Transcript Details
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Dosing Practices in sHPT

ANNOUNCER: You're listening to ReachMD. This week's Medical Industry Feature, "*Spotlight on Nephrology: Dosing Practices in sHPT,"* is sponsored by Amgen.

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

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. Sensipar® is not indicated for use in patients with CKD who are not on dialysis because of an increased risk of hypocalcemia.

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

RUSSELL: Welcome to today's program, I am your host, Dr. John Russell. We're going to talk with experts in the field of nephrology to discuss what has become a rather controversial subject—the practice of administering oral cinacalcet "3 times in the chair," which is inconsistent with the FDA-approved label. It's happening in dialysis clinics all over the country—but our guests today have some strong opinions about this practice.

Joining me today is Dr. Abdul Abdellatif, a nephrologist from Houston, Texas, and Debbie Glidden, a Nurse Practitioner from Orlando, Florida. Let's start out by discussing this new practice. Dr. Abdellatif, do you have any thoughts on this?

ABDELLATIF: Where shall I begin?! I have been a nephrologist for many years and have used oral cinacalcet many times over the years—but always dosing it on the approved use of daily dosing of the medication.[1] Now, I do not write oral cinacalcet as often as I used to, but if I did, that's how I would write it. I have heard that some nephrologists start administering oral cinacalcet 3 times in the chair, which is clearly not consistent with the FDA-approved label.

RUSSELL: And how do you feel about this suggestion?

ABDELLATIF: In my personal opinion, I don't think this is a good idea. Again, nowhere in the prescribing information for oral cinacalcet does it say "go ahead, give it 3 times a week when the patient is in the dialysis center."[1] The label clearly states it should be given once daily, with food or shortly after a meal."[1] I don't know about most practices, but it's not common for my patients to be eating a full meal in the waiting room or while they're receiving hemodialysis.

RUSSELL: Why do you see "3 times in the chair" cinacalcet to be problematic?

ABDELLATIF: There is a reason this drug is dosed once daily. It has to do with the science behind the drug. For instance, after oral administration of cinacalcet, C-max is achieved in approximately 2 to 6 hours.[1] Oral cinacalcet has a half-life of approximately 6 hours.[1] So, I don't see how this medication can be prescribed other than once daily.

RUSSELL: I see. Dr. Abdellatif is not the only nephrology professional pushing back against this new trend. Nurse Practitioner Debbie Glidden also agrees that the only correct way to dose oral cinacalcet is once daily.

GLIDDEN: Oh, I think it's absurd to do anything else!

RUSSELL: So why the push to this regimen?

GLIDDEN: I have no idea. As Dr. Abdellatif told you earlier, oral cinacalcet 3 times in the chair is not consistent with the FDA-approved label for the drug.[1] Given the half-life of oral cinacalcet and the fact that steady state is achieved within 7 days,[1] it's my opinion that once daily dosing of oral cinacalcet, per label, is the only way I feel comfortable giving it.

RUSSELL: You make a strong argument. If you're just tuning in, you are listening to this week's Medical Industry Feature sponsored by Amgen. I'm your host, Dr. John Russell. We're talking about the controversy surrounding giving oral cinacalcet "3 times in the chair," a practice that is not consistent with the FDA-approved label. We'll be back in just a moment.

ANNOUNCER: Here's some additional important safety information for Parsabiv® and Sensipar®. 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. Sensipar® treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL). And now, back to the program.

RUSSELL: Now, back to the topic at hand. Dr. Abdellatif, if oral cinacalcet 3 times in the chair is wrong, what would you recommend?

ABDELLATIF: If controlling administration in the chair is the goal, there is a logical solution— Parsabiv®. I use Parsabiv® for my patients with secondary hyperparathyroidism. I can control administration and deliver Parsabiv® 3 times in the chair and know my patients are getting the medication I prescribed to them. More important, I have had good results using Parsabiv® to treat my appropriate patients with secondary hyperparathyroidism, even with some patients for whom I could not generate good results in the past.

RUSSELL: Interesting. In speaking with Ms. Glidden, personal preference is far from the only reason to consider Parsabiv®.

GLIDDEN: I like being able to control administration. My patients come in 3 times a week for hemodialysis, and we can give them Parsabiv® when they are here at the clinic. It just makes sense to me. That's how it was tested and how it was approved.[3]

RUSSELL: So ultimately, what is going to dictate your treatment decision to sHPT?

GLIDDEN: At the end of the day, prescribers have to do what they feel is best for their patients. I am responsible for choosing the treatment that I feel is right for them. And for me, I like that Parsabiv® allows me to truly control administration—in an approved fashion—to help manage my patients' secondary hyperparathyroidism.

RUSSELL: Thanks for sharing that. Dr. Abdellatif, you get the last word. What have you done when faced with the suggestion to try cinacalcet 3 times in the chair, which—as we've state repeatedly, is not consistent with the FDA-approved label—and how would you advise a colleague faced with a similar situation?

ABDELLATIF: When it's happened to me, and I felt uncomfortable with the idea, I have followed the proper channels to push back and discuss alternatives. Again, if the goal is to control administration in the clinic, we have a way to do that and it's called Parsabiv®. I would tell any prescriber that if they are faced with such a situation, "raise your hand, take control—it's up to you to make the decision you feel is best for your patients. We should rely on our professional opinion on what is right for any particular patient. We owe that to our patients!

RUSSELL: Well, this has been a very enlightening discussion. I want to thank Dr. Abdellatif and Ms. Glidden for their time and opinions regarding this subject. Definitely a lot to think about when it comes to the appropriate dosing of calcimimetics. We've spoken a lot about Parsabiv®—come back for our next episode when we'll discuss the most important topic—its impact on patients. Thanks for listening.

Announcer: And now heres the complete imortant safety information for Parsabiv® and Sensipar®.

Contraindications:

- Parsabiv® (etelcalcetide) is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.
- Sensipar® (cinacalcet) treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL).

Hypocalcemia:

- Parsabiv® and Sensipar® lower serum calcium and can lead to hypocalcemia, sometimes severe. Life threatening events and fatal

outcomes associated with hypocalcemia have been reported in patients treated with Sensipar®, including pediatric patients. The safety and effectiveness of Sensipar® have not been established in pediatric patients.

- Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Cases of QT prolongation and ventricular arrhythmia have been reported in patients treated with Sensipar®. 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® or Sensipar®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv® or Sensipar®.
- 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® or Sensipar®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv® or Sensipar®.
- Concurrent administration of Parsabiv® or Sensipar® with calcium-lowering drugs including other calcimimetics could result in severe, life-threatening hypocalcemia. Parsabiv® and Sensipar® should not be given together. Patients switching from Sensipar® to Parsabiv® should discontinue Sensipar® for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® or Sensipar® 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.
- Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months.

Hypotension, Worsening Heart Failure and/or Arrhythmias:

- 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.
  - In Sensipar® post marketing use, isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia were reported in patients with impaired cardiac function. The causal relationship to Sensipar® therapy could not be completely excluded and may be mediated by reductions in serum calcium levels.

Upper Gastrointestinal Bleeding:

- Cases of gastrointestinal (GI) bleeding, mostly upper GI bleeding, have occurred in patients using calcimimetics, including Sensipar®, from post marketing and clinical trial sources.
- In clinical studies, 2 patients treated with Parsabiv® in 1,253 patient years of exposure had upper GI bleeding at the time of death. There were too few cases to determine whether these cases were related to Parsabiv®.
- The exact cause of GI bleeding in these patients is unknown. 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® or Sensipar®. Monitor patients for worsening of common Parsabiv® or Sensipar® GI ad® or Sensipar® 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%).

- In clinical trials of patients with secondary HPT comparing Sensipar® to placebo, the most commonly reported side effects were nausea (31% vs. 19%), vomiting (27% vs. 15%), and diarrhea (21% vs. 20%).

Announcer: Please visit parsabivhcp.com and sensiparhcp.com for the Parsabiv and Sensipar 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.