

ACC 22: Results From the EMPULSE Study – Empagliflozin Proves Beneficial for Patients With HF

- Hi, I'm Mikhail Kosiborod. I'm a cardiologist at Saint Luke's Mid America Heart Institute.

Study Rationale

In this analysis of EMPULSE trial, we looked at the effects of empagliflozin SGLT2 inhibitor, on health status which is symptoms, physical limitations, and quality of life in patients hospitalised with acute heart failure.

Just to take a step back, we presented the main result of EMPULSE at the American Heart Association a few months ago and it was just published recently. And it is important to keep in mind that patients hospitalised with acute heart failure experience, very high burden of symptoms in physical limitations and poor quality of life. And we have a dearth of therapies that can be effective in improving those outcomes. In the main EMPULSE study, we previously showed that empagliflozin is compared with placebo significantly improved, what we call total clinical benefit, which is a composite theoretical, composite of death recurrent heart failure events, and change in Kansas City Cardiomyopathy Questionnaire, which is a measure of symptoms, physical limitations, and quality of life.

But in this analysis specifically, we wanted to concentrate on the effects of empagliflozin on those very outcomes, very important outcomes to patients with acute heart failure, which is the symptom burdens a burden of physical limitations and the poor quality of life.

Study Design and Patient Population

EMPULSE trial enrolled over 500 patients as it were hospitalised with acute heart failure. It's really a unique trial in many ways because it included patients with acute heart failure regardless of the ejection fraction.

So, both those reduced the preserved ejection fraction, were enrolled as well as those with or without diabetes. And those with either worsening chronic heart failure or de novo heart failure. Which means that was a new diagnosis of acute heart failure patients were hospitalised with.

So, all of those types of patients were included in the study and while on hospitals they were randomised to either empagliflozin or placebo and treated for 90 days. Specifically for the outcomes that we concentrated on in this analysis, Kansas City Cardiomyopathy Questionnaire which is a gold standard of health status that was assessed at randomization as well as 15, 30 and 90 days.

Main Findings

So, in this particular and analysis there were two key objectives. One is to evaluate the effective empagliflozin on the primary endpoint, which was a total clinical benefit, across the totals of Kansas City Cardiomyopathy Questionnaire scores.

So, essentially to try to understand whether this is a clinical total clinical benefit of empagliflozin different, depending on degree of symptomatic impairment of baseline.

And second, perhaps even more importantly to look at the effect of empagliflozin on symptoms, physical limitations of quality of life during the treatment period. So, you know, what happens after 15, 30 and 90 days of treatment?

ACC 22: Results From the EMPULSE Study – Empagliflozin Proves Beneficial for Patients With HF

So in terms of what we found for the first objective. We saw that empagliflozin as compared with placebo, significantly benefit patients in terms of a total clinical benefit to against that hierarchical composite of death, heart failure events and change in Kansas City Cardiomyopathy Questionnaire to a similar extent, regardless of the degree of symptomatic impairment at baseline.

And for the second objective, we found that patients treated with empagliflozin had significantly greater improvement in the symptoms, as well as physical limitations and quality of life over time. And importantly, that benefit emerged already at 15 days and was sustained up to 90 days. So very, very quick onset of benefit and then consistent benefit over time.

Recommendations for Use

Right, so, as I mentioned earlier, we have durable treatments in acute heart failure that have been proven to significantly improve symptoms, physical limitations, quality of life, in those patient populations that's really symptomatically and functionally impaired. And I think the message from this data is that SGLT2 inhibition for patients acutely hospitalised with heart failure is a treatment that won't just potentially improves clinical events. But also make patients feel better and enable them to be able to do more. Which is a critical goal of care in this patient population.

So yet another very important incentive to potentially think about initiating SGLT2 inhibitors in the hospital, in patients with heart failure regardless of what type of heart failures they have whether it's reduced or preserved ejection fraction. Whether it is chronic decompensated or de novo heart failure. Because we thought that the results on health status were very consistent across all of those subgroups.

Further Research Required

Well, I think we already have a lot of data on SGLT2 inhibition and heart failure, all different types of heart failure. But, in the acute heart failure space there is more data coming. I think importantly. So there are ongoing studies looking at dapagliflozin in acute decompensated, heart failure. I think that will further better the evidence base.

And then also very importantly, we also have in heart failure with preserved ejection fraction, a second large outcome trial with dapagliflozin, DELIVER which will be the largest trial of patients with HFpEF with the longest duration of follow up. So, really will help hopefully solidify the evidence base for patients with heart failure and preserve them which is really need of additional therapies.