Transcript: ISCHEMIA-CKD EXTEND Results (Investigator Tor Biering-Sørensen)

The Ischemia-CKD Extend Trial is the long term follow-up of the Ischemia-CKD Trial. The Ischemia-CKD Trial, in the randomized phase, we ask the question: in patients who have moderate or severe ischemia and advanced chronic kidney disease, which we defined as eGFR less than 30, or patients on dialysis, does adding cardiac catheterization and revascularization to guideline-directed medical therapy improve clinical outcomes when compared to initial conservative strategy of guideline-directed medical therapy alone?

The primary results of the main Ischemia-CKD Trial was published two years ago in the "New England Journal" and showed no significant difference between an invasive strategy compared to that of a conservative strategy at a median follow-up of 2.4 years for the composite outcome of death or MI. In that primary publication, we observed a signal towards increase in procedural MI and a decrease in spontaneous MI with invasive strategy when compared to the conservative strategy.

For the long-term follow-up, these patients are being followed up long-term for all-cause mortality and also cardiovascular mortality. I presented the five-year interim results at ESC as a late-breaking science, and these patients will continue to be followed up for a median of around nine years.

So, at five years follow-up, an initial invasive strategy did not significantly reduced death when compared to initial conservative strategy. It's important to note that the five-year death rates were around close to approximately 40% both in the invasive and conservative strategy.

For the outcome of cardiovascular death, the results were similar. No significant difference between invasive and conservative strategy for the outcome of cardiovascular death with a five-year cardiovascular death rate of close to around 30%.

There was no heterogeneity of treatment effect based on pre-specified sub-groups including patients with the severe ischemia and also patients who had diabetes.

So in conclusion, the five-year follow-up trial we observed a couple of things. One is a high rate of all-cause mortality 40% at five years, and a high rate of cardiovascular death at close to approximately 30% at five years, an initial invasive strategy and an initial conservative strategy at similar survival.

In terms of implications to our clinical practice, I think this trial emphasizes that patients with advanced CKD who have moderate or severe ischemia have significant high rate of all-cause mortality and cardiovascular mortality. And invasive strategy does not alter this risk, so we urgently need therapies to reduce the risk in this high-risk group of patients.

We'll continue to follow these patients for a median of nine years. And we'll see if there is any signal that the early separation of curves for spontaneous MI would that lead to longer term benefit. Thank you.