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ns-MRAs and Biomarkers: The NT-proBNP Connection

Announcer:

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

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Dr. Vaduganathan:

Hello and welcome. My name is Muthiah Vaduganathan from the Brigham and Women's Hospital at Harvard Medical School, and we'll be discussing bridging the gap, nonsteroidal MRAs in cardio-kidney-metabolic syndrome. And this particular episode is on nonsteroidal MRAs and biomarkers.

This is a CME on PACE-CME and ReachMD, and I'm joined by my dear colleague, Dr. Orly Vardeny, from the University of Minnesota and the VA.

So, Orly, we have such a wealth of evidence coming out from the FINEARTS-Heart Failure trial, including from the recent American Heart Association meeting in Chicago. So beyond that top-line results of FINEARTS-Heart Failure, the pivotal trial for finerenone in patients with heart failure with mildly reduced or preserved ejection fraction, what can you tell us about some of the data that was presented at the American Heart Association meeting? Specifically, I'm interested in the sex-specific analysis from the FINEARTS-Heart Failure trial.

Dr. Vardeny:

Sure. So these were, as you mentioned, data that were presented at the American Heart Association meeting on looking at the efficacy and safety of finerenone in women and men that were enrolled in the FINEARTS-HF trial. And that trial enrolled approximately 45% women. There were some baseline differences between men and women. Women tended to be older with higher BMIs and higher left ventricular ejection fractions, lower eGFRs, and tended to have worse New York Heart Association functional class and were more severely limited in their health status as measured by the Kansas City Cardiomyopathy Questionnaire.

And the main findings were that finerenone reduced the primary endpoint, that is the composite of cardiovascular death in total worsening heart failure events, to a similar extent in women and men, with a rate ratio of about 0.78 in women and 0.88 in men. And these results were also consistent in secondary outcome data, and there were also similar changes in potassium and serum creatinine in response to finerenone between men and women. So there were consistent efficacy, similar safety between men and women.

Dr. Vaduganathan:

Yeah. Really, really important data, especially since previous therapies in this population suggested potential, even, heterogeneity between men and women. So the consistency here with this therapy across men and women, I think, is important. And, as you said, women are unfortunately burdened with excess symptoms and worse health status compared with men. And so to have a therapy that improves that health status and clinical events in women is really, really important.

So I'd seen some data about hyperkalemia, and hyperkalemia has been described as the Achilles heel of MR antagonism in general, and so I'm curious: What were the findings related to hyperkalemia in the FINEARTS-Heart Failure trial?

Dr. Vardeny:

Yes. You touched on a very important point in that all mineralocorticoid receptor antagonists cause elevations in potassium levels. But we should keep in mind that they also reduce the risk for hypokalemia or low potassium levels.

In FINEARTS, as we saw, finerenone resulted in approximately a 0.19 increase in potassium at 1 month compared to placebo. At 3 months, that elevation in potassium was 0.23 difference between finerenone and placebo. And there were several characteristics that were associated with increases in potassium, and these included higher baseline potassium, type 2 diabetes, lower eGFR, and then higher NT-proBNP levels, which were associated with both high potassium and low potassium. As we know, NT-proBNP is a marker of risk and potential disease severity. So it makes sense that it was elevated in both cases.

What was found was finerenone had an increased frequency of potassium levels greater than 5.5 as well as greater than 6.0 compared to placebo, but as mentioned, less frequent potassium levels less than 3.5. Now, adverse events that resulted in hospitalizations due to hyperkalemia were very infrequent, and there were no deaths that were related to hyperkalemia in either treatment arm.

What we also found was that both high and low potassium levels at the end of the spectrum were associated with increased subsequent risk of the primary endpoint, but that individuals that were taking finerenone had lower event rates compared with the placebo, and the benefit of finerenone relative to the placebo was maintained even when potassium increased to above levels of 5.5.

Dr. Vaduganathan:

Critically important data as the community digests the FINEARTS-Heart failure trial analyses to understand how finerenone can be implemented, and I think those data especially are compelling that finerenone can be safely used under well-monitored settings, and even in the presence of mild to moderate hyperkalemia.

So thank you so much. Unfortunately, that's all the time we have today. And, Dr. Vardeny, it's always a pleasure to be able to discuss these issues with you and a pleasure talking to you. And thank you all for listening.

Dr. Vardeny:

My pleasure. Thank you.

Announcer:

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