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Management of sHPT: A Dietitian's Perspective

Announcer:
You're listening to ReachMD. This medical industry feature, titled "Management of sHPT: A Dietitian's Perspective,"is sponsored by Amgen.

Before we begin, let's review some Important Safety Information for Parsabiv®.

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Stay tuned for the complete Important Safety Information for Parsabiv® at the end of this podcast. This program is intended for healthcare professionals only.

Dr. Russell:
This is ReachMD. And I'm Dr. John Russell. On today's program I have the opportunity to talk to professionals in the field of nephrology to discuss the use of Parsabiv® for adult patients with chronic kidney disease on hemodialysis who suffer from secondary hyperparathyroidism, also known as sHPT.

I have two guests joining me today for this discussion. First up is Colleen Guffee, a renal dietitian from Columbia, South Carolina. Colleen, it's a pleasure having you with us today!

Ms. Guffee:
Glad to be here.

Dr. Russell:
Also joining us today is Jillian Golan, a fellow renal dietitian from Philadelphia, Pennsylvania. Thanks for being here today, Jillian.

Ms. Golan:
It's my pleasure, thank you.

Dr. Russell:
So, I can only begin to imagine what a challenging time these past months have been for people with chronic kidney disease, including those with secondary hyperparathyroidism. Colleen, let's start with you, can you share with us what the pandemic has meant for your patients?

Ms. Guffee:
Sure thing. It's never easy for patients on dialysis, especially for those who develop secondary hyperparathyroidism. They have a lot of responsibility when it comes to maintaining their health. Many of them have comorbidities or anxiety due to the risk of contracting COVID-19. And economic hardships have made it even harder for people to eat right, and harder for some to even get to a dialysis center three times a week. We saw depression rates rise, especially among our elderly patients.

Dr. Russell:
So, Jillian, how have you and your peers responded to these challenges?

Ms. Golan:
Great question. Our teams have had to come together like never before, communicate better, and do a lot of problem solving on the fly, all while trying to help patients with sHPT stay within KDIGO® target goal range,[1] which I feel is one of the biggest responsibilities that I have to patients.

Dr. Russell:
I looked at the KDIGO® guidelines for sHPT management in preparation for our talk today. One of the recommendations sounds simple enough—keep PTH in target range 2x to 9x the upper normal limit for the assay, defined as approximately 130-600 pg/mL).[1,2] But it's not that simple, is it? I'll summarize it by saying treatment decisions should be based on serial assessments of PTH, phosphate, and calcium levels, considered together. And the guidelines suggest lowering elevated phosphate levels towards the normal range while avoiding hypercalcemia.[1] Colleen, can you tell me a little more about this?

Ms. Guffee:
Sure. Managing sHPT is definitely not simple. You can have two patients of the same gender, same age, and same stage of the disease, yet they could respond very differently to changes in diet and treatment. That just means that we've got to be on our toes with each patient and customize our approach.

Dr. Russell:
Now I understand that the two of you share the same approach for managing sHPT labs that you feel might help other dietitians. Is that correct, Jillian?

Ms. Golan:
That's true. Patient responses can differ, so if we align to a 3-phase approach to managing sHPT called Trend, Assess, and Intervene, it helps us take those differences into account and guide changes specifically to each patient, yet it's simple enough to keep top of mind.

Dr. Russell:
Sounds simple. Trend, Assess, Intervene. But Jillian, what is it about those three words specifically?

Ms. Golan:
Well, for starters, they help me stay organized. I see about 115 patients with a range of comorbidities each week, so efficiency is huge. I really like that this approach is action oriented because sHPT is a silent disease, so it can creep out of control if you're not really focused. The Trend, Assess, Intervene reminds me to always be alert and involved.

Dr. Russell:
And, Colleen, I sense that you are shaking your head in agreement.

Ms. Guffee:
Yes, Jillian makes a good point. People with sHPT don't necessarily feel symptoms when their PTH, phosphorus, or calcium are out of target range. And even if you've worked in dialysis care for a while and have great instincts for when a patient's levels may be progressing, I think Trend, Assess, Intervene really boils down to the essence of what we need to be doing each day.

Dr. Russell:
Got it, seems like a smart approach. So, take me a little deeper into it. Colleen, what's the importance of Trend?

Ms. Guffee:
Trend is about seeing what's happening with lab values over time. This is kind of where we live as dietitians, watching for changes, and looking for increases or decreases that indicate to us that something is going on. But we can't go by a single measurement, so we track these values. That's a good way to develop a deep understanding of our patients.

Dr. Russell:
I imagine some of your peers are wondering how they could be putting Trend to work in their practices. Jillian, how would you recommend they do that?

Ms. Golan:
I think you'll want to have a minimum of 3 months of data to give you a baseline with each patient. If the patient is on a calcimimetic, you want to be checking calcium levels weekly, or for PTH, every 4 weeks following dose initiation or adjustment.[3,4] And that's going to give you a good series of numbers to look at to identify increases and decreases. If you have a patient on hold, you still want to capture their

lab values as you don't want to see the lab values creep back out of goal range.

Dr. Russell:
Colleen, by this point in the process, you're developing a good bit of data. Assess then means to analyze that data?

Ms. Guffee:
Yeah, Assess is really critical because, cumulatively, there's a lot going on and a lot of factors that can cause lab values to change beyond medication. We've got to put that all together. I'm a numbers person so I feel like I'm always kind of aware, but having that Assess step helps me to block out time so that I can answer important questions like: Is the patient stable? If so, are they within goal range? If I see some fluctuations in their lab values, are they heading toward an excursion? The final question then is do I need to do something to help them get back in range? And, of course, each of these questions might prompt me to talk with the patient, our nurses, and techs to learn more about what's going on with that patient in that moment.

Dr. Russell:
Alright, Intervene then frames up how you address issues. I'm sure you both have thoughts, so let's start with Jillian.

Ms. Golan:
Sure. Intervene is about helping patients get and keep their PTH, phosphorus, and calcium at a healthy goal range. We, of course, always start with diet, but Trend, Assess, Intervene becomes all the more important when a patient is on a medication like Parsabiv®.

Dr. Russell:
And Parsabiv® is an IV calcimimetic that you administer after hemodialysis, correct?[4]

Ms. Golan:
That's right. Intervene is about integrating and adjusting treatments when you recognize those lab values are on the move with the goal to get a maintenance dose that can help hold the patient's lab values at a good level. If we're seeing that kind of response and achieving the low end of the KDIGO® target range,[1] we might need to reduce the patient's dose.[4]

Dr. Russell:
What's another aspect of the Intervene phase that listeners need to keep in mind, Colleen?

Ms. Guffee:
Probably one of the biggest keys to success for all of this is the relationship you have with your nephrologists and the treatment team. I feel very fortunate to work with nephrologists who are so open-minded and who care so much about helping patients proactively manage their sHPT so that they can maintain their lab values. And, as Jillian described, Intervene encompasses the aspects of treatment management after initiating Parsabiv® such as titrating up or down or holding at a dosage. So, yeah, we're constantly communicating because it really helps to Intervene as a team.

Dr. Russell:
For those just tuning in, you're listening to ReachMD. I'm Dr. John Russell and I'm talking with certified dietitians Jillian Golan and Colleen Guffee, who specialize in caring for adult patients with chronic kidney disease and secondary hyperparathyroidism. Colleen, can you share a real-world example to illustrate the efficiencies of Trend, Assess, Intervene?

Ms. Guffee:
Definitely. There have been a lot over the past few years. I can remember when Parsabiv® was first approved, back around 2017,[4] that was kind of a big deal because it gave us another calcimimetic option. A couple of the patients we were managing had PTHs over 1100. Two months after starting on Parsabiv®, their PTH levels were reduced down to a range we were comfortable with. That was eye-opening in a couple ways. It made it pretty clear that we need to Trend because we may see those labs come down in ways we hadn't seen before. And, it also made me think, you know, what could have happened if that patient had been able to start sooner before they were so far out of target range?

Dr. Russell:
Before we continue, let's review some Important Safety Information for Parsabiv®.

Announcer:
Here's some additional important safety information for Parsabiv®. Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation

and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

Dr. Russell:
Jillian, is there anything that you'd like to share from your experiences?

Ms. Golan:
Actually yes, I kind of alluded to it earlier, but I've had more than a few patients who had responded to Parsabiv® to the point that their lab values were heading toward the low end of the target. That's the value of Trend, Assess, Intervene—you see those changes and you have ample time to respond. In these cases, we were able to reduce their doses of Parsabiv® until we landed on a good maintenance dose that helped them stay in goal range.

Dr. Russell:
So, Colleen, what would you say to any fellow dietitians out there who are interested in adopting some of the approaches we've talked about today?

Ms. Guffee:
I'd say to believe in yourself because patients need difference makers on their side. There's a lot of aspects of dialysis care that are out of the patient's control, especially people with sHPT, so we need to do what's right for them. If your gut instinct is telling you that a patient needs something, even though there may be hurdles in front of you, push for what's right.Eventually, you will have the data and trends to show that you're doing the right thing.

Dr. Russell:
That's great advice. And Jillian Golan, you get the final word. Is there anything else you'd like our listeners to know about managing sHPT?

Ms. Golan:
Sure. Well, if you're like me, you love the relationship that you develop with your patients. You're with them three times a week, I mean sometimes that's more than you're with your own family members. So, if you care enough to Trend and Assess their labs, I'd encourage you to work with your facility manager to explore all their options to intervene. If you have a patient who you believe could benefit from a treatment like Parsabiv®, I think it's our actual responsibility to help them get the care they need.

Dr. Russell:
Jillian Golan, thanks for joining me today.

Ms. Golan:
My pleasure!

Dr. Russell:
And Colleen Guffee, I want to thank you as well.

Ms. Guffee:
It's been fun, thanks!

Dr. Russell:
Well, this has been a very helpful discussion, I want to thank renal dietitians Jillian Golan and Colleen Guffee for joining us and providing their insights to help us better understand how we can approach treatment of patients with secondary hyperparathyroidism using Parsabiv®.

Announcer:
And now here's the complete Important Safety Information for Parsabiv®.

Hypocalcemia: Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Worsening Heart Failure: In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

Upper Gastrointestinal Bleeding: In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv®. Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® therapy.

Adynamic Bone: Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions: In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

Please visit parsabivhcp.com for the Parsabiv® full prescribing information.

This Medical Industry Feature was sponsored by Amgen. To learn more about Amgen, please visit Amgen.com. And, if you missed any part of this discussion, please visit (Reachmd.com/Parsabiv). This is ReachMD. Be Part of the Knowledge.

References:

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3. Sensipar® (cinacalcet) prescribing information, Amgen.
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