Empagliflozin in Heart Failure with a Preserved Ejection Fraction

Design

Randomized,double blind, placebo controlled

Aim: to evaluate efficacy and safety of empagliflozin versus placebo,in patients with or without diabetes.

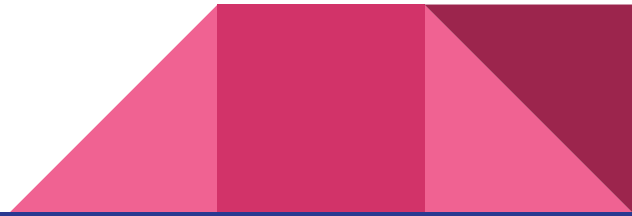
population: T2DM or non T2DM,age more than 18 ,chronic HF,GFR more than 20 ,raised NT pro BNP,preserved LVEF

Total screened: 11,583

Total number of enrollees: 5,988

Duration of follow-up: 26.2 months (median)

Mean patient age: 72 years



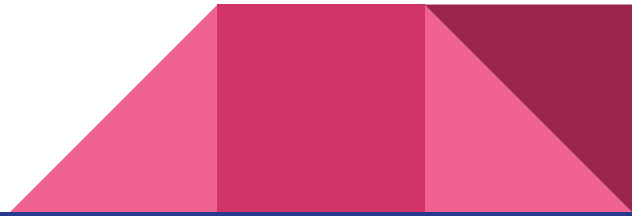
RESULTS

The primary outcome, cardiovascular (CV) death or HF hospitalization, for empagliflozin vs. placebo, was 13.8% vs. 17.1%

CV death: 7.3% vs. 8.2%

HF hospitalization: 8.6% vs. 11.8%

For the primary outcome, the benefit was similar among patients with or without type 2 diabetes.



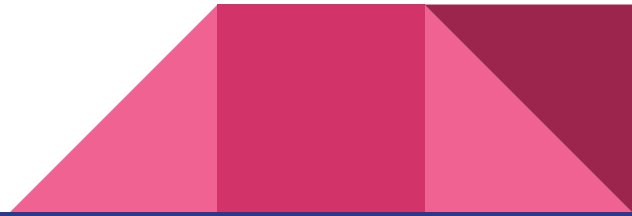
Results

Secondary outcomes for empagliflozin vs. placebo:

Total hospitalizations: 407 vs. 541

Change in mean eGFR slope/year: -1.25 vs. -2.62

Composite renal outcome 3.6% vs. 3.7%



Conclusion

Efficacy: The results of this trial indicate that empagliflozin is superior to placebo in improving HF outcomes among patients with symptomatic stable HFpEF (EF >40%), irrespective of diabetes status.

Safety: Serious adverse events occurred in 47.9% of patients in the empagliflozin group and in 51.6% of those in the placebo group. Uncomplicated genital and urinary tract infections and hypotension were more common with empagliflozin.

LIMITATIONS AND REMAINING QUESTIONS

- In this trial, empagliflozin did not significantly reduce the incidence of cardiovascular death alone.

Cardiovascular and Renal Outcomes with Empagliflozin in Heart Failure

Method

Aim:to assess the safety and efficacy of empagliflozin in patients with symptomatic heart failure with reduced ejection fraction (HFrEF), irrespective of diabetes status.

Inclusion criteria:

Age ≥18 years

Chronic HF, New York Heart Association (NYHA) functional class II/III/IV

Left ventricular EF (LVEF) ≤40%

HF hospitalization within 12

NT-proBNP≥600 pg/ml if EF ≤30%; ≥1000 pg/ml if EF 31-35%; ≥2500 pg/ml if EF >35%

If concomitant atrial fibrillation, then above thresholds were doubled)

Design

Patients were randomized in a 1:1 fashion to either empagliflozin 10 mg (n = 1,863) or matching placebo (n = 1,867). All the patients were receiving appropriate treatments for heart failure.

Total screened: 7,220

Total number of enrollees: 3730

Duration of follow-up: 16 months (median)

Mean patient age: 67 years

Results

The primary outcome, cardiovascular death or HF hospitalization, for empagliflozin vs. placebo, was 19.4% vs. 24.7%

Cardiovascular death: 10% vs. 10.8%

HF hospitalization: 13.2% vs. 18.3%

Secondary outcomes:

Total hospitalizations: 388 vs. 553

Composite renal outcome (chronic hemodialysis, renal transplantation, profound sustained reduction in eGFR): 1.6 vs. 3.1

All-cause mortality: 13.4% vs. 14.2%

Conclusion

The results of this trial indicate that empagliflozin is superior to placebo in improving HF outcomes among patients with symptomatic stable HFrEF (EF ≤40%) ,irrespective of diabetes status. Benefit is primarily driven by a reduction in HF hospitalizations, not mortality.

Even though the sodium-glucose cotransporter 2 (SGLT2) inhibitors were introduced as type 2 diabetes management drugs, the results of the EMPA-REG OUTCOME trial and others indicated a clear benefit in HF management. This trial enrolled a dedicated HF population, and conclusively shows a benefit in this patient population, irrespective of diabetes status. These drugs will likely have a prominent role in future HF management guidelines.