UZ LEUVEN

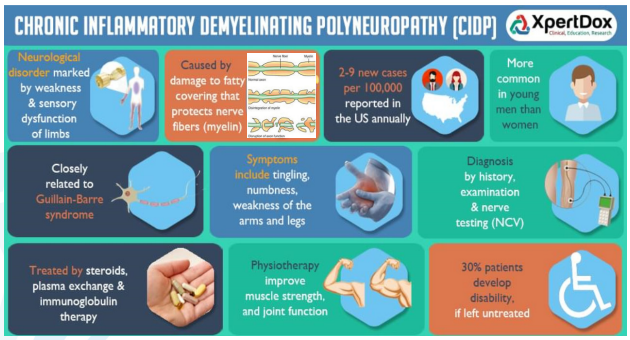
BNS satellite symposium CSL Behring

Subcutaneous Immunoglobulins in CIDP: Getting Under the Skin - Introduction

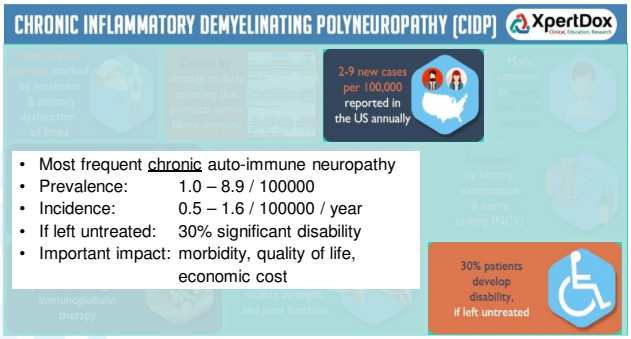
Antwerpen, 08-12-2018

UZ Leuven | Herestraat 49 B - 3000 Leuven | www.uzleuven.be tel. +32 16 33 22 11 | UNIVERSITY HOSPITALS LEUVEN

CIDP: Overview



CIDP: Impact



- Most frequent chronic auto-immune neuropathy
- Prevalence: 1.0 – 8.9 / 100000
- Incidence: 0.5 – 1.6 / 100000 / year
- If left untreated: 30% significant disability
- Important impact: morbidity, quality of life, economic cost

CIDP: Treatment

Guidelines EFNS/PNS for the treatment of CIDP

European Journal of Neurology 2010, **17:** 356–363 doi:10.1111/j.1468-1331.2009.02930.x

EFNS TASK FORCE/CME ARTICLE

European Federation of Neurological Societies/Peripheral Nerve Society Guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society — First Revision

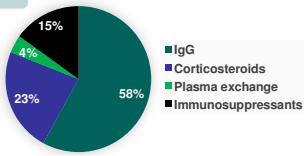
Members of the Task Force: P. Y. K. Van den Bergh[a], R. D. M. Hadden[b], P. Bouche[c], D. R. Cornblath[d], A. Hahn[e], I. Illa[f], C. L. Koski[g], J.-M. Léger[h], E. Nobile-Orazio[i], J. Pollard[j], C. Sommer[k], P. A. van Doorn[l] and I. N. van Schaik[m]

CIDP: Treatment

Guidelines EFNS/PNS for the treatment of CIDP

First line treatments	Second line treatments
• IgG therapy • Corticosteroids • Plasma exchange	• Immunosuppressants

GBS/CIDP foundation (2010): IgG is the most frequently used treatment in CIDP



EFNS/PNS recommendations **IVIG: first choice treatment for CIDP**, max. 2 g/kg over 2-5 d, followed by maintenance dose of 1 g/kg over 1-2 d every 3 weeks

CIDP: IgG therapy (ICE-trial)

Intravenous Immune Globulin CIDP Efficacy (ICE) Trial

→ Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial

Richard A C Hughes, Peter Donofrio, Vera Bril, Marinos C Dalakas, Chunqin Deng, Kim Hanna, Hans-Peter Hartung, Norman Latov, Ingemar S J Merkies, Pieter A van Doorn, on behalf of the ICE Study Group*

Lancet Neurol 2008; 7: 136–44 Published Online January 7, 2008 DOI:10.1016/S1474-4422(07)70320-0

Summary

Background Short-term studies suggest that intravenous immunoglobulin might reduce disability caused by chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) but long-term effects have not been shown. We aimed to establish whether 10% caprylate-chromatography purified immune globulin intravenous (IGIV-C) has short-term and long-term benefit in patients with CIDP.

→ Short-term and long-term efficacy and safety of IVIG, and
→ Supports use of IVIG as a therapy for CIDP

CIDP: IgG therapy (PRIMA-trial)

CSL Behring/Privigen Impact on Mobility and Autonomy (PRIMA) Trial

Journal of the Peripheral Nervous System 18:130–140 (2013)

RESEARCH REPORT

Intravenous

Efficacy and safety of Privigen® in patients with chronic inflammatory demyelinating polyneuropathy: results of a prospective, single-arm, open-label Phase III study (the PRIMA study)

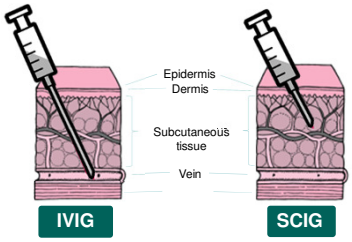
Jean-Marc Léger[1], Jan L. De Bleecker[2], Claudia Sommer[3], Wim Robberecht[4], Mika Saarela[5], Jerzy Kamienowski[6], Zbigniew Stelmasiak[7], Orell Mielke[8], Björn Tackenberg[9], Amgad Shebl[8], Artur Bauhofer[8], Othmar Zenker[8], and Ingemar S. J. Merkies[10]; on behalf of the PRIMA study investigators†

CIDP: IgG therapy IV vs. SC

Two administration methods for IgG therapy : intravenous (IVIG) and subcutaneous (SCIG).

Efficacy, safety and tolerance of IVIG in CIDP have been shown in large RCTs (ICE, PRIMA trial)

SCIG is a new option for maintenance therapy in CIDP (PATH trial)



CIDP: IgG therapy (PATH-trial)

Subcutaneous immunoglobulin for maintenance treatment in chronic inflammatory demyelinating polyneuropathy (PATH): a randomised, double-blind, placebo-controlled, phase 3 trial

Ivo N van Schaik, Vera Bril, Nan van Geloven, Hans-Peter Hartung, Richard A Lewis, Gen Sobue, John-Philip Lawo, Michaela Praus, Orell Mielke, Billie L Dorn, David R Cornblath, Ingemar S J Merkies, on behalf of the PATH study group*

Summary

Background Approximately two-thirds of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) need long-term intravenous immunoglobulin. Subcutaneous immunoglobulin (SCIg) is an alternative option for immunoglobulin delivery, but has not previously been investigated in a large trial of CIDP. The PATH study compared relapse rates in patients given SCIg versus placebo.

Lancet Neurol 2018; 17: 35–46
Published Online November 6, 2017
http://dx.doi.org/10.1016/S1474-4422(17)30378-2

→ Efficacy and safety of SCIG as a maintenance treatment for CIDP

Satellite symposium: Overview

1) **Expanding the evidence for subcutaneous immunoglobulins in CIDP: PATH and beyond.**
   Prof. dr. Jan De Bleecker, UZ Gent

2) **The profiling of the patient with intravenous or subcutaneous immunoglobulin therapy.**
   Prof. dr. Nicolas Mavroudakis, ULB Erasme