Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/long-term-subcutaneous-immunoglobulin-scig-in-cidp-the-maintenance-phase/15749/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Long-Term Subcutaneous Immunoglobulin (SCIg) in CIDP: The Maintenance Phase

ReachMD Announcer:
Welcome to *Clinician's Roundtable* on ReachMD.

This medical industry feature, titled "Long-Term Subcutaneous Immunoglobulin (SCIg) in CIDP: The Maintenance Phase," is sponsored by CSL Behring.

Here's your host, Dr. Charles Turck.

Dr. Turck:
When managing chronic inflammatory demyelinating polyneuropathy, or CIDP, intravenous immunoglobulin has been a mainstay of therapy. However, a significant number of patients with CIDP who are stable on intravenous immunoglobulin, struggle with symptom return between infusions. So, is there an alternative?

This is ReachMD and I'm Dr. Charles Turck. Joining me to discuss maintenance phase subcutaneous immunoglobulin therapy, also known as SCIg for CIDP, are Dr. Karissa Gable and Dr. Suraj Muley.

Dr. Gable is an Associate Professor of Neurology at Duke University School of Medicine. Dr. Gable, welcome to the program.

Dr. Gable:
Thank you for having me.

Dr. Turck:
Also with us is Dr. Muley, who's the Medical Director of Neurology at Bob Bové Neuroscience Institute at HonorHealth in Scottsdale, Arizona. Dr. Muley, thank you for joining us today.

Dr. Muley:
It's great to be here. Thank you.

Dr. Turck:
And before we move on to our discussion on SCIg, or Hizentra®, let's take a moment to review the Indications and some Important Safety Information.

ReachMD Announcer:
INDICATIONS AND USAGE
Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, is indicated for:

- Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.

– Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

IMPORTANT SAFETY INFORMATION
WARNING: Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Please stay tuned to hear more Important Safety Information in this program.

Please see full prescribing information for Hizentra including boxed warning at Hizentra.com/HCP.

Dr. Turck:
Now that we've reviewed some Important Safety Information, let's start our discussion with you, Dr. Gable. Can you give us a brief overview of CIDP and how it can affect patients?

Dr. Gable:
Sure. So, CIDP is a rare immune mediated neurological disorder that causes demyelination of the peripheral nerves, which triggers symmetric muscle weakness and impaired sensation in the arms and legs. It develops in a progressive or relapsing way over at least 2 months and can affect up to 9 in 100,000 adults in the United States.[2,3]

Now the good news is that unlike other neuropathies, CIDP is treatable and in some cases, reversible. We have several treatment options available, including corticosteroids, plasmapheresis, and intravenous immunoglobulin, or IVIg therapy. And for patients who are stable on IVIg, some may consider switching to SCIg because of their lifestyle and preferences, which we'll dig into a bit later.

It's important for patients, particularly those in the maintenance phase of CIDP, to know that they have options. It's so crucial to approach this discussion with patients through shared decision-making and making sure we take their personal preferences into account, which the clinical guideline from the European Academy of Neurology and Peripheral Nerve Society, or EAN/PNS, also supports.[3]

So, with my patients we'll discuss efficacy and safety, as well as their goals and preferences to determine which option is best for them. Ultimately, for long-term maintenance, we want to set patients up for success by prescribing a treatment that is actually sustainable for them and encouraging adherence to therapy.[1]

Dr. Turck:
And if we turn to you now, Dr. Muley, how do you approach your patients with CIDP when it comes to treatment?

Dr. Muley:
I agree with Dr. Gable here, and take into account the EAN/PNS guideline, but also my own experience treating CIDP patients. I want to note that SCIg receives a strong recommendation for CIDP maintenance treatment, despite the guideline also stating no preference between IVIg or SCIg for maintenance treatment. And as a follow through, I discuss SCIg with every one of my patients receiving IVIg maintenance therapy for CIDP.

There are several reasons why I consider SCIg, namely Hizentra®, as a maintenance therapy for all my patients with CIDP who are stable on an IVIg, besides it being supported in the guideline. First, Hizentra is 20 percent liquid immunoglobulin, or Ig, concentration versus 10 percent for IVIg, and this allows patients to receive smaller volumes of Ig more frequently to control and prevent CIDP relapses.[2]

In addition, because Hizentra is delivered subcutaneously, there's no need to find a vein, which is particularly helpful for patients with venous access issues.[2] And with less volume, patients can self-administer the SCIg infusion from the comfort of their own home in about an hour, instead of spending up to five hours receiving IVIg treatment at a hospital or medical center.[1]

In addition to its proven efficacy in maintaining CIDP control, perhaps most appealing for my patients is that, because Hizentra requires more frequent infusions, patients may benefit from a more consistent concentration of Ig by reducing the peaks and troughs experienced by many patients on IVIg.[1,2,4,5] Systemic side effects, like headache and nausea, are common with immunoglobulin therapy, but generally less frequent or severe from SCIg compared to IVIg.[2]

So with these benefits, some of my patients tend to prefer SCIg over IVIg. This is also reflected in a CSL Behring-sponsored Harris Poll, in which 76 percent of 29 CIDP patients who have used both IVIg and SCIg preferred SCIg, compared to 24 percent who favored IVIg.[6] But again, it's a shared decision based on what's best for each individual patient and their preferences.[2]

Dr. Turck:
And coming back to you now, Dr. Gable, if it's appropriate for a patient to transition to SCIg, how do you address their concerns if they're established on IVIg in the maintenance phase?

Dr. Gable:
When transitioning from IVIg to SCIg, I always try my best to address patient concerns, and I find that helping patients set expectations about the process can be a good starting point.

First and foremost, I find that timing is really important. We recommend patients start Hizentra® seven days after the last IVIg infusion. This keeps the serum immunoglobulin G concentration high enough for a smooth transition to a consistent level.[1,7]

And it's good to discuss the number of needle sticks and the anticipated duration, frequency, and volume of infusion. For example, a typical 80-kilogram patient with CIDP may require between two and four subcutaneous sites per infusion per week on SCIg. The duration of the infusion will depend on the volume being infused, the number of infusion sites, the infusion rate, and patient tolerance. Again, weekly SCIg infusions usually take about an hour to complete.[1]

Once established on SCIg, patients can usually tolerate volumes up to 50 milliliters per site and infusion rates up to 50 milliliters per hour per site. But it's important to note the initial infusion rate should be up to 20 milliliters per hour per site and the initial volume per site is up to 20 milliliters, according to the prescribing information. After that, it's up to the patient and healthcare professional to decide if an increase in infusion rate and/or volume per site is appropriate for successive infusions.[1,7]

I also let patients know to be aware of local infusion site reactions that may occur with SCIg, as these are the most common reactions. They can include redness, itching, swelling, and/or bruising, but in most cases, they are mild to moderate and tend to decrease over time.[1,2]

Lastly, it's crucial for patients to receive adequate training and monitoring from a healthcare professional in order to self- administer SCIg. Hizentra® is available in vials or prefilled syringes, the latter of which may be easier for patients with decreased dexterity or coordination to use.[1,7]

Dr. Turck:
For those just tuning in, you're listening to *Clinicians' Roundtable* on ReachMD.

I'm Dr. Charles Turck, and today I'm speaking with Dr. Karissa Gable and Dr. Suraj Muley about CIDP patients on maintenance therapy.

And how about you, Dr. Muley? Do you have any other helpful tips for making the transition from IVIg to SCIg as smooth as possible?

Dr. Muley:
Yes, we want to make sure we're carefully monitoring patients who are transitioning from IVIg to SCIg.

Developing and instituting transition protocols are a great way to minimize any potential interruption or impact of a change in therapy. By making sure patients have access to necessary equipment, supplies, training, and support, we can help ensure a successful transition.[2]

Both nurses and pharmacists play an important role in providing continued support to patients. This includes patient education, initial and refresher self-administration training, assessing treatment response in between appointments, identifying treatment barriers, helping patients understand and manage local reactions, monitoring adherence, and reporting back to the treating physician.[1]

And documenting stable CIDP control or relapse can help both clinicians and patients feel more confident in continuing with SCIg, adjusting the dose, or potentially shifting back to IVIg. It's important to remember that there may be some variation in the dose needed for optimal benefit for an individual patient when it comes to chronic maintenance therapy.[2]

Finally, this is where having a support program in place for patients transitioning to SCIg can be critical to building confidence and promoting successful long-term adherence.[1] In one study with 19 patients, a nurse-led program that included teaching sessions, written materials, and a clear care plan helped successfully transition patients with neurological disorders from IVIg to SCIg. In fact, SCIg retention rates were as high as 90 percent at six months.[1]

Dr. Turck:
Dr. Gable, now because this seems like such an important topic, can you share with us any other insights that come to mind from your experience in transitioning CIDP maintenance treatment from IVIg to SCIg?

Dr. Gable:
Yes, I think most importantly, we should remember that long- term maintenance therapy should be individualized based upon the patient's response and need for continued therapy.[3]

The recommended Hizentra dose for CIDP is 0.2 grams per kilogram body weight per week, administered in one or two sessions over one or two consecutive days. A dose of 0.4 grams per kilogram body weight per week is also safe and effective in preventing CIDP relapse.[7] Physicians may also consider a one-to- one ratio, per week according to the EAN/PNS guideline. But if the treatment effect isn't sufficient, the dose should be adjusted using reliable outcome measures. And if the dose is high, for example, greater than 20 to 30 grams per infusion, options include splitting doses over one or two days or using multiple injection sites.[3] In my practice, I generally do it this way.

Dr. Turck:
Now we're just about out of time for today, but before we come to a close, I'd like to hear final thoughts from the both of you. Dr. Muley, what key takeaways would you like to leave with our audience?

Dr. Muley:
For me it's important to consider SCIg as a treatment option for CIDP patients who have improved on IVIg and need continued maintenance treatment. Advantages with SCIg include more consistent Ig levels which may reduce the wearing-off effect experienced by some patients on IVIg. Systemic adverse effects such as headache and fatigue may occur less frequently versus IVIg and lastly it offers autonomy and schedule flexibility for patients receiving Ig therapy.[2,3]

Key points for clinicians are that SCIg may address some of the unmet needs associated with IVIg therapy, specifically the frequency of systemic adverse effects, IVIg wearing-off between infusions, and IV access issues. SCIg can give patients more autonomy and flexibility in their maintenance treatment while providing proven CIDP control.[1,2]

Still, there are patients who prefer IVIg because they may find self-administration of treatments daunting, coupled with an increase in treatment frequency, while others prefer treatment administration in a clinical setting.

Dr. Turck:
Thank you for sharing, Dr. Muley. And Dr. Gable, you get the final word.

Dr. Gable:
Sure. I agree, particularly for long-term maintenance, I would consider SCIg as a proven treatment option for patients. Also, I'd like to emphasize the need to individualize treatment plans. It's so important to use shared-decision best practices and discuss all the benefits and potential risks of treatment options with our patients, considering the disease presentation, comorbidities, and preferences. Collectively, these considerations may encourage treatment adherence and help to manage patient expectations.[1,2]

Dr. Turck:
Thank you both. These are great takeaways from our discussion. And with those final thoughts in mind, I want to thank my guests, Dr. Karissa Gable and Dr. Suraj Muley, for sharing their insights into transitioning treatment for CIDP maintenance phase patients.

Dr. Gable, Dr. Muley, it was great speaking with you both today.

Dr. Gable:
Thank you. It was a pleasure to be here.

Dr. Muley:
Thank you for having me.

Dr. Turck:
I'm Dr. Charles Turck. Please stay tuned to hear some important safety information.

ReachMD Announcer:
IMPORTANT SAFETY INFORMATION
Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin (Ig) or components of Hizentra (eg, polysorbate 80), as well as in patients with immunoglobulin A deficiency with antibodies against IgA and a

history of hypersensitivity. Because Hizentra contains L-proline as stabilizer, use in patients with hyperprolinemia is contraindicated.

IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions. Thrombosis may occur following treatment with Ig products, including Hizentra.

Monitor patients for aseptic meningitis syndrome (AMS), which may occur following treatment with Ig products, including Hizentra. In patients at risk of acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine and urine output. In addition, monitor patients for clinical signs of hemolysis or pulmonary adverse reactions (eg, transfusion-related acute lung injury [TRALI]).

Hizentra is derived from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

The most common adverse reactions (observed in ≥5% of study subjects) were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

The passive transfer of antibodies can interfere with response to live virus vaccines and lead to misinterpretation of serologic test results.

Please see full prescribing information for Hizentra including boxed warning at Hizentra.com/HCP.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ReachMD Announcer:
This program was sponsored by CSL Behring. If you missed any part of this discussion, or to find others in this series, visit *Clinicians' Roundtable* on ReachMD.com, where you can Be Part of the Knowledge.

References:

1. Goyal NA, Karam C, Sheikh KA, Dimachkie MM. Subcutaneous immunoglobulin treatment for chronic inflammatory demyelinating polyneuropathy. *Muscle Nerve*. 2021;64(3):243-254. doi:10.1002/mus.27356
2. Allen JA, Gelinas DF, Freimer M, Runken MC, Wolfe GI. Immunoglobulin administration for the treatment of CIDP: IVIG or SCIG?. *J Neurol Sci*. 2020;408:116497. doi:10.1016/j.jns.2019.116497
3. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision. *J Peripher Nerv Syst*. 2021;26(3):242-268. doi:10.1111/jns.12455
4. van Schaik IN, Bril V, van Geloven N, et al. Subcutaneous immunoglobulin for maintenance treatment in chronic inflammatory demyelinating polyneuropathy (PATH): a randomised, double-blind, placebo-controlled, phase 3 trial [published correction appears in Lancet Neurol. 2018 Jan;17 (1):26] [published correction appears in Lancet Neurol. 2018 Aug;17(8):661]. *Lancet Neurol*. 2018;17(1):35-46. doi:10.1016/S1474-4422(17)30378-2
5. Tortorici MA, Yuraszeck T, Cornblath D, et al. Pharmacometric analysis linking immunoglobulin exposure to clinical efficacy outcomes in chronic inflammatory demyelinating polyneuropathy. C*PT Pharmacometrics Syst Pharmacol*. 2021;10(8):839-850. doi:10.1002/psp4.12647
6. Data on File. Available from CSL Behring as DOF HIZ-014.
7. Hizentra® [Prescribing Information]. CSL Behring. April 2023.