

Progress for patients with weak hearts

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Until now, patients with heart failure with preserved ejection fraction—the most common type of heart failure in the elderly—have had no access to evidenced-based treatments. For the first time, a large clinical trial led by Prof. Dr. Stefan Anker from Charité – Universitätsmedizin Berlin has identified a drug which has a distinctly

positive effect on prognosis. In patients affected by this type of heart failure, the drug—empagliflozin—reduces the risk of hospitalization or cardiovascular death by 21 percent. The results of this research have been published in the *New England Journal of Medicine*.

When the heart is no longer able to pump a sufficient volume of blood around the body, it is said to be failing; this is known as heart failure. Organs such as muscles, nerves and the brain no longer receive optimal supplies of oxygen and nutrients. In many cases, this will initially manifest as temporary fatigue upon exertion and shortness of breath. As the disease progresses, patients will begin to develop shortness of breath after minor exertion or even at rest. Another symptom of a failing heart is fluid retention (resulting, for instance, in swollen ankles). Symptoms of heart failure do more than merely impair a patient's quality of life. When left untreated, a patient's risk of dying from heart failure within five years will increase to up to 50 percent. The disease affects approximately 60 million people worldwide.

Treatment options for patients with 'heart failure with preserved [ejection fraction](#)' (HFpEF) – the most common form of heart failure seen in the elderly—have historically been extremely limited. "Until now, the professional guideline recommendations for HFpEF have focused on the management of comorbidities—such as hypertension and diabetes—and of symptoms," explains the study's lead investigator, Prof. Dr. Stefan Anker of Charité's Department of Internal Medicine and Cardiology on Campus Virchow-Klinikum. "The last few years have seen a number of large clinical trials which have explored a range of different treatment approaches for HFpEF. However, none of the drugs tested produced a clinically relevant and statistically significant improvement in prognosis. Our own work has now shown that, with empagliflozin, the situation is quite different. It is the first [drug](#) to produce a statistically significant effect which is also (and more importantly) clinically relevant."

Empagliflozin has been used to treat patients with diabetes for a number of years. Thanks to the international phase II clinical trial entitled "EMPEROR-Preserved", it has now been shown to be effective in patients with heart failure. The trial, which included a total of just under 6,000 patients with mild to moderate HFpEF (irrespective of diabetes status), examined whether the drug would reduce the patients' risk of hospitalization or death from cardiovascular events. The participants had a mean age of 72 years and were recruited from sites across 23 different countries. Approximately half of all participants received one tablet of empagliflozin daily for an average of just above two years; the other half received a placebo. During the follow-up period, 17.1 percent of participants in the [placebo group](#) were either hospitalized or died. In the empagliflozin group, the corresponding figure was 13.8 percent. This means that, in patients with HFpEF, the drug reduced the relative risk of the trial's combined outcome of hospitalization or death by 21 percent. Participants receiving the drug also reported fewer symptoms.

Empagliflozin treatment was associated with a slight increase in the frequency of the following side effects when compared with placebo: low blood pressure was reported in 10.4 percent (vs 8.6 percent in the placebo group); [urinary tract infections](#) in 9.9 vs 8.1 percent; and genital infections in 2.2 vs 0.7 percent of participants. "These side effects are mild and easily treated," says Prof. Anker, who also works at the BIH Center for Regenerative Therapies (BCRT). Summing up the study's findings, he adds: "In my view, this result represents a major advance in the field of cardiology. For the first time in the treatment of [heart](#) failure with preserved ejection fraction, we will be able to offer patients a drug which will improve both their prognosis and their wellbeing—and which offers a very good safety profile."

In Europe, empagliflozin is currently approved for the treatment of type 2 diabetes mellitus and for the treatment of [heart failure](#) with reduced ejection fraction (with or without diabetes mellitus). Use in patients with

diabetes who go on to develop HFpEF would be covered by the drug's current marketing authorization. The manufacturer plans to apply to extend its current marketing authorization to include the treatment of HFpEF.

More information: Stefan D. Anker et al, Empagliflozin in Heart Failure with a Preserved Ejection Fraction, *New England Journal of Medicine* (2021). [DOI: 10.1056/NEJMoa2107038](https://doi.org/10.1056/NEJMoa2107038)

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