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Sotagliflozin Significantly Reduces Cardiovascular Death, Myocardial Infarction, and Stroke in the SCORED Trial

Dr. Bhatt:
Hello, this is Dr. Deepak Bhatt from Brigham and Women's Hospital and Harvard Medical School. And it's really a pleasure for me to provide a recap of the scored late breaking clinical trial presentation I gave at the American College of Cardiology in 2022. My disclosures include research funding from Lexicon and my presentation will include off-label and investigational uses of drugs.

The evolution of SGLT2 inhibitors in heart failure management has been nothing short of spectacular, with multiple trials showing significant reductions in heart failure late-breaking endpoints with SGLT2 inhibitors as a class. Sotagliflozin is a SGLT2 inhibitor, but it is additionally an SGLT1 inhibitor. SGLT1 is expressed in the kidney, as is SGLT2, but it is also expressed in the gut. So Sotagliflozin has this dual mechanism of action.

The score trial consisted of over 10,000 patients with diabetes and chronic kidney disease randomized to Sotagliflozin or placebo. The primary endpoint of total cardiovascular deaths, hospitalizations for heart failure, and urgent heart failure visits was significantly reduced with Sotagliflozin versus placebo. Interestingly, in addition to that reduction in heart failure endpoints, there was also a significant reduction in major adverse cardiovascular events. And this effect was significant by about three months. So a relatively early effect in a stable outpatient population. And this reduction in MACE consisted of a significant reduction in total fatal or nonfatal myocardial infarctions, and total fatal or nonfatal strokes.

What I presented at ACC was the effects of Sotagliflozin on MACE as a function of whether patients had a history of cardiovascular disease at baseline or did not have such a history at baseline. And each of these subgroups was a bit over 5,000 patients. What we found was a consistent reduction in MACE in those patients with a history of CVD and in those patients without a history of CVD. The same pattern was evident for the endpoint of total myocardial infarction, for those with a history of CVD, and also those without a history of CVD. And the same pattern was also evident for stroke, where there were consistent reductions in those with a history of CVD and in those without a history of CVD.

And in fact, the benefits on MACE for sotagliflozin versus placebo were consistent across patients with coronary artery disease, cerebral vascular disease, and peripheral artery disease. So, to conclude then, in patients with diabetes and chronic kidney disease, sotagliflozin significantly reduced heart failure-related events by 26% with a very early benefit on that endpoint by around three months. But in addition, MACE was significantly reduced, by 23%, potentially due to the SGLT1 effect or perhaps the specific patient population we studied. And this effect on MACE was also significant by around three months and included significant reductions in both MI, but also in stroke. And finally, these MACE benefits were consistent across subgroups, including prior coronary, cerebral, or peripheral artery disease, and even in those without established cardiovascular disease. So potentially, if approved, sotagliflozin will be a new option to reduce cardiovascular risk in patients with diabetes. And these reductions would include not only heart failure events, but also MACE events. Thank you very much for your attention.