PolyNeuro exchange

SCIG in Multifocal Motor Neuropathy

Objectives

- Previous studies of subcutaneous immunoglobulin (SCIG) for multifocal motor neuropathy (MMN)
- Results from a recent open-label study of SCIG for MMN at the University of Toronto (Katzberg H, Rasutis V, Bril V)

Relevant disclosures

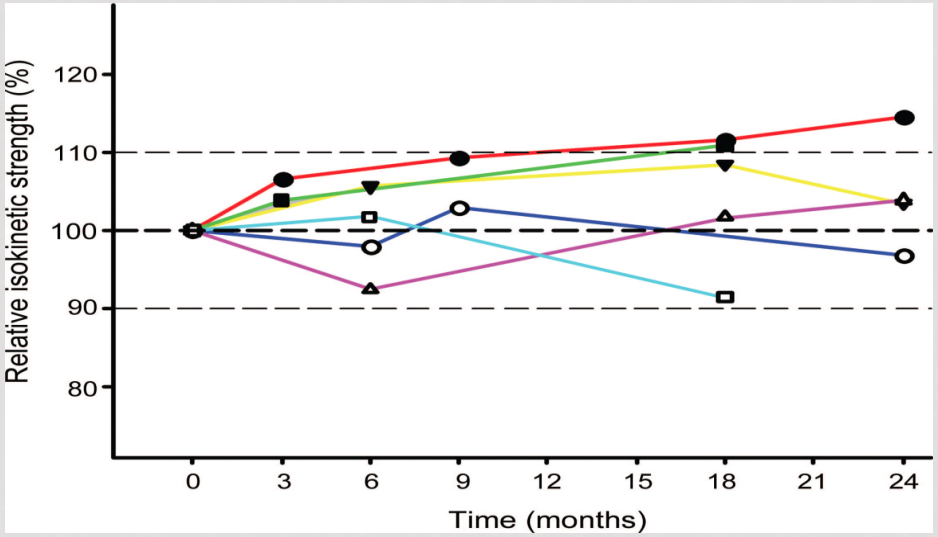
- Support for speaking engagements, ad-hoc medical advisory board and an investigator-initiated research grant on SCIG in MMN from CSL Behring

- The presentation contains information outside the labelled indication for SCIG

SCIG for MMN

- Eftimov et al 2009 (n=10, 16% SCIG)[1]
  - 50% IVIG maintenance: 5/10 patients deteriorated or withdrew
  - 100% IVIG maintenance: 4/5 maintained improvement

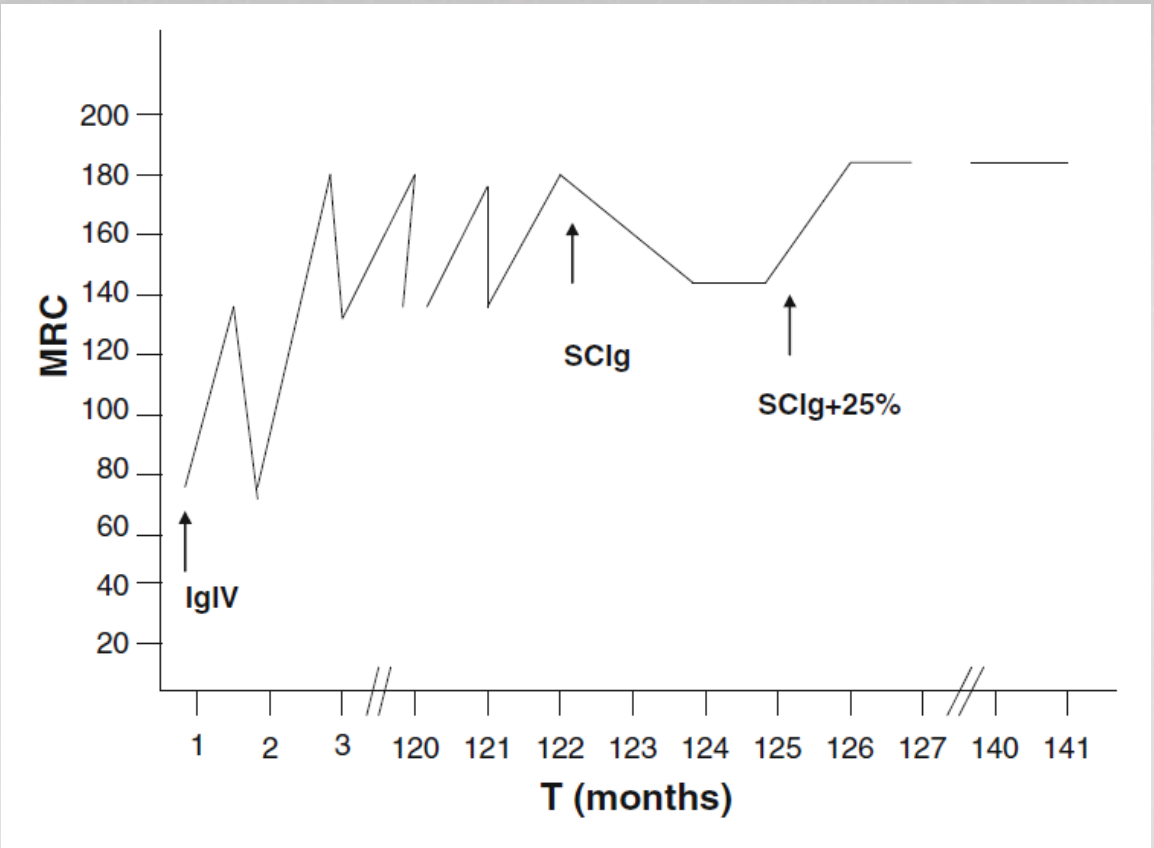
- Harbo et al 2010 (n=6, 16% SCIG)[2]
  - During SCIG treatment, muscle performance remained stable with an increase of isokinetic strength of the paretic muscles (+3.7%; p=0.36)



1. Eftimov F et al. J Peripher Nerv Syst 2009;14:93-100
2. Harbo T et al. Neurology 2010;75:1377-80

SCIG for MMN

- MRC scale score over time[1]



1. Dacci P et al. Neurol Sci 2010;31:829-31

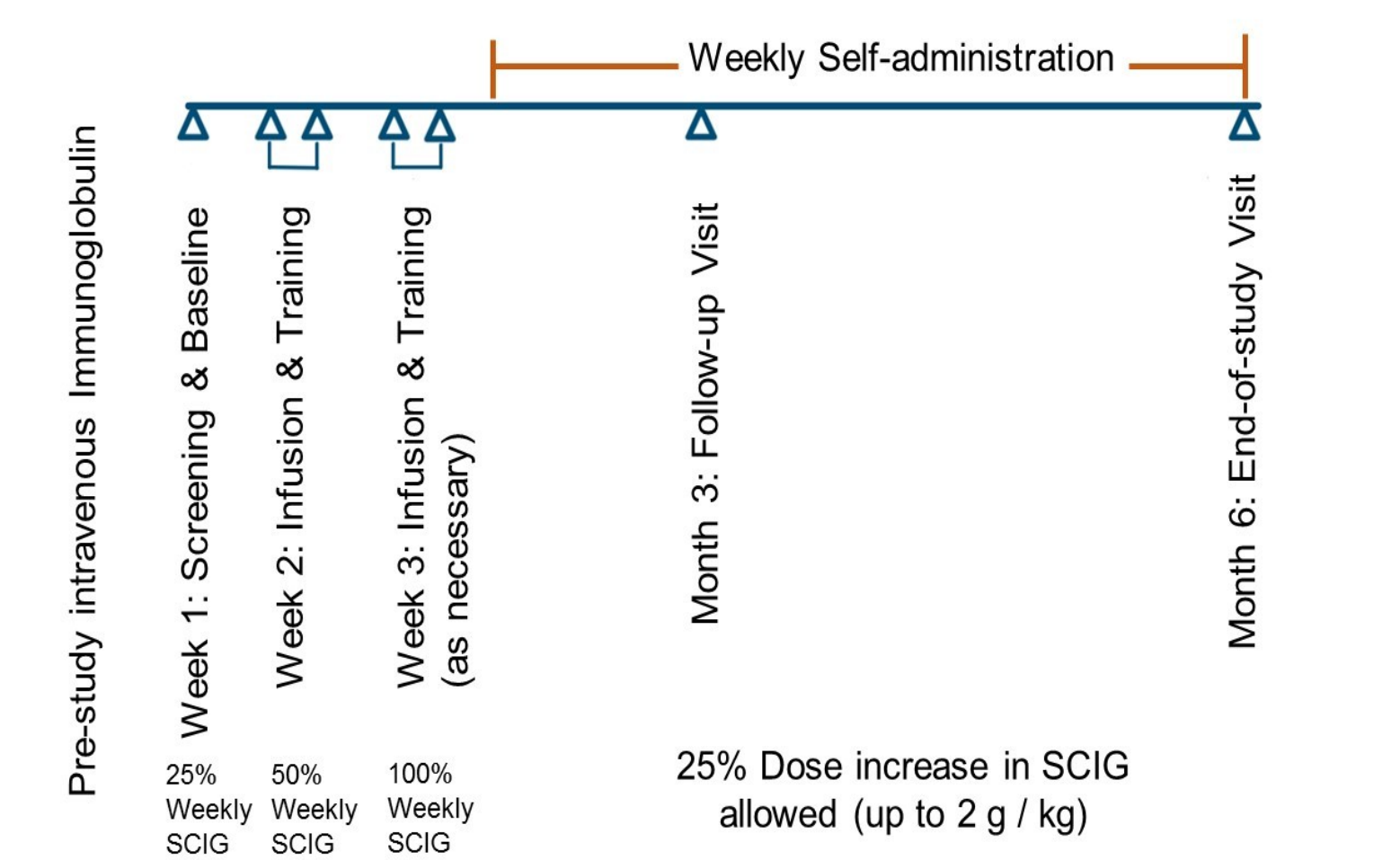
Study: High dose SCIG for maintenance treatment of MMN

- **Aim**: To evaluate if SCIG is a safe and effective alternative to maintenance IVIG for treatment of MMN

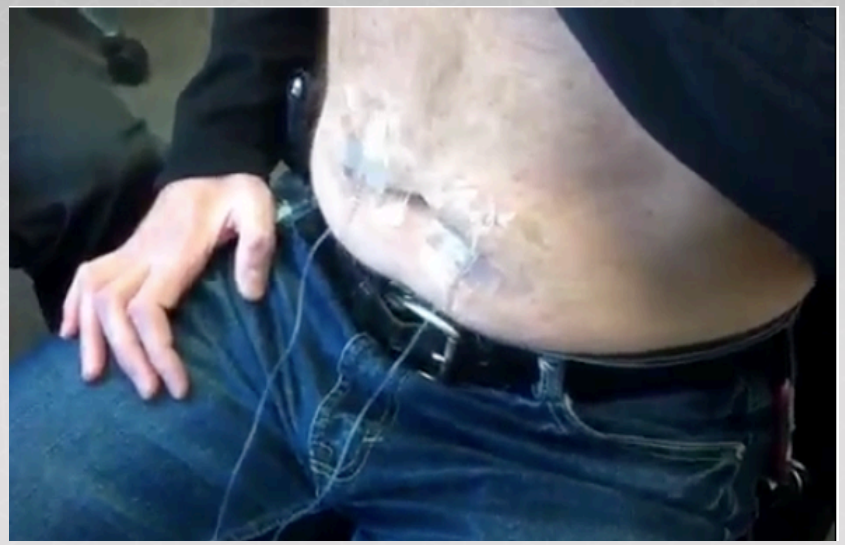
- Patients with a EFNS confirmed diagnosis of MMN who were clinically active on regular dose of IVIG were included

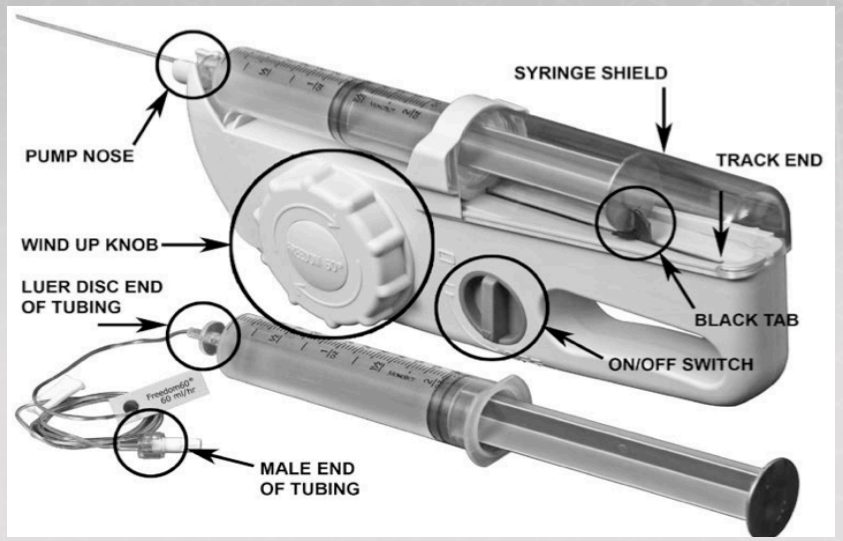
- Open-label study transitioning 15 patients from IVIG to SCIG in 1:1.5 dosing ratio
  - Maximum 2 g/kg/month immunoglobulin dose

Study design: Smooth transition protocol



SCIG administration





- Infusion: multiple ports (up to 4) used in order to infuse total amount of SCIG (6–9 mm needles)
- Freedom 60 (mL) mechanical pump or EMED infuser

Infusion details

- 15 patients were recruited to the study:
  - 11 men, 4 women
  - Aged 31–82 years
  - Duration of symptoms 2–41 years
  - IVIG doses ranging from 0.3–2 g/kg/month

- **Two to three** clinic visits were required for training, ranging from **2–3** hours each

- Five of thirteen patients had family members or caregivers present for the training sessions; only **3 required caregivers** to administer SCIG at home

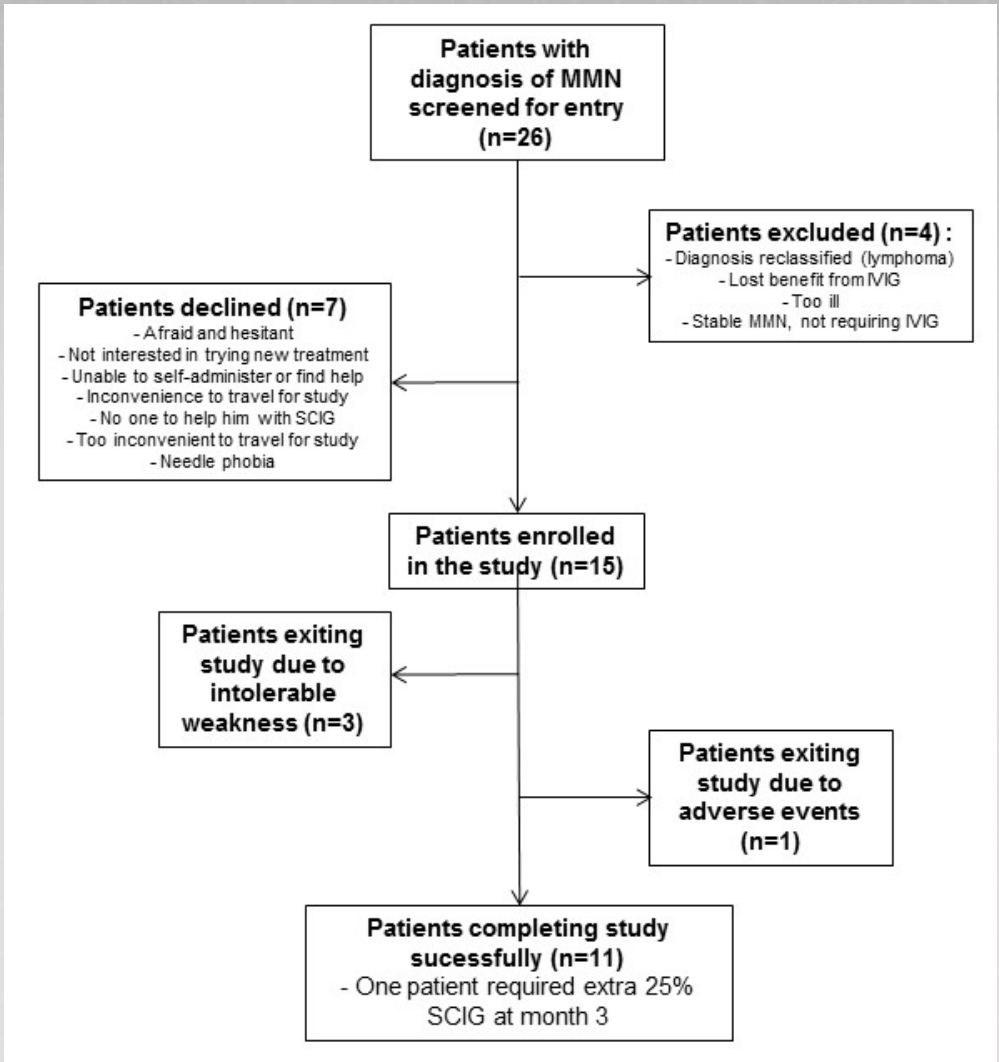
Infusion details

- Number of sites for infusion ranged from **2–4** with a maximum initial volume of 20 mL/site/week
  - Infusion volume increased to **40 mL/site/week** as tolerated

- Average total infusion volume of **150 mL** (range 50–305 mL/week)
  - Average total infusion time per week was **1.6 hours** (range 1–2.5 hours) per session

- Infusion sites
  - Eleven of 15 patients chose to infuse in the **abdomen**
    - Four of whom also chose to rotate sites to the **thighs and lower back**
  - The remaining 4 patients primarily infused in the **thighs**

Study flowchart

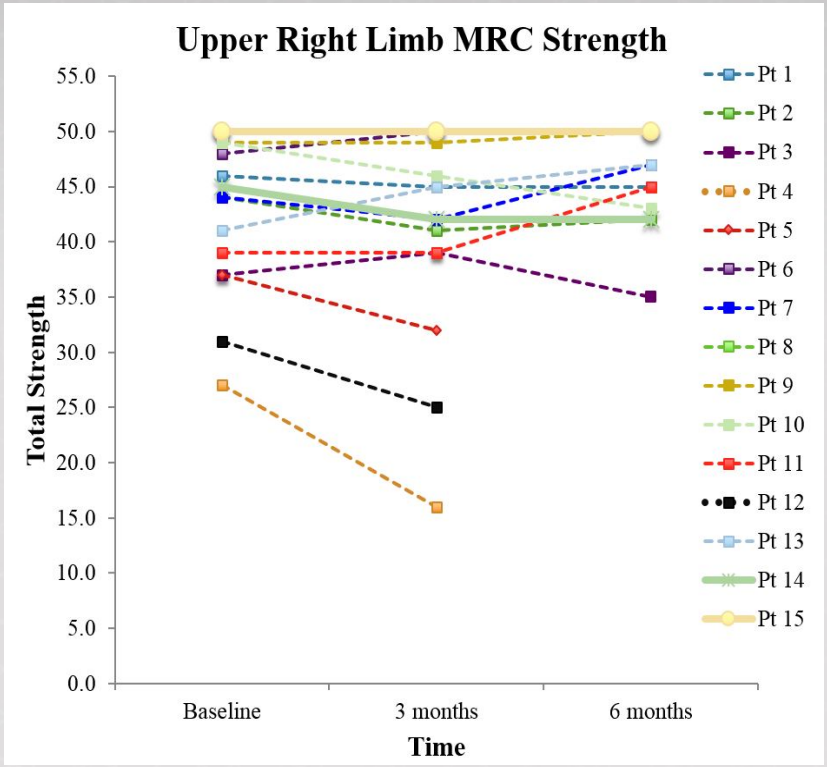


Main results

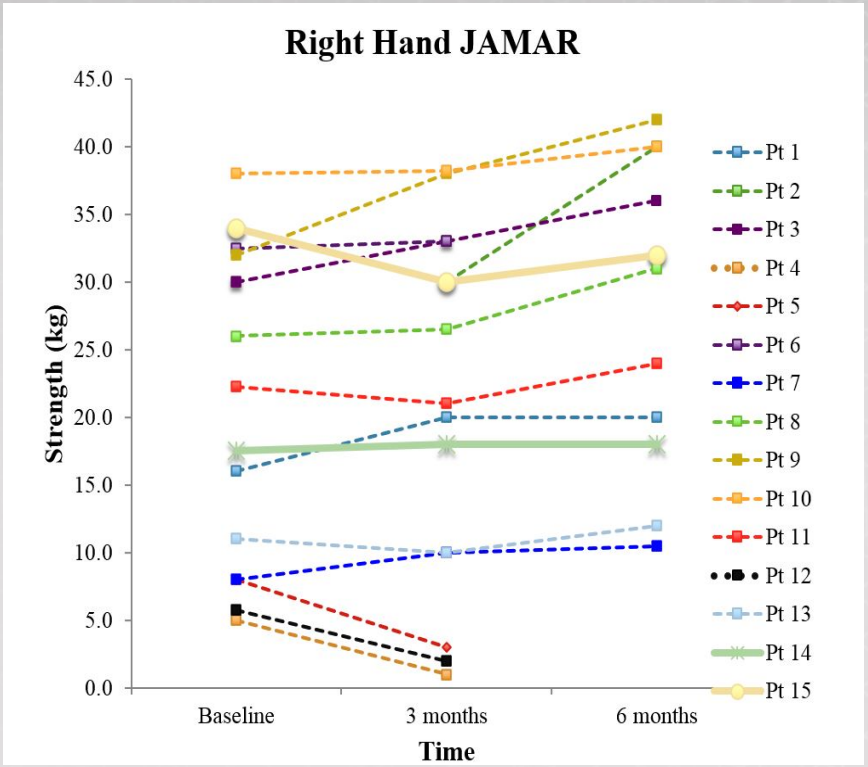
- 11 of 15 patients (**73%**) completed the 6 month study
  - MRC score, Jamar grip strength, Health Utility Index QOL and Guy's disability score were maintained
  - One patient required a 25% increase in SCIG at month 3 due to increased weakness (stabilized by month 6)
- 3 of 15 patients (**20%**) on 2 g/kg (1:1 replacement) experienced a drop in IgG levels and intolerable deterioration in upper extremity strength
  - IVIG rescue was required
- Mean patient satisfaction scores were **17.8–19.9 (of a maximum score of 20)**

Results: MRC strength score and JAMAR grip strength

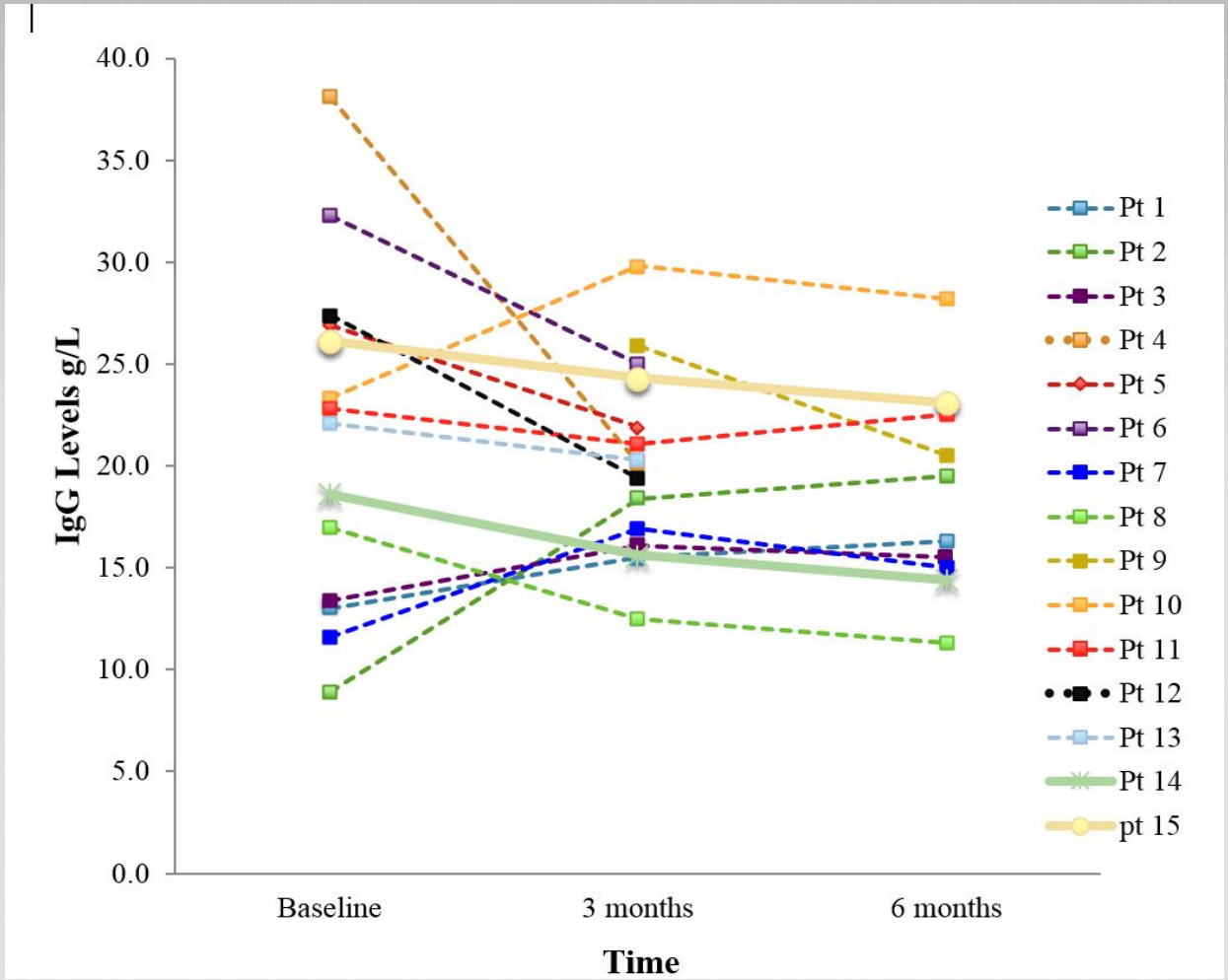
- MRC strength score



- Grip strength



Results: IgG levels



Adverse events

	Redness	Swelling	Soreness	Skin Induration	Fever	Malaise	Palpitations	H/A	Pruritus	Elevated blood pressure	Bruising
Total n (% out of 439)	51 (11.6)	87 (19.8)	46 (10.5)	28 (6.4)	1 (0.2)	45 (10.2)	2 (0.4)	6 (1.4)	2 (0.4)	28 (6.4)	27 (6.2)
Proportion of patients with adverse events (% out of 15)	40	53.3	33.3	13.3	6.6	20	13.3	6.6	6.6	6.6	26.6

- One patient responding to SCIG developed intolerable skin erythema, swelling and elevated liver enzymes
- One patient exiting the study developed pancytopenia (unrelated)

Conclusions

- High dose SCIG is feasible to infuse in patients with MMN
  - Most patients tolerate infusion and maintain strength for at least 6 months
- Intolerable weakness associated with IgG level drop in some patients warrants close monitoring
  - May occur more frequently in patients receiving 1:1 replacement
- Although most common reactions (redness, swelling, soreness) are manageable, intolerable local reactions to high dose SCIG can occur and should be monitored for