EVOLUT LOW RISK TRIAL
(Long Term Results)

CLINICAL TRIAL SUMMARY

Presenters	Medtronic Cardiovascular
Objectives	To assess the 5-year clinical and hemodynamic outcomes of transcatheter aortic valve replacement (TAVR) compared to surgical aortic valve replacement (SAVR) in patients enrolled in the Evolut Low Risk trial..

Source: https://www.jacc.org/doi/10.1016/j.jacc.2025.03.004

TRIAL DESIGN

A multinational, prospective, randomized interventional trial

SAMPLE SIZE

1,414 patients underwent an attempted implant (n = 730 TAVR, n = 684 surgery)

INCLUSION CRITERIA

- Severe trileaflet aortic valve stenosis,
- A low predicted risk of death (<3%) following surgical aortic valve replacement
- Anatomic suitability for both TAVR and surgery

METHODOLOGY

- The trial randomized patients in a 1:1 ratio to undergo either TAVR using a supra-annular, self-expanding valve or surgery with a bioprosthetic valve.

- Clinical endpoints included 5-year rates of all-cause mortality or disabling stroke, valve performance by Doppler echocardiography, paravalvular regurgitation at 30 days and 5 years, quality of life (KCCQ), and NYHA class. Prespecified safety endpoints included 5-year rates of stroke, new permanent pacemaker implantation, prosthetic valve endocarditis or thrombosis, and aortic valve rehospitalization. Post hoc analyses assessed the composite of all-cause mortality, disabling stroke, or aortic valve rehospitalization at 5 years.

RESULTS

At 5 years the Kaplan-Meier estimate for the primary endpoint of all-cause mortality or disabling stroke was 15.5% and 16.4% for the TAVR group and the surgery group, respectively. Cardiovascular mortality was 7.2% and 9.3% in the TAVR group and surgery group, respectively, while non-cardiovascular mortality was 6.8% and 6.2% in the TAVR group and the surgery group, respectively.

Over 5 years, valve reintervention rate was 3.3% and 2.5% for TAVR and surgery, respectively.

Both groups showed sustained improvements in quality of life, with nearly identical mean KCCQ scores (88.3 for TAVR vs. 88.5 for surgery).

CONCLUSION

At 5 years, patients with severe aortic stenosis treated with either TAVR or surgery showed comparable rates of all-cause mortality and disabling stroke, with both groups demonstrating excellent valve durability and performance. These midterm findings support the noninferiority of TAVR to surgery in low-risk patients.