Evolut Low Risk: Transcatheter Aortic-Valve Replacement With a Self-Expanding Valve in Low-Risk Patients



Multicenter, noninferior, randomized controlled trial

Objective: To compare outcomes with TAVR with a self-expanding bioprothesis vs. surgery in patients with severe aortic stenosis and low surgical risk.











Patients with severe AS and low surgical risk

TAVR with self-expanding valve vs. surgery

Clinical outcomes



1,468 patients with severe aortic stenosis with suitable anatomy for TAVR or surgery and no more than 3% risk of death by 30 days with surgery were randomized to:



TAVR with self-expanding valve (n=734)



Surgery (n=734)



Primary Outcome

5.3%

Death or disabling stroke at 24 months posterior probability of noninferiority, >0.999

6.7%

Secondary Outcome

5.3%

Composite of death, disabling stroke, major bleed, vascular complication or acute kidney injury at 30 days

10.7%

p < 0.05

In patients with severe aortic stenosis who were at low surgical risk, TAVR with a self-expanding supraannular bioprosthesis was noninferior to surgery with respect to death or stroke at 24 months.