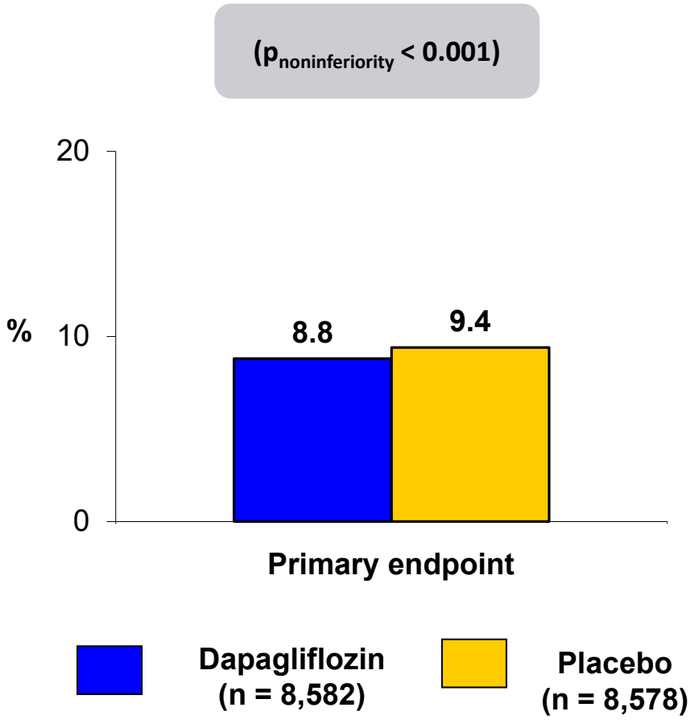
DECLARE-TIMI 58

#AHA18

AMERICAN COLLEGE of CARDIOLOGY

Trial description: Patients with type 2 diabetes mellitus (DM2) and either established CV disease or multiple risk factors were randomized to dapagliflozin 10 mg or matching placebo. Patients were followed for 4.2 years.



RESULTS

- Primary endpoint: MACE for dapagliflozin vs. placebo: 8.8% vs. 9.4%, $p_{noninferiority} < 0.001$; $p_{superiority} = 0.17$
- HF hospitalization for dapagliflozin vs. placebo: 2.5% vs. 3.3%, $p < 0.005$; all-cause mortality: 6.2% vs. 6.6%, $p > 0.05$
- Genital infections for dapagliflozin vs. placebo: 0.9% vs. 0.1%, $p < 0.001$; amputation: 1.4% vs. 1.3%, $p = 0.53$

CONCLUSIONS

- Dapagliflozin is noninferior for reducing MACE events in patients with DM2 and high CV risk compared with placebo. A reduction in HF hospitalizations was noted, but no increased risk of amputations.

Wiviott SD, et al. N Engl J Med 2018;Nov 10:[Epub]