INTRODUCTION

Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a rare immune-mediated neurological disorder leading to symptoms of impaired sensation, fatigue, weakness, pain, and substantial functional impact1,2. Current European Academy of Neurology/Peripheral Nerve Society guidelines recommend intravenous immunoglobulin (IVIG) as a first-line induction or maintenance treatment for CIDP, as well as conventional subcutaneous immunoglobulin (SCIG) as an alternative maintenance therapy for MIS-responsive patients with active disease3.

Hyaluronic acid–facilitated subcutaneous immunoglobulin (fSCIG): HYQVIA® (HyQvia, Basel, US, Inc., a Takeda company, Cambridge, MA, USA) was approved in January 2020 for the Fda as maintenance therapy for CIDP of a dual- veil of immunoglobulin G (IgG) 10% (GAMMAGARD LIQUID, Baxter US, Inc., Kiovig, Takeda Manufacturing AG, Vienna, Austria) and recombinant human hyaluronidase (RH)–fSCIG 10% as maintenance therapy for MIS-responsive patients with active disease3.

These features increase flexibility for patients requiring high-viscosity SCIG 10% administration, such as patients with CIDP.

- Individualization of RHSCIG regimens could improve patient experiences in CIDP, with nursing professionals playing a vital role in supporting patients with their treatment

OBJECTIVE

To review the evidence for RHSCIG 10% based on results from the ADVANCE-CIDP 1 trial, and highlight practical nursing considerations to optimize the patient treatment experience in CIDP

METHODS

STUDY DESIGN AND ELIGIBILITY CRITERIA

- ADVANCE-CIDP 1 was a phase 3, randomized, double-blind, placebo-controlled study (NCT02427470) conducted at 54 sites in 24 countries from December 2015 to February 2022 (Figure 1), with full details reported in a prior publication11. Eligible patients were adults with definite or probable CIDP (per latest AAN and EAN criteria for CIDP) for the past 12 months with paraparesis or paraparesis (sensory axonal disease), adjustable Inflammatory Neuropathy Cause and Treatment (INCAT) disability scores of 0–1 inclusive, and who were IgG- responsive and receiving stable IVIG for 3–12 weeks

RESULTS

PATIENT DEMOGRAPHICS

- Overall, 112 patients were enrolled and received fSCIG 10% (n = 62) or placebo (n = 70) during ADVANCE-CIDP 1

- Patients had a mean age of 54.4 years, the majority were male (56.1%), and the median age was 54.4 years

RELAPSE RATE

- ADVANCE-CIDP 1 achieved its primary endpoint: RHSCIG 10% significantly reduced CIDP relapse rate versus placebo (p = 0.003) in 62 patients, respectively, absolute difference: –18.3%, P = 0.0014

SAFETY AND TOLERABILITY

- In total, 495 AEs were reported in 89 patients, with event rates of 0.39 per infusion, 0.37 per patient, and 84.8% per patient year

- With fSCIG 10%, 24 patients (38.7%) experienced 141 local AEs and 43 (69.4%) reported 201 system events, versus 8 patients (11.4%) reporting 20 local and 39 system events

- Treatment-related AEs occurred in 38 patients (61.3%) receiving fSCIG 10% and 19 patients (27.1%) receiving placebo, with the most common (> 5% of patients) being infusion/injection site erythema, infusion/injection site pain, nausea, pruritus, infusion/injection site edema, headache, infusion/injection site pruritus, and fatigue

- Fewer patients reported treatment-related AEs with fSCIG 10% than with placebo

- Of 1247 infusion administered, 72 (5.8%) were interrupted, stopped, or reduced in rate; only 0.3% were affected by intolerability

DISCUSSION

- Local infusion site reactions are among the most common AEs reported with fSCIG 10% – Nurses can help manage these events and the intolerability of high-volume fSCIG 10% through consideration of needle placement and length, patient position during infusions, and initial use of leukoreduced needle sets during the ramp-up period. Reminding patients to wear comfortable clothing may also help

- Nursing professionals hold a vital role in both training and supporting patients with their infusions, and nurse knowledge and confidence are key during patient education for self-administration of fSCIG 10%

- The nurse working most closely with the patient should assess whether they have the strength and dexterity to perform techniques requiring fine motor skills (such as inserting a needle into the skin and insertion of needle into the skin), and whether the patient has a caregiver to support them if they are unable to do so

- The duration of fSCIG 10% infusion may facilitate single-day administration for high doses, potentially benefiting patients by reducing treatment burden and the stress of having to travel for infusion, and financial expenses (such as staying overnight for multi-day therapy – 1–5 days with IVIG maintenance therapy regimens)

- Treatment preference findings suggest that infusion volumes administered were well tolerated by both blinded facilitated subcutaneous therapies, with placebo patients likely in remission at the time of measurements at study end

CONCLUSIONS

Patients in both groups demonstrated overall preferences for facilitated subcutaneous therapy, with most patients preferring study treatment to their prior IVIG

Nursing professionals play a key role in supporting individualization of fSCIG 10% treatment and improving patient experiences in CIDP, and empowering patients in optimizing their own care

Realistic patient expectations should be set and appropriately managed during treatment

DISCLOSURES

- IBD is an employee of Takeda Development Center Americas, Inc. and a Takeda shareholder. AL, AR, AW, AE, and AK are employees of Takeda Clinical Research Organization and act as clinical trial monitors. The authors report no other potential conflicts of interest.

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