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## Unveiling the Latest Advancements in CKD-Associated Pruritus Care

### Announcer:

Welcome to CME on ReachMD. This activity, titled "Unveiling the Latest Advancements in CKD-Associated Pruritus Care" is provided by Medtelligence.

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### Dr. Jacobson:

Chronic kidney disease-associated pruritus, or CKD-aP, is an underreported and underdiagnosed condition that affects a significant proportion of patients with advanced kidney disease undergoing dialysis. But with the approval of difelikefalin, many patients have experienced symptom improvement not only in their itching, but also in their quality of life.

This is CME on ReachMD and I'm Dr. Stefan Jacobson.

### Dr. Narváez:

And I am Dr. Carlos Narváez from Puerta del Mar University Hospital in Cádiz, Spain.

### Dr. Jacobson:

Let's get started with you, Carlos, with the results from the Andalusia study.

### Dr. Narváez:

Thank you, Stefan. I'm pleased to share the findings from our study conducted in Andalusia, which focused on the use of difelikefalin, a kappa-opioid receptor, KOR, agonist. Our primary goal was to evaluate the effectiveness of the difelikefalin in reducing pruritus severity in this patient group, and to assess its safety and tolerability profile.

We conducted the study with 14 hemodialysis patients who were experiencing moderate to very severe pruritus due to CKD. These patients received difelikefalin at a dose of 0.5 µg/kg per session, administered 3 times a week. We assess pruritus severity using the worst itch numerical rating scale, WINRS, and evaluated quality of life using the self-assessed disease severity score, SADS.

The results were promising. Most patients experienced a rapid reduction in pruritus severity within the first 2 weeks of treatment.

By week 4, 92% of the patients achieved a clinically significant improvement defined as a reduction of at least 3 points on the WINRS.

Additionally, 43% of patients reported improvement in their quality of life within 2 weeks, moving from an initial severe SADS score to a moderate to mild score.

By week 6, nearly 85% of patients maintained a reduction in severity, which is a significant outcome for those suffering from CKD-aP.

However, it is important to note that 35% of the patients experienced some adverse effects. Despite this, 11 out of the 14 patients continued treatment with sustained benefits in each intensity and overall quality of life over the longer term.

Our findings aligned with the results of previous studies, such as KALM-1 and KALM-2, confirming that difelikefalin is effective and

generally well tolerated in this patient population. It offers significant potential to improve the lives of those affected by CKD-associated pruritus, which remains a prevalent and challenging symptom in patients undergoing hemodialysis.

In summary, difelikefalin presents a valuable and effective treatment option for CKD-aP, providing both rapid relief and sustained benefits in pruritus reduction and quality of life improvement.

**Dr. Jacobson:**

I want to highlight the rapid response to treatment with difelikefalin within 4 weeks in patients who likely have suffered from pruritus for a long period of time, as well as a sustained effect up to 6 months and also the significant improvement in quality of life. As many as two-thirds of patients experienced improvements in quality of life after 6 months. This is very important information to both patients and clinicians.

**Dr. Narváez:**

It is important to recognize that CKD-associated pruritus is not only about managing itching, but also about addressing the broader impact on a patient's quality of life. The data from the Andalusia study confirm that difelikefalin provides rapid and sustained relief, which can significantly improve a patient's overall well-being and daily functioning.

Stefan, what were the highlights from the CENSUS?

**Dr. Jacobson:**

CENSUS-EU is a cross-sectional, real-world, multicenter study to assess the prevalence and burden of chronic kidney disease-associated pruritus in hemodialysis patients in 7 countries in Europe. The primary aim of CENSUS-EU was to estimate the prevalence of CKD-aP using the Worst Itch Numeric Rating Scale in a random selection of patients undergoing hemodialysis in participating centers and its impact on health-related quality of life.

Altogether, 1,842 patients who had been on dialysis for more than 3 months completed the Worst Itch Numeric Rating Scale divided into 4 subgroups: no pruritus, mild pruritus, moderate pruritus, and severe pruritus. And also, the 5-D Itch Scale, integrated palliative care outcomes symptom list for end-stage kidney disease, and a management and communication survey. In addition, medical records were used to gather information on treatment and healthcare resource utilization.

The results of the CENSUS-EU study showed that, overall, 53% of the patients reported mild to severe itching, and the 13.5% had severe itching, with scores between 7 to 10 in the Worst Itch Numeric Rating Scale.

Another interesting and important observation was that 41% of patients with severe pruritus who had ever suffered from itch while on dialysis were not receiving any antipruritic treatment.

The data also revealed that as pruritus severity increases, sleep, depression and disabilities scores worsen, potentially demonstrating a substantial impact of pruritus on health-related quality of life.

**Dr. Narváez:**

Thanks for that summary, Stefan. Are there any other results you'd like to share?

**Dr. Jacobson:**

Yes, Carlos. There were at least 2 other studies from the ERA that reported interesting data. The first is from Fresenius Medical Care in the United States, in which they reported 1-year follow-up of patients after completion of 12-weeks of treatment with difelikefalin. In a real-world follow-up analysis, they observed that 81% of patients received further administration of difelikefalin, and in a subset of 29 patients they observed a decrease in mean itch severity during treatment with difelikefalin and a return to higher itch severity when treatment with difelikefalin was discontinued.

The other study I'd like to mention is from Italy by Dr. Di Giovanni and colleagues in Rome. They reported a significant decrease in itching score already after 4 weeks of treatment with difelikefalin in 19 patients on hemodialysis. Furthermore, they observed a significant and lasting effect of difelikefalin treatment on sleep quality, again demonstrating an association between pruritus with difficulties in sleeping and the possibility to relieve that problem with treatment with difelikefalin.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Stefan Jacobson, and here with me today is Dr. Carlos Narváez. We're discussing highlights from the ERA and the latest results from trials in CKD-aP.

**Dr. Narváez:**

Stefan, let's start with treatment. When our patients on dialysis are diagnosed with CKD-aP, when and how should providers initiate KOR agonist therapy?

**Dr. Jacobson:**

Previously, gabapentin was used off-label to treat CKD-aP, but there is lack of evidence for long-term treatment with gabapentin. Antihistamines have also been used, previously, to treat CKD-aP, but the use of antihistamines is not recommended by current guidelines.

The effect of the difelikefalin in hemodialysis patients with CKD-aP has been documented in large, randomized, placebo-controlled, multicenter trials, published in *The New England Journal of Medicine*, and it is now the only widely approved therapy for CKD-aP in patients on hemodialysis.

When it comes to initiating treatment with difelikefalin, most physicians start treatment in patients with more severe pruritus and high itching scores. But when dialysis nurses and physicians see the positive effects and become more familiar with the drug, many will initiate treatment with difelikefalin in patients with moderate pruritus and lower itching scores from 4 and more.

Most patients start treatment with difelikefalin on top of other treatments, but when we observe itch relief, we stop the other medication. Recently, more patients are prescribed difelikefalin as the first choice when treating CKD-associated pruritus.

Patients often ask if difelikefalin will work and what side effects they may experience, the same questions we hear from many patients when new treatments are introduced in clinical practice. The side effects experienced by the patients on difelikefalin are most often mild. Nausea and dizziness are often manageable with other medications. Itch intensity should be assessed on a regular basis using the Worst Itch Numeric Rating Scale. It's most often the dialysis nurses who are asking the question to the patients, since they are closest to the patients to have these conversations.

Another phenomenon we have observed is that patients who have been treated with difelikefalin with positive effects on both pruritus intensity and sleep disturbances share their experience with other patients, which makes their fellow patients interested in testing difelikefalin.

Well, this has certainly been an excellent conversation. But before we wrap up, Carlos, can you share one take-home message with our audience?

**Dr. Narváez:**

My take-home message is that difelikefalin represents a promising option for patients with CKD-associated pruritus on dialysis, significantly improving both symptoms and quality of life with rapid response and good tolerability. I encourage healthcare professionals to consider this therapy in managing CKD-aP.

**Dr. Jacobson:**

My take-home messages are ask your dialysis patients if they have pruritus and if so, use the Worst Itch Numeric Rating Scale to document this. Difelikefalin is the only well-documented and the only approved treatment for CKD-aP. The effect is rapid and relief of pruritus is observed within 2 to 4 weeks, with few and mild side effects. Studies have also documented improvements in quality of life during treatment with difelikefalin.

I want to thank the audience for listening in and thank you, Dr. Carlos Narváez, for joining me. It was great speaking with you today.

**Dr. Narváez:**

It was a pleasure to be here with you today.

**Announcer:**

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