Transcript Details
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Sotagliflozin in HFpEF Without Diabetes: Inside the SOTA-P-CARDIA Trial from AHA 2025

Opening:
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Dr. Badimon:
This is ReachMD, and I am Dr. Juan Badimon. After much anticipation, the SOTA-P-CARDIA trial results are here and shedding light on dual SGLT1/2 inhibition with sotagliflozin in the patients with heart failure with preserved ejection fraction without diabetes.

The study rationale and the design of the study is clear because it was based in that the HFpEF is the most prevalent form of heart failure, and especially in older, obese, hypertensive patients; but yet, limited treatment exists. The specific SGLT2 inhibitors have showed the benefit in the EMPEROR-Preserved and the DELIVER trial, but mainly in diabetics or mixed population. On the other hand, the dual SGLT1/2 inhibitor sotagliflozin has shown a reduction in cardiovascular outcomes in patients with heart failure and diabetes regardless of the ejection fraction.

SOTA-P-CARDIA investigated the effect of sotagliflozin, as I said before, a dual SGLT1/2 inhibitor in non-diabetic HFpEF patients. And this is important because one of the requirement was to have an ejection fraction of more than 50%. The study was a single-center, randomized, double-blind, placebo-controlled with 6 months of a follow-up.

The primary endpoint of the trial was changes in LV mass between the two groups, and it was assessed by cardiac MRI. Additional secondary endpoints were peak VO_2, but especially the patient-reported quality of life, and they were assessed by using the test of the 6-minute walking test and the Kansas questionnaire.

The important thing is that we went to the primary endpoint. Remember, it was changes in LV mass, and it was significant difference, but not only difference for versus placebo, but the SOTA group was able to demonstrate a regression of the adverse remodeling process affecting these patients.

The secondary endpoints also—the 6-minute walking—the patients, they walked more than 35 meters. And remember that an improvement of 12 meters is already considered as clinical outcome, and this is highly, highly significant. In the other side, the Kansas Quality Control also demonstrated a significant improvement in the group, sotagliflozin.

The safety and adverse events, it was important because even though this was in a small study, the sotagliflozin was very well tolerated. Only two patients, they had a small infection, but they were treated.

Probably you are asking whether I could compare the result of the SOTA-P-CARDIA with some other trials such as the EMPEROR with empagliflozin and the DELIVER with dapagliflozin. Those studies were great and they demonstrated great benefits, but it was done mostly in diabetic patients or mixed HFpEF. And one of the important things is that the benefit seems to be attenuated with increasing ejection fraction.

On the other side, the SOLOIST and the SCORED were two large clinical trials with sotagliflozin, and they were done mostly in diabetic patients with CKD. One of the questions that we have there is, what is the effect of sotagliflozin in non-diabetic patients with HFpEF? And this is important because we have to differentiate between the mechanism of action of the specific SGLT2 inhibitors that you know they work at the renal level, but the SGLT1 is also present. In addition to being in the renal, it's also present in the intestine, interfering with the intestinal absorption of the glucose. So what we demonstrated is that when the glucose is inhibited, you increase the level of glucose in the intestine, and then the intestine sends a message and our body releases more GLP-1.

Okay. What are the study limitations of this trial? I have said it before: it is the limited number of the patients. But remember, since this was a mechanistic trial and it involved MRI, so this is typical of all the MRI studies.

What are the potential implications of our data? If you allow me to put together our observation with those of the large SOLOIST and SCORED, I will say that two are the major implications.

In one side, we have demonstrated that sotagliflozin is effective in the treatment of HFpEF without diabetes. Remember that in the SOLOIST and the SCORED, all the patients were diabetics, and that this seems to support the use of sotagliflozin in the management of heart failure patients independent of the ejection fraction and glycemic status. Because our trial, we had a very strict criteria and all the patients were HFpEF because ejection fraction more than 50 was a requirement, and it was measured at the time of randomization.

So what can we state? I think that our study really supports the hypothesis that SOTA may be used in all types of patients, and one of the benefits of the dual inhibition is that it has been demonstrated that we have seen in the SOLOIST and SCORED, that it not only reduces the heart failure outcomes but also reduce atherothrombotic events such as myocardial infarction and strokes. And remember that those atherothrombotic events are very frequent in this population.

What are the takeaways that we have to consider when considering sotagliflozin for the HFpEF population without diabetes? Again, I think that we should consider the difference between the dual and the selective SGLT2 inhibitors, taking into account the benefits in atherothrombotic effects. And today I think that we have demonstrated that the dual inhibition of SGLT1 and 2 are here to stay. So we need to get more familiar with this dual inhibition.

Okay, thank you very much. This is all the time that we have today, and I want to thank you for joining me as we explore what the SOTA-P-CARDIA data we saw may mean for the future of HFpEF patients. And I would like to tell you stay tuned because we still have more data to come, such as the effects on epicardial fat, proteomics. But be patient, everything is coming. Thank you. Thank you very much.

Closing:
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