Transcript Details
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Examining Maintenance Treatment Options in CIDP

ReachMD Announcer:
You're listening to *Clinician's Roundtable* on ReachMD.

This medical industry feature, titled "Examining Maintenance Treatment Options in CIDP," is sponsored by CSL Behring.

Here's your host, Dr. Charles Turck.

Dr. Turck:
Chronic inflammatory demyelinating polyneuropathy, or CIDP, is a rare neurological disorder that affects the peripheral nervous system. With symptoms like sensory loss and muscle weakness,[1] what treatment options do we have to help patients find relief?

This is ReachMD, and I'm your host Dr. Charles Turck. Joining me to examine maintenance treatment options for CIDP is Dr. Karissa Gable, who 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, I'm excited to be here.

Dr. Turck:
To start us off, Dr. Gable, in what ways do we currently treat patients with CIDP?

Dr. Gable:
So first-line CIDP treatments include corticosteroids, plasmapheresis, and immunoglobulin, or Ig, therapy.[1] Plasma exchange, though, isn't feasible or generally tolerated for patients severely affected by CIDP, or for those who have treatment-refractory disease. And corticosteroid treatment is really typically optimal for short-term treatment due to concerns about chronic corticosteroid exposure.[2]

Considering all first line CIDP treatment options, Ig therapy has shown efficacy for chronic or maintenance treatment of immunoglobulin-dependent patients with CIDP.[2]

Although the complete mechanism of action of Ig therapy for CIDP isn't fully understood, a broad spectrum of immunomodulatory effects is thought to be involved, including the neutralization and opsonization of autoantibodies.[3,4] And through these postulated mechanisms of action, Ig therapy results in decreased inflammation[4] and improvement in CIDP-related disability.[3]

Now we have a couple different types of Ig therapy available. Intravenous immunoglobulin, or IVIg, was approved in the US in 2008 for CIDP treatment.[5] And it has demonstrated long-term efficacy as a maintenance therapy. In fact, in an online survey of 100 US community neurologists, nearly half reported using IVIg alone as their first treatment choice for CIDP.[5]

And so IVIg has long been used for CIDP maintenance therapy and is strongly recommended by the European Academy of Neurology and the Peripheral Nerve Society, or EAN/PNS,[1] but it does come with its share of challenges.

Patients often grapple with systemic adverse events linked to IV administration, such as headache, along with issues in maintaining venous access—either of which can limit continuation of therapy.[2] Also, symptoms and disability may return toward the end of an IVIg treatment cycle due to low IgG trough levels.[5]

Additionally, the logistics of healthcare-provider-administered IV infusions can pose practical constraints, which limits patients' autonomy over their treatment schedule.[2] So perhaps unsurprisingly, a CSL Behring-sponsored Harris Poll survey revealed that 46 percent of the 56 patients who had ever received IVIg treatment for CIDP were dissatisfied with their ability to personalize their treatment.[6]

Dr. Turck:
And you mentioned that there are two types of Ig therapy. Can you talk about the second option?

Dr. Gable:
Yes, we also have subcutaneous Ig—also called SCIg—one of them being Hizentra®. Hizentra® has been used to treat other conditions for over 20 years, and was approved in 2018 based on efficacy and safety for maintenance treatment of IVIg-stabilized, immunoglobulin-dependent CIDP.[5]

Dr. Turck:
Before we take a closer look at Hizentra, let's pause for a moment and 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:
As we return from that Important Safety Information message, Dr. Gable, could you tell us more about where Hizentra fits into the current CIDP treatment landscape, perhaps starting with clinical guidelines?

Dr. Gable:

That's a good question. The clinical guidelines from the EAN/PNS make a strong recommendation for SCIg in CIDP maintenance treatment. While the guidelines make no preference between SCIg or IVIg for maintenance treatment, they do emphasize the importance of considering patients' personal preferences and clinical benefits when choosing between these treatments.

This guideline also recommends that patients on SCIg should have their dose tailored according to their individual treatment response—and so patients on SCIg should be monitored closely for objective improvement—and the dose can be increased or decreased to help control symptoms.[6]

Dr. Turck:
Now with that in mind, Dr. Gable, what are some potential advantages of SCIg that would make it a preferred choice for patients?

Dr. Gable:
Well there are no head-to-head data that directly compare SCIg to IVIg in terms of relapse rates.[2,5]

But when deciding between these treatment options with your patients, what one patient may find desirable, another may find daunting. And so, potentially improving adherence relies on truly personalizing treatment based on patient preferences.[2]

Consistent Ig levels with weekly SCIg dosing take care of the extreme peaks and troughs patients experience with IVIg between infusions.[5]

Another major difference in the treatments is the requirement for adequate IV access to continue IVIg, which can become challenging over time, and lead to the need for central venous access.[2,5]

Also due to the IV access requirement, IVIg needs a healthcare professional to administer the infusion typically at a medical facility. Hizentra, however, can be self- or caregiver-administered at a convenient place and time, usually at home. This autonomy allows for increased flexibility not only with scheduling but also with location. The patient can travel with their immunoglobulin and supplies and is not tethered to a scheduled infusion appointment.[2,5]

Another difference is the concentration of the products. Where IVIg is a 10 percent concentration, SCIg is more concentrated at 20 percent, which means that not only smaller volumes are required for infusion, but also less time is needed to complete each infusion. An IVIg infusion takes three to five hours once every three weeks, however SCIg infusions would take about one hour to infuse once a week.[2,5]

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

I'm Dr. Charles Turck, and today I'm speaking with Dr. Karissa Gable on the pros and cons of SCIg and IVIg maintenance therapy in CIDP.

Dr. Gable, now that you've broken down some of the significant differences, and potential benefits, of Hizentra over IVIg, I'd like to turn our attention to safety. Can you tell us about the safety profile of Hizentra compared to IVIg, and how it can impact the treatment decision-making process?

Dr. Gable:
I'm glad you asked because in the PATH study for SCIg treatment of CIDP, patients on SCIg experienced a 3.6-fold lower rate of systemic adverse reactions per infusion after transitioning from IVIg.[3] So although SCIg and IVIg both can have some similar types of adverse events because they're both immunoglobulins, SCIg infusions tend to have fewer systemic adverse reactions.[2]

But I'd like to note that SCIg is associated with a higher frequency of local infusion site reactions. The most common reactions patients on SCIg experienced in the PATH study included erythema, swelling, pain, induration, warmth, hematoma, and pruritus. In most patients, these tend to decrease over time.[3]

Dr. Turck:
Thank you for addressing safety concerns. Now how do you set patient expectations for those who want to transition from IVIg to SCIg?

Dr. Gable:
Transitioning to SCIg can seem daunting to patients. So I definitely have a thorough discussion to learn their preferences, and understand any fears that they may have. And I let them know that SCIg is a fairly simple procedure to learn, and I'm here to teach them how to self-infuse. After all, this is a shared decision-making process.

And timing is very important, so I make sure patients know to start SCIg seven days after the final IVIg infusion. This will keep serum immunoglobulin G levels high enough for a smooth transition.[3,5]

Typically patients require between two and four subcutaneous needle sites per infusion per week on SCIg, and the duration of the infusion depends on the concentration of the product being infused, the number of infusion sites, and the patient's tolerance. Again, most SCIg infusions take about an hour per infusion session.[5]

Finally, make sure patients know that transition protocols are put in place to minimize complications in the transition period. These protocols ensure that patients receive the right equipment, supplies, training, and support needed to begin SCIg.[2]

Dr. Turck:
And before we conclude, Dr. Gable, are there any key takeaways from our discussion you'd like to provide our audience with today?

Dr. Gable:
Absolutely. It's important to note that while IVIg is a commonly used treatment for CIDP maintenance, SCIg is a recommended option with established safety and efficacy in IVIg-dependent patients with CIDP that offers potential benefits in terms of more consistent Ig levels, convenience, and fewer systemic side effects.[2]

The CIDP guideline does not recommend one treatment over another when it comes to IVIg versus SCIg for CIDP maintenance treatment, but does strongly recommend SCIg for CIDP maintenance. It also emphasizes the role of patient preference and benefits in treatment decision-making.[6]

Dr. Turck:
That's a great way to round out our discussion on this subject.

And I want to thank my guest, Dr. Karissa Gable, for helping us better understand the differences in CIDP maintenance therapy options.

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

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

Dr. Turck:
I'm Dr. Charles Turck.

And before we close, let's take a moment to review 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, visit *Clinicians' Roundtable* on ReachMD.com, where you can Be Part of the Knowledge.

References:

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