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Nonsteroidal MRAs: The CKD/T1D Potential

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. McMurray:
Hello, my name is John McMurray. I'm professor of medical cardiology at the University of Glasgow in Scotland in the United Kingdom.

Dr. Heerspink:
Hello, my name is Hiddo Heerspink. I'm professor of clinical pharmacology at the University Medical Center Groningen in the Netherlands.

Dr. McMurray:
Hiddo, we already know a lot about finerenone in patients with type 2 diabetes. The FIDELIO and the FIGARO-DKD trials have given us a lot of information. What about type 1 diabetes?

Dr. Heerspink:
Yes, indeed. There has been a lot of clinical trials in type 2 diabetes, in general. We have seen the benefits of SGLT2 inhibitors, GLP-1 receptor agonist, finerenone, all in type 2 diabetes. And unfortunately, these trials did not enroll patients with type 1 diabetes. In fact, the last drug that was developed for patients with type 1 diabetes and kidney disease was 30 years ago, captopril, the old captopril. So we need new medications for type 1 diabetes. And fortunately, there is a trial now ongoing.

So if we look at the pathology of kidney disease and type 2 diabetes and type 1 diabetes, they are very common mechanisms. So all the drivers that are active in type 2 diabetes that cause kidney disease progression, hyperglycemia, hypertension, inflammation, also play a role in type 1 diabetes. So it makes sense that a drug that targets the kidney in type 2 diabetes could also be beneficial in type 1 diabetes. And that is the rationale for conducting the FINE-ONE trial with finerenone in type 1 diabetes.

Now, what do we know about finerenone in type 2 diabetes? You already alluded to the FIDELIO-DKD trial that demonstrated that finerenone reduced the risk of kidney failure and a doubling of creatinine. Now, in that trial finerenone also reduced albuminuria, an important kidney risk marker, by 33%. Actually, it turned out that 88% of the benefit of finerenone in reducing the risk of kidney failure was explained by the reduction in albuminuria. So albuminuria appears to be a very important surrogate outcome and can be used to translate evidence from type 2 diabetes to type 1 diabetes. And that's why the regulatory agencies have suggested that albuminuria can be used as a so-called bridging biomarker, a marker that bridges evidence from one setting to another setting.

So based on that data, the FDA has recommended that a trial can be done with finerenone to reduce albuminuria, which could lead to a new indication for finerenone for the treatment of chronic kidney disease in type 1 diabetes.

And so the FINE-ONE trial was designed to assess the efficacy of finerenone in reducing albuminuria. The advantage is that you don't need a trial for years, but only a trial of 6 months in 220 patients. And if you demonstrate that you reduce albuminuria based on the data

and the relationship between albuminuria and outcome during finerenone treatment, you get a new indication for kidney protection in type 1 diabetes.

So this trial, FINE-ONE, is ongoing. 220 patients with type 1 diabetes, high albuminuria, and eGFR between 25 and 90 are enrolled. Patients with potassium greater than 4.8 are excluded, just like in the FIDELIO trial. The trial is ongoing, and we hope to present the results already next year, because you only need 6 months of follow-up, so you get your results very soon.

Dr. McMurray:
Very exciting, Hiddo. Now, this is a question asked by a cardiologist, so it might be a stupid question but, you mentioned in type 2 diabetes, we've got SGLT2 inhibitors and GLP-1 receptor agonists as additional treatments for this type of patient. What about type 1 diabetes? Is there any role for those drugs in addition?

Dr. Heerspink:
That is definitely not a stupid question. Many investigators ask us this question: Can these patients also use SGLT2 inhibitors? But there is no indication right now for use of SGLT2 inhibitors in type 1 diabetes, despite the fact that in some practices people prescribe them off-label. But in our trial, patients with SGLT2 inhibitors and GLP-1 receptor agonists are excluded.

Dr. McMurray:
So potentially then, if this trial is positive, finerenone will be only the second drug that's indicated for kidney protection in type 1 diabetes.

Dr. Heerspink:
Yes, it's the first drug in 30 years, if successful, to have an indication for the treatment of chronic kidney disease in type 1 diabetes. But I hope that many other drugs will follow in the future because these patients also need new medications.

Dr. McMurray:
So something to look out for in the near future. Congratulations.

Dr. Heerspink:
Thank you.

Announcer:
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