Durability and Valve Performance at 5 Years for the Evolut Low-Risk Trial

Objective: There are limited intermediate-term and long-term data evaluating transcatheter aortic valve replacement (TAVR) vs surgery in patients with aortic stenosis at low risk for surgery. The Evolut Low Risk Trial (NCT02701283) is the largest randomized trial comparing self-expanding TAVR vs surgery in younger, low-risk patients. Five-year outcomes for the full study population will be presented at the American College of Cardiology 2025 annual meeting (March 29-31, Chicago, IL). The objective of the current study is to evaluate durability and valve performance outcomes in the Evolut Low Risk Trial from a surgical perspective.

Methods: The Evolut Low Risk Trial is a multinational, prospective, randomized, interventional study comparing the safety and efficacy of TAVR to surgery in patients with severe aortic stenosis with a 10-year follow-up. The trial randomized patients 1:1 to either TAVR with a self-expanding, supra-annular valve (CoreValve, Evolut R, or Evolut PRO, Medtronic) or surgery between March 2016 and May 2019. Surgical valve type was based on physician discretion and included multiple manufacturers. The primary endpoint was the composite of all-cause mortality or disabling stroke through 2 years. This 5-year analysis will include annual reporting of the primary endpoint, safety events, and valve durability and performance as determined by echocardiography.

Results: Aortic valve replacement was attempted in 1,414 patients (TAVR: 730 and surgery: 684). Patients had a baseline mean age of 74 years in each arm and Society of Thoracic Surgeons Predicted Risk of Mortality scores of 2.0% for the TAVR group and 1.9% for the surgery group. At 4 years, the composite endpoint of all-cause mortality or disabling stroke was 10.7% in the TAVR group and 14.1% in the surgery group (HR: 0.74; 95% CI: 0.54-1.00; log-rank p=0.05). At 5 years, a total of 671 patients in the TAVR group and 598 patients in the surgery group were available for analysis. Durability and valve performance outcomes through 5 years will be presented from a surgical perspective.

Conclusions: This 5-year analysis of the Evolut Low Risk Trial will provide important intermediate-term valve durability and performance data in low-risk patients with symptomatic severe aortic stenosis treated with TAVR or surgery.

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Additional Resources

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