

Five-year Outcomes of Transcatheter Aortic Valve Replacement Versus Surgery in Low-risk Aortic Stenosis: Insights from the Evolut Low Risk Trial

Saliha Erdem, Sachin S Goel and Michael J Reardon

Houston Methodist Hospital, DeBakey Heart and Vascular Institute, Houston, TX, USA

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The Evolut Low Risk trial (Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement; ClinicalTrials.gov identifier: NCT02701283) provides reassuring evidence that transcatheter aortic valve replacement remains non-inferior to surgery at 5-year follow-up with regard to mortality and disabling stroke in low-risk patients. Valve performance, durability and quality-of-life improvements were excellent in both groups.

Keywords

Aortic stenoses, aortic stenosis, aortic valve calcification, aortic valve stenosis, low-risk aortic stenosis, surgical aortic valve replacement (SAVR), transcatheter aortic valve implantation (TAVI), transcatheter aortic valve replacement (TAVR)

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Corresponding author: Saliha Erdem, Department of Cardiology, DeBakey Heart and Vascular Institute, Houston Methodist Hospital, 1850 Old Main St, Apt 3107, Houston, TX 77030, USA. E: serdem@houstonmethodist.org

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The Evolut Low Risk trial (Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement; ClinicalTrials.gov identifier: NCT02701283) provides reassuring evidence that transcatheter aortic valve replacement (TAVR) remains non-inferior to surgery at 5-year follow-up in low-risk patients with severe aortic stenosis (AS).¹ This editorial discusses the clinical implications of the trial's 5-year outcomes, including valve performance, reintervention rates, conduction disturbances, quality-of-life improvements and long-term considerations in younger patients.

TAVR has revolutionized the management of severe AS. Based on randomized trial data, TAVR is approved for the treatment of patients across all surgical risk levels.^{2–8} The 5-year results of the Evolut Low Risk trial provide pivotal data reinforcing the durability and efficacy of TAVR compared with surgical aortic valve replacement (SAVR) in patients at low surgical risk.¹ This multinational, prospective, randomized trial demonstrated similar clinical outcomes between TAVR and SAVR at 5 years. The primary endpoint, a composite of all-cause mortality or disabling stroke, was comparable between groups (15.5% for TAVR versus 16.4% for surgery, $p=0.47$). Importantly, this mid-term durability provides crucial data as the indication for TAVR has broadened to patients with longer life expectancy.

Analysing Kaplan–Meier curves reveals subtle but clinically relevant divergences between the groups. For all-cause mortality or disabling stroke, initial divergence begins within the first 12 months. This is likely due to the more invasive nature of SAVR. This divergence becomes more pronounced around 36 to 48 months, with a 26% reduction in hazard for death or disabling stroke in favour of TAVR at 4 years.⁹ However, between 4 and 5 years, the curves become less divergent, and the statistical significance between the primary outcomes in the two groups disappears. This is related to higher non-cardiovascular deaths in the SAVR group up to 4 years, subsequently, a higher frequency of non-cardiovascular deaths in the TAVR group between 4 and 5 years. While the causes of non-cardiovascular deaths were not the focus of this analysis, they likely reflect comorbidities and baseline patient characteristics. At 5 years, all-cause mortality was similar between the SAVR and TAVR groups (14.9% versus 13.5%, $p=0.39$). Interestingly, the cardiovascular mortality curves continue to diverge out to 5 years in favour of TAVR (7.2% TAVR versus 9.3% SAVR, $p=0.15$), although not statistically significant. This observation may warrant further investigation, particularly in relation to the haemodynamic performance of the valve. On the other hand, non-cardiovascular mortality curves overlap closely (6.8% TAVR versus 6.2% SAVR, $p=0.73$); these deaths are not directly related to the valve or the procedure itself but rather reflect the patients' comorbidities. For all-stroke and disabling stroke (9.5% TAVR versus 8.6% SAVR, $p=0.58$), the event rates remain similar throughout the 5-year follow-up.

The secondary outcomes of the trial revealed important differences. TAVR was associated with superior valve haemodynamics over SAVR, evidenced by lower mean gradients (10.7 mm Hg versus 12.8 mm Hg, $p<0.001$), larger effective orifice areas (2.1 cm² versus 1.9 cm², $p<0.001$) and higher Doppler velocity index (0.51 ± 0.15 versus 0.46 ± 0.12 , $p<0.001$), potentially translating

into improved valve durability and fewer complications related to prosthesis–patient mismatch. However, aortic paravalvular leak (PVL) of mild or greater severity was significantly more frequent with TAVR (14.7% versus 0.5%, $p<0.001$). Transcatheter valves are deployed within the patient’s calcified aortic valve without removing the native tissue. This can result in incomplete sealing between the prosthetic valve and the native annulus, especially if there is heavy or irregular calcification, leading to a higher risk of PVL. Importantly, while PVL remains more common in the TAVR group, data from this trial showed that most cases of mild PVL observed at 30 days improved over time, with 110 of 154 patients demonstrating resolution or reduction in AR severity. Furthermore, mild PVL at 1 month did not translate into higher long-term mortality. At 5 years, all-cause mortality was 14.1% in patients with mild PVL compared with 13.0% in those with none or trace PVL ($p=0.67$). Contemporary strategies, including improved valve sizing, sealing skirts and pre-procedural imaging, are being employed to mitigate PVL and its potential long-term effects.

Another key consideration in the lifetime management of AS is valve durability in TAVR recipients, particularly in younger and more active patients who may outlive their bioprosthesis. Although only a small proportion of patients were under the age of 65 (5.8% in TAVR versus 7.0% in SAVR), this subgroup is particularly relevant when considering long-term valve durability, lifetime reintervention planning and valve-in-valve compatibility. In younger patients, strategies must prioritize not only procedural outcomes but also the feasibility of future reinterventions, coronary access and minimizing structural valve deterioration over decades. Over 5 years, valve reintervention rates were similar in the TAVR and SAVR groups (3.3% versus 2.5%, $p=0.44$). In the TAVR group, structural causes like aortic regurgitation (PVL or transvalvular), severe stenosis and endocarditis were the most common indications for reintervention. Most reinterventions in both groups were surgical. While a small number of deaths occurred among patients undergoing reintervention, the low event rates and lack of statistical analysis preclude definitive conclusions regarding mortality differences between groups.

Conduction disturbances and the risk of arrhythmia also differed. Atrial fibrillation was less frequent after TAVR compared with SAVR (16.3%

versus 41.2%, $p<0.001$). Although the difference narrowed in later years, the lower incidence in the early post-procedural period remained favourable for TAVR, likely reflecting the less invasive nature of the transcatheter approach. Conversely, TAVR was associated with higher permanent pacemaker implantation rates (27% versus 11.3%, $p<0.001$) driven by higher need for pacemaker implantation in the first 2 years (21% versus 8%, $p<0.001$). Recent advances in implantation techniques, such as improved positioning techniques, have decreased the current pacemaker implantation rates after TAVR.¹⁰

Quality-of-life metrics, assessed by the Kansas City Cardiomyopathy Questionnaire, remained consistently high and similar through 5 years (88.3 ± 15.8 versus 88.5 ± 15.8 ; 95% CI: -2.2 to 1.8; $p=0.83$).¹ Additionally, most patients maintained New York Heart Association (NYHA) functional class I, indicating that both procedures provide significant and sustained symptomatic relief.

While these findings are promising, it is essential to recognize that Evolut Low Risk was a carefully controlled trial population. Real-world outcomes may vary due to differences in operator experience, comorbidities and anatomy. Ongoing post-market surveillance and registry data will be essential in validating these results across broader patient populations.

In conclusion, the 5-year results of the Evolut Low Risk trial support TAVR with the supra-annular, self-expanding Evolut valve as a safe and effective alternative to surgery in patients with severe AS and low surgical risk. Similarly, the 5-year outcomes of the PARTNER 3 trial (A Prospective, Randomized, Controlled, Multi-Center Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement; ClinicalTrials.gov identifier: NCT02675114) showed no significant difference in the primary composite endpoint between TAVR and surgery, with comparable rates of death, stroke and bioprosthetic valve failure.⁷ While both trials provide reassuring mid-term data, longer term follow-up, including the planned 10-year results, will be essential to thoroughly assess durability, valve performance and repeatability to guide lifetime management in younger patients. □

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