 weeks, then discontinue.
  - Each step in the reduction process should be monitored 6 to 12 weeks for signs of deterioration.
- Prior studies showed 28 – 30% success with no relapse in 60 weeks follow-up, and 97% of relapses occurred within 12 weeks
  (Adrichem ME, et al. Brain 2022;145(5):1641-52. Gorson KC, et al. J Periph Ner Syst 2010;15(4):326-33)
- Tapering of SCIg in a 55 patient's; 35 relapsed, and 20 (36%) no relapse after 2 years. In relapsing patients median dosage successfully reduced by 10%
  (Markvardsen LK, et al. Journal of Neuromuscular Diseases 2023;10:787-96)

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2nd Line Therapy in CIDP

- Azathioprine 2 - 3 mg/kg/day
- Methotrexate* 25 mg/week

3rd Line Therapy in CIDP

- Rituximab
- Cyclosporine 3 -6 mg/kg/day
- Mycophenolate -mofetil 2 – 3 gm/day
- Cyclophosphamide 1.5 – 2 mg/kg monthly IV pu 3 - 6lse

- **New Therapy in CIDP**
  - "efgartigimoid alfa and hyaluronidase" SC .

JRMC Trial Group Lancet Neurol 2009; 8: 158–64
Neurol Neurosurg Psychiatry 2011;82:306-308
The Lancet Neurology 2024;10:1013-1024

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CLINICAL RESEARCH ARTICLE

MUSCLE&NERVE WILEY

Rituximab in refractory chronic inflammatory demyelinating polyneuropathy

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Abstract

Introduction: Chronic inflammatory demyelinating polyneuropathy (CIDP) is a disorder in which early effective treatment is important to minimize disability from axonal degeneration. It has been suggested that some patients with CIDP may benefit from rituximab therapy, but there is no definitive evidence for this.

Methods: Baseline and post–rituximab-therapy neuromuscular Medical Research Council (MRC) sum scores, Inflammatory Neuropathy Cause and Treatment (INCAT) disability score, and functional status were assessed in 11 patients with refactory CIDP.

Results: The MRC sum score, INCAT disability score, and functional status improved in all patients after rituximab therapy.

Discussion: Our study provides evidence of the efficacy of rituximab therapy in at least some patients with CIDP. A placebo-controlled study to assess the effectiveness of rituximab therapy in CIDP with and without nodal antibodies is required to identify disease markers that predict responsiveness.

KEYWORDS

CIDP, neuropathy, refractory, rituximab, treatment

Rituximab Efficacy in CIDP

- Rituximab is considered in refractory CIDP patients and some CIDP variants.
- Rituximab is an anti-CD20 monoclonal antibodies that depletes immune cells responsible for making antibodies that attack peripheral nerves.
- The dose vary depending on patient's weight, overall health and response
    - Induction dose is 1000 mg twice two weeks apart, maintenance dose 1000 mg every 6 months.
- Treatment significantly improves overall motor and sensory neurological disability in some patients.
- Disability scores and nerve conduction studies demonstrate significant improvement with Rituximab treatment.
- It is essential to consider AEs "infusion reaction, fever, chills, rash, infection, headache, nausea, fatigue"

Thomas Roux et al. J Peripheral Nerv Syst; 2018, Dec (23)4.

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Immunosuppressive Agents

- Are often used together with corticosteroids to reduce the need for IVIg or PE, or in none responders' patients.
- No RCTs have been reported (class VI), except for Azathioprine
- Azathioprine showed no benefit in 2 CTs when added to prednisone

(Dyck et al., and Hughes et al.)

- Cyclosporine 2.5 mg/kg/ day, then taper to minimum effective dose in refractory cases, or when prednisone is not indicated
- Methotrexate; 7.5 to 25 mg p.o. on weekends

(RMC Trial Group Lancet Neurol 2009; 8: 158–64)

- Cyclophosphamide; monthly IV pulse x 6; for refractory patients
- β-Interferon in a large BPC study showed no benefit

(open label small study showed improvement in 56% (Vallat et al).

- Oral Fingolimod study results negative (FORCIDP trial)

(Lancet Neurol. 2018 Aug;17(8):689-698)

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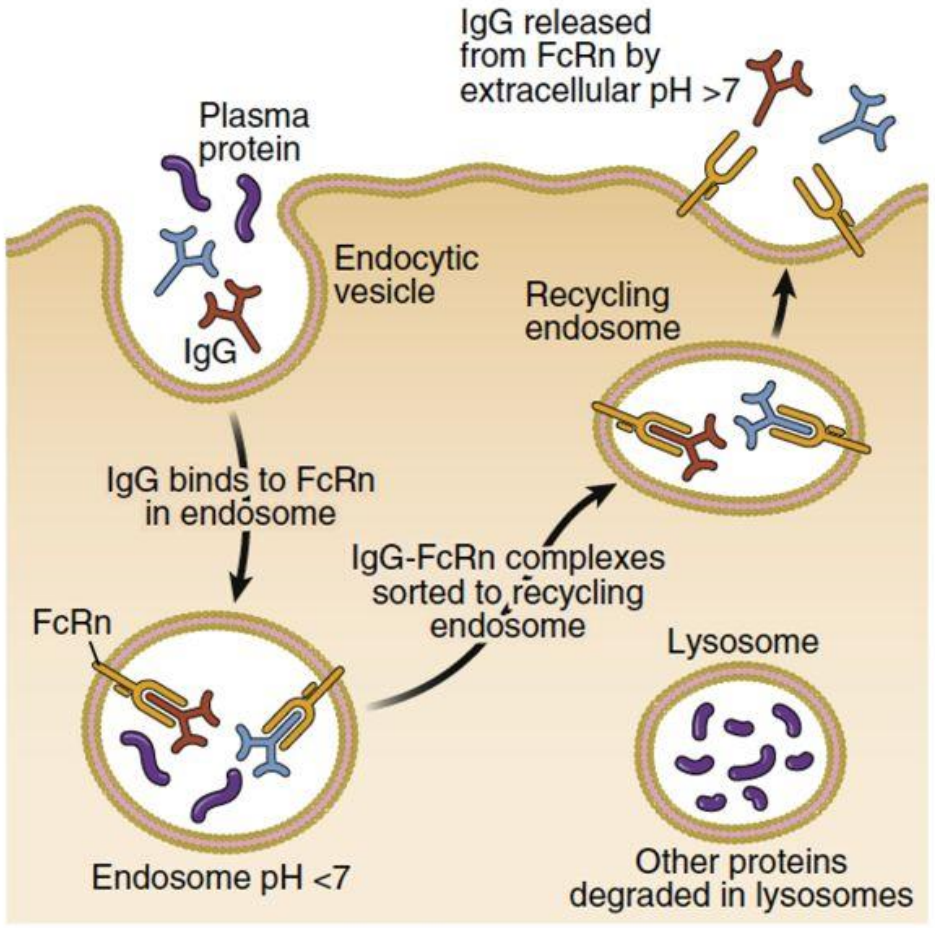
IgG recycling by "neonatal" FcR (FcRn)



Abbas, Lichtman and Pillai. *Basic Immunology 5th edition 2015, Elsevier*

New Therapy in CIDP

- FDA approved efgartigimod alfa - hyaluronidase SC June 2024
- ADHERE/ADHERE+ multicenter RBCT
  - A neonatal Fc receptor blocker and an endoglycosidase that increase absorption
  - Stage A showed 221out of 322 showed improvement on lNCAT, grip strength, and ADL
  - Stage B showed maintained function on an INCAT measured weekly
  - Reduced risk of CIDP getting worse was 61% lower
  - Weekly subcutaneous injection (1,008 mg/ 11,200 units) given by health professionals over 30 to 90 seconds.
  - Most common AEs included infection (respiratory & urinary), headache, muscle pain, and injection site reaction.

The Lancet Neurology 2024;10:1013-1024

The indication to switch and the place of FcRN inhibitor in CIDP therapy ?.

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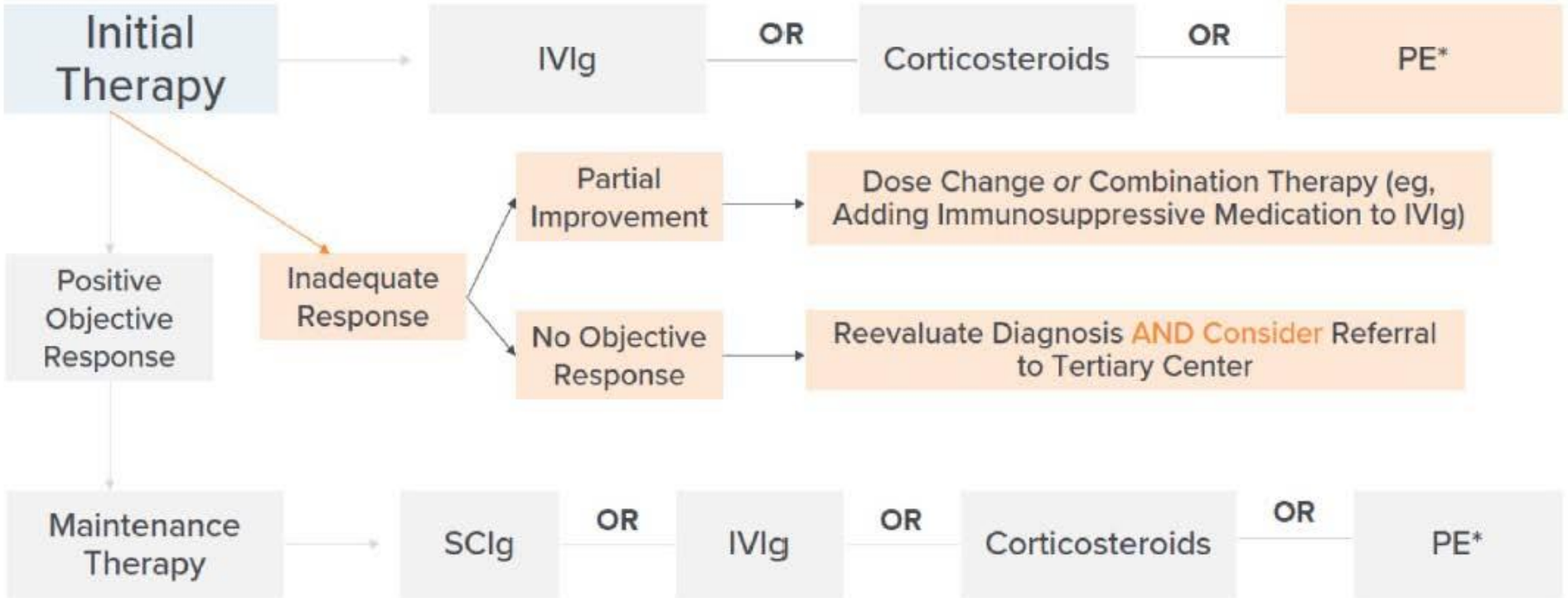
Treatment Options: Inadequate Response to Initial Therapy



IVIg, intravenous immunoglobulin; PE, plasma exchange; SCIg, subcutaneous immunoglobulin.
*PE should be considered when patients do not respond to IVIg or a corticosteroid; it may also be an initial option for severe CIDP when a rapid response is needed.
Van den Bergh PYK, et al. J Peripher Nerv Syst. 2021;26:242-268; Ryan M, et al. Am J Manag Care. 2018;24(17 suppl):S371-S379.

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Refractory CIDP: High Dose IVIG

INTERNATIONAL JOURNAL OF NEUROSCIENCE, 2016
http://dx.doi.org/10.1080/00207454.2016.1269328

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

A new treatment regimen with high-dose and fractioned immunoglobulin in a special subgroup of severe and dependent CIDP patients

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ABSTRACT

Background: Chronic inflammatory demyelinating polyneuropathy (CIDP) is treated with intravenous immunoglobulins (IVIg), corticosteroids or plasma exchange (PE). IVIg dosage is not universal and markers for treatment management are needed. *Methods:* We report the response to high-dose and fractioned IVIg in a subgroup of definite CIDP patients, resistant to corticosteroids and PE, responders to IVIg but with an efficacy window <15 d. *Results:* Four patients were included with similar predominantly clinical motor form and conduction abnormalities. Treatment management consisted of fractioning IVIg and increasing the monthly cumulated dose (mean: 3 g/kg/month). Serum IgG concentration was measured and correlated to the clinical state. Monitoring of serum IgG helped to guide IVIg administration dosage and frequency. A mean of 10 months was required to improve symptoms; therapy was then switched to subcutaneous (SC) route (maintenance dose: 3.5 g/kg/month). The mean Overall Neuropathy Limitations Scale was improved from 11 to 3.2 and the mean Medical Research Council scale from 26 to 90. *Conclusion:* It is important to distinguish patients with short IVIg efficacy window from those with classical resistance since the former may benefit from fractioning and increasing the IVIg dose. The monitoring of serum IgG level and its correlation to the clinical response could be of help in monitoring each individual's dosage.

ARTICLE HISTORY
Received 21 September 2016
Revised 25 November 2016
Accepted 3 December 2016

KEYWORDS
Chronic inflammatory demyelinating polyneuropathy (CIDP); resistant CIDP; serum IgG monitoring; intravenous immunoglobulin (IVIg); subcutaneous immunoglobulin (SCIg)

Introduction

We report our experience in treatment management

Measuring Treatment Effect in CIDP

- In one study, 47% (N=27) of cases were misdiagnosed as CIDP
- 2/3 misdiagnosed cases reported subjective improvement with IVIg
- Since response to treatment is part of the supportive criteria for CIDP, it is important to employ objective, reliable and validated yardsticks
- Start by asking about impact of CIDP on self care (ADLs)
- Monitor with a combination of patient reported outcome measures and objective assessments
- Selecting metrics that are easy to use and quick to administer is important in the clinical care such as ADLs and improved grip strength

Allen JA, Lewis RA. Neurology. 2015 Aug 11;85(6):498-504.
Allen JA, et al. Neurology. 2021;96(14):e1876–e1886.

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INCAT Disability Scale

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Assessing Treatment Response

- INCAT
- R-ODS
- Dynamometry
- Muscle strength, MRC
- CAPPRI

Score	Arm Disability	Score	Leg Disability
0	No upper limb problems	0	Walking not affected
1	Symptoms, in 1 arm or both arms, not affecting ability to perform any of the following functions: doing all zippers and buttons, washing or brushing hair, using knife and fork together, handling small coins	1	Walking affected, but walks independently outdoors
2	Symptoms, in 1 arm or both arms, affecting but not preventing any of functions listed above	2	Usually uses unilateral support (stick, single crutch, 1 arm) to walk outdoors
3	Symptoms, in 1 arm or both arms, preventing 1 or 2 of functions listed above	3	Usually uses bilateral support (sticks, crutches, frame, 2 arms) to walk outdoors
4	Symptoms, in 1 arm or both arms, preventing 3 or all of functions listed above, but some purposeful movements still possible	4	Usually uses wheelchair to travel outdoors, but able to stand and walk few steps
5	Inability to use either arm for any purposeful movement	5	Restricted to wheelchair, unable to stand and walk a few steps with help

INCAT: Inflammatory Neuropathy Cause and Treatment

R-ODS: Rasch-built Overall Disability scale is a patient-based 24 questionnaire to measure limitations in activity and social participation.

CAPPRI: Chronic Acquired Polyneuropathy Patient Reported Index is a 15 questionnaire to assess health-related quality of life in polyneuropathy.

EAN/EFNS 2021 CIDP Treatment Recommendation Summary

- IVIg and oral or IV corticosteroids (CS) are strongly recommended as initial Rx in typical CIDP & CIDP variants
- Plasma exchange strongly recommended if IVIg & CS are ineffective
- IVIg should be considered as first-line treatment in motor CIDP
- Induction treatment of IVIG 2g/kg followed by maintenance treatment, IVIg, SCIg or CS recommended
- *If IVIG is infective, or maintenance dose of any of these is high* consider combination treatments or adding an immunosuppressant or immunomodulatory drug (Good Practice Point)
- *If pain is present*, consider drugs against neuropathic pain & multidisciplinary management (Good Practice Point)

(Van den Bergh PYK, et al.Eur J Neurol. 2021;1–28. https://doi.org/10.1111/ene.14959).

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Key Takeaway

- The 2021 EFNS/PNS guidelines enable more accurate diagnosis and treatment
- A systematic approach reduces misdiagnosis and inappropriate therapy
- New diagnostic tools help, but don’t replace clinical and electrodiagnostic criteria
- Variant recognition empowers clinicians for better patient care

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CIDP in Diabetes mellitus

- **The diagnosis challenge remains is it CIDP in DM or Proximal Diabetic Neuropathy (Diabetic Amyotrophy, Radiculoplexus NP, Thoracic Radiculopathy)?**
- The amenability of CIDP in DM to treatment makes its identification important.
- More severe NP, with similarity and differences from CIDP and DSNP which is ≥80% of DNP.
- Differences from CIDP; older age, more axonal loss, more gait imbalance, possible associated autonomic dysfunction and less magnitude of functional recovery.
- Difference from DSNP; slower CV, more prominent weakness and high CSF protein.
- Treatment is guided by treatment of CIDP, with variable response to treatment. (Corticosteroids 56%, PE 20% and IVIG 44%)

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Chan YC et al. Cochrane Database Systematic Review 2017

Gorson et al Muscle & Nervem(2000)23. Dyck et al. Jour of Peripheral Nervous Society, 2010;15

Rajabally et al. Nature Reviews Neurology, (2017) 13.

Potential Emerging Therapy and Research into future CIDP treatment

- Therapy targeting Complement C1s “Riliprubart” a humanized, immunoglobulin IgG4 monoclonal antibody, that selectively inhibits activated C1s in the complement pathway. Phase 2 study support safety profile and suggest a long-term benefit.

- Preliminary stem cell therapy results from ongoing clinical trials reveal that certain types of stem cells may have the ability to modulate the immune response and promote nerve regeneration.
  - The trials have mostly involved mesenchymal stem cells and hematopoietic stem cells, both known for their regenerative properties.
  - Initial reports suggest a favorable safety profile, and potential long-term improvement

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Questions