

DapaTAVI

CLINICAL TRIAL SUMMARY

Presenters

Spanish Society of Cardiology

Objectives

To analyze the benefits of dapagliflozin treatment in patients with severe aortic stenosis discharged after transcatheter aortic-valve implantation (TAVI).

Source: <https://clinicaltrials.gov/study/NCT04696185>

**TRIAL
DESIGN**

Pragmatic, controlled, prospective, randomized, open-label, evaluator-blind clinical trial (PROBE design)

**SAMPLE
SIZE**

620 patients received dapagliflozin and 637 received standard care alone after TAVI; Primary analysis included 1222 patients after exclusions.

INCLUSION CRITERIA

- 18 years and older
- Patients with aortic stenosis who were undergoing TAVI.
- Patients with history of heart failure plus at least one of the following: renal insufficiency, diabetes, or left ventricular systolic dysfunction

METHODOLOGY

- Patients will be 1:1 randomized to either intervention group (sodium-glucose cotransporter-2 (SGLT-2) inhibitor therapy with daily oral dose of dapagliflozin 10 mg) or control group (no SGLT-2 inhibitor therapy with dapagliflozin). 620 patients received dapagliflozin and 637 received standard care alone
- The primary outcome was a composite of all-cause mortality or worsening heart failure—defined as either hospitalization or an urgent care visit—within one year of follow-up.

RESULTS

The primary outcome even was reported in 15% patients and 20.1% patients in the dapagliflozin group and standard care group, respectively (hazard ratio, 0.72).

All-cause mortality was reported in 7.8% and 8.9% in the dapagliflozin group and standard care group, respectively (hazard ratio, 0.87). Heart failure worsening was in 9.4% in the dapagliflozin group and 14.4% patient in the standard care group (subhazard ratio, 0.63).

Hypotension and genital infection were significantly more common in the patients in the the dapagliflozin group.

CONCLUSION

In high-risk older adults with aortic stenosis undergoing TAVI, dapagliflozin significantly reduced all-cause death or heart failure worsening compared to standard care.

Raposeiras-Roubin S, Amat-Santos IJ, Rossello X, et al. Dapagliflozin in Patients Undergoing Transcatheter Aortic-Valve Implantation. *N Engl J Med*. 2025;392(14):1396-1405. doi:10.1056/NEJMoa2500366