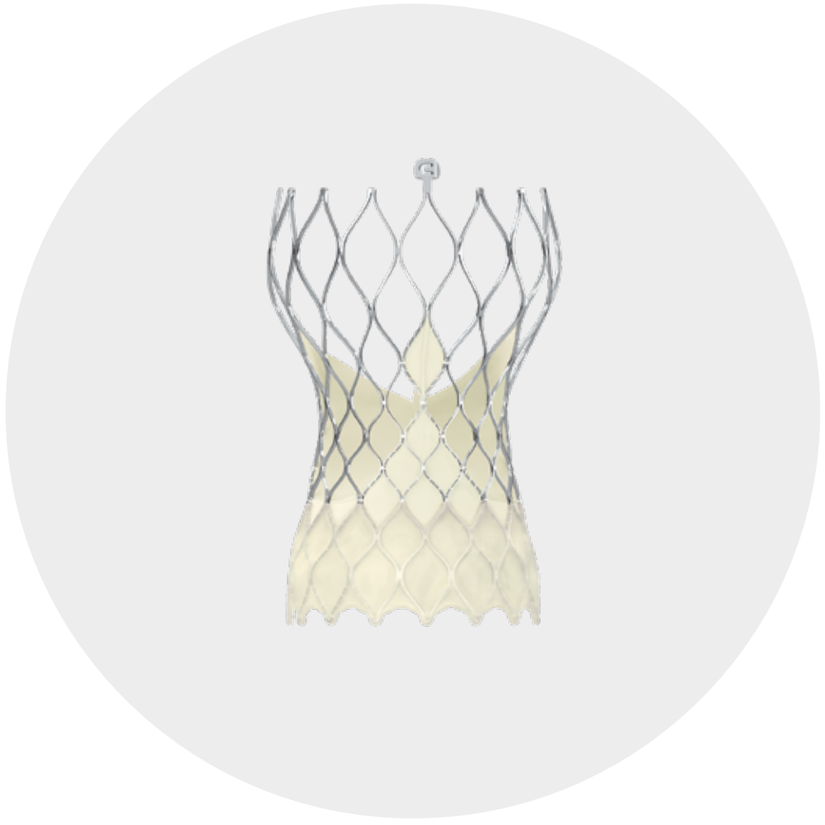
Medtronic

Medtronic transcatheter aortic valve

Clinical trial summary



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References and brief statements

EXPAND II Trial – Currently enrolling

Objective
The EXPAND TAVI II Trial is a multicenter, international, prospective, randomized clinical trial to obtain safety and effectiveness data to support indication expansion for the Medtronic Evolut™ PRO+ and Evolut™ FX transcatheter aortic valve replacement (TAVI) systems to include patients with moderate, symptomatic aortic stenosis. The primary objective of this trial is to demonstrate that the Medtronic TAVI system administered in conjunction with guideline-directed management and therapy (GDMT) is superior to GDMT alone in terms of safety and effectiveness.
Specifics
Study status/duration 1-year and 2-year outcomes to be reported/10-year follow-up
Sample size 650 subjects, up to 100 sites
Primary outcomes to be measured 1. Safety: Composite of all-cause mortality, all stroke, life-threatening or fatal bleeding, acute kidney injury, hospitalization due to device or procedure-related complication, or valve dysfunction requiring reintervention at 30 days (life-threatening or fatal bleeding is defined as BARC Type 3 or 4 and acute kidney injury is defined as VARC-3 Stage IV). 2. Effectiveness: Non-hierarchical composite of all-cause mortality, heart failure hospitalization or event, or medical instability leading to aortic valve replacement or re-intervention at two years.
Device Evolut™ PRO+ and Evolut™ FX
Key takeaways
The study will evaluate the safety and effectiveness of the Evolut™ PRO+ TAVI and Evolut™ FX TAVI systems combined with GDMT compared to GDMT alone in the patient population with moderate, symptomatic aortic stenosis. The data may be used to support future regulatory submissions to expand the current indications for the Evolut™ TAVI platform.

Optimize PRO Study[1]

Objective
The primary objective of the Optimize PRO study is to collect clinical evidence on valve performance and procedural outcomes associated with an "optimized" pre- and post-procedural TAVI care pathway, including the cusp overlap technique to deploy the Evolut™ TAVI system.
Specifics
Study status/duration 30-day outcomes reported/1-year follow-up
Sample size Up to 650 patients
30-day outcomes Interim results on 400 patients (main cohort) 0.7% Disabling stroke 0.8% All-cause mortality 9.8% PPI
Devices Evolut™ PRO 8.3%/Evolut™ PRO+ 91.3%
Key takeaways
The interim analysis of the Optimize PRO study reveals excellent outcomes at 30 days. The study showed minimal all-cause mortality and stroke occurrences, with a new pacemaker implantation rate of 9.8%. Aortic regurgitation (AR) rates were exceptionally low, with no instances of moderate or severe AR observed upon discharge. Patients typically had a median length of stay of one day and excellent post-procedure hemodynamics. As experience with cusp overlap and refined procedural techniques continues to grow, improved outcomes are anticipated.

Key: primary device used

CoreValve™ TAV · Evolut™ PRO TAV · Evolut™ R TAV · Evolut™ PRO+ TAV · Evolut™ FX

Optimize PRO FX Addendum[2]

Objective
The Optimize PRO FX study evaluates valve performance and procedural outcomes using an optimized TAVI care pathway and cusp overlap technique in patients receiving the Evolut™ FX TAVI platform.
Specifics
Study status/duration 30-day outcomes reported/1-year follow-up
Sample size 151 patients
30-day outcomes 1.3% all-cause mortality, 1.3% disabling stroke, 6.7% PPI
Devices Evolut™ FX 100%
Key takeaways
At 30 days, the use of standardized optimized care pathways and cusp overlap technique with the next generation Evolut™ FX TAVI system is associated with low PPI rates and no moderate/severe aortic regurgitation. The Evolut™ FX TAVI platform demonstrated favorable clinical and hemodyanmic outcomes with low 30-day all-cause mortality or stroke (2.7%), large EOAs and mean gradients (at discharge), and a median length of stay of 1 day. Continued excellent clinical outcomes are anticipated as procedural techniques continue to be refined.

SMART Trial[3]

Objective
The SMall Annuli Randomized to Evolut™ or SAPIEN™* (SMART) trial is a prospective, multicenter, international, randomized, controlled, post-market study comparing the Medtronic Evolut™ self-expanding valve (SEV) to the Edwards SAPIEN balloon-expanding valve (BEV). This study focuses on patients with symptomatic severe aortic stenosis (AS) and a small annulus size of 430 mm^2 or less.
Specifics
Study status/duration 1-year outcomes reported/5-year follow-up
Sample size N = 716 patients
1-year outcomes Clinical Outcome Co-primary endpoint†: Evolut™ SEV 9.4%, SAPIEN BEV 10.6% Valve Function Co-primary endpoint‡: Evolut™ SEV 9.4%, SAPIEN BEV 41.6%
Devices Evolut™ PRO/Evolut™ PRO+/Evolut™ FX and SAPIEN 3/SAPIEN 3 Ultra
Key takeaways
The purpose of this trial is to generate randomized clinical evidence on valve safety and performance of Evolut™ SEV versus SAPIEN BEV in patients with symptomatic severe native aortic valve stenosis. The primary objectives of the trial are to demonstrate clinical noninferiority and hemodynamic superiority of the Evolut™ TAVI system when compared to subjects treated with the SAPIEN 3/Ultra system at 1 year post-procedure. At 1 year follow-up, patients with symptomatic severe aortic stenosis and small aortic annuli undergoing Evolut™ SEV implantation were associated with similar clinical outcomes and superior valve function outcomes compared with SAPIEN BEV.

† Composite of all-cause mortality, disabling stroke, or heart failure hospitalization at 12 months.
‡ BVD is a composite including any of the following: hemodynamic structural valve dysfunction (mean gradient ≥ 20 mmHg), non-structural valve dysfunction (severe PPM or ≥ moderate aortic regurgitation), thrombosis, endocarditis, and aortic valve reintervention.

FORWARD PRO Study[4]

Objective
The objective of the FORWARD PRO Study was to evaluate the acute and long-term clinical performance and safety of the Evolut™ PRO system in patients with symptomatic severe aortic stenosis or failed bioprosthesis in routine practice.
Specifics
Study status/duration 3-year outcomes/5-year follow-up
Sample size N = 629
30-day outcomes 3.2% All-cause mortality 2.9% Disabling stroke 18.9% New PPI 3-year outcomes 25.0% All-cause mortality 6.5% Disabling stroke 24.7% New PPI
Device Evolut™ PRO
Key takeaways
The results of the FORWARD PRO Study highlighted the exceptional safety profile of the Evolut™ PRO valve. The Evolut™ PRO valve demonstrated outstanding hemodynamics and favorable sealing around the annulus, as evidenced by a 0% occurrence of moderate/severe paravalvular leakage (PVL) after three years, among patients with complete echocardiographic follow-up.

Evolut™ PRO Study[5]

Objective
The Evolut™ PRO Study was a prospective, multicenter, nonrandomized, single-arm study. Primary safety endpoints were all-cause mortality and disabling stroke at 30 days, and the primary efficacy endpoint was percentage of patients with no or trace aortic regurgitation at 30 days.
Specifics
Study status/duration 3-year outcomes reported/5-year follow-up
Sample size N = 60
30-day outcomes 1.7% All-cause mortality 1.7% Disabling stroke 11.8% New PPI 3-year outcomes 25.8% All-cause mortality 10.7% Disabling stroke 15.9% New PPI
Device Evolut™ PRO
Key takeaways
Three-year outcomes from the Evolut™ PRO Study demonstrated consistent and excellent performance of the Evolut™ PRO TAVI system. The primary safety and efficacy endpoints were achieved, maintaining a 0% occurrence of moderate/severe paravalvular leak (PVL) at 30 days and sustaining this outcome over a span of three years in a small patient population.

Evolut™ Low Risk Bicuspid Trial[6]

Objective
The objective of this multicenter, international, prospective, randomized, interventional, premarket trial was to evaluate the procedural safety and efficacy of the Medtronic TAVI system in patients with bicuspid aortic anatomy and severe aortic stenosis at low risk.
Specifics
Study status/duration 3-year outcomes reported/10-year follow-up
Sample size N = 150
30-day outcomes 1.3% All-cause mortality or disabling stroke 15.1% New PPI 0.0% > Mild PVL 3-year outcomes 4.1% All-cause mortality or disabling stroke 19.4% New PPI 0.0% > Mild PVL
Devices Evolut™ R 43%/Evolut™ PRO 57%
Key takeaways
Transcatheter aortic valve replacement in low-surgical risk patients with bicuspid aortic valve stenosis achieved excellent 3-year clinical outcomes, with low rates of death and stroke. The mean AV gradient at 3-years was 9.1 mmHg and effective orifice area was 2.2 cm^2. TAVI patients with bicuspid aortic valves had sustained improvement in NYHA and KCCQ scores at 3 years with low reintervention rates (1.4%). These results are comparable to the 3-year results of the Evolut™ valve in low surgical risk patients with tricuspid aortic valve stenosis.

Evolut™ Low Risk Trial[7]

Objective
The Evolut™ Low Risk Trial was a prospective, randomized, multicenter, noninferiority study to assess the safety and efficacy of the Evolut™ TAVI system compared with surgical aortic valve replacement (SAVR) in patients with a low predictive risk of 30-day surgical mortality.
Specifics
Study status/duration 4-year outcomes reported/10-year follow-up
Sample size TAVI = 725 and SAVR = 684
30-day outcomes 0.5% All-cause mortality 0.5% Disabling stroke 0.1% Clinical valve thrombosis 4-year outcomes 9.0% All-cause mortality 84.7% None/trace PVL 0.3% Clinical valve thrombosis
Devices Evolut™ R 73%/Evolut™ PRO 23.4%/CoreValve 3.6%
Key takeaways
The Low Risk trial's four-year findings highlighted the impressive performance of the Evolut™ TAVI system among patients with severe aortic stenosis at a low surgical risk. The primary endpoint of all-cause mortality or disabling stroke at 4 years was 10.7% TAVI vs 14.1% SAVR; p = 0.05; HR 0.74 (95% CI 0.54–1.00). At 4 years, there was a 26% relative reduction in the hazard (p = 0.05) for all-cause mortality or disabling stroke with TAVI compared to SAVR. The absolute difference between treatment arms for the primary endpoint continued to increase over time. Additionally, the system showcased statistically better hemodynamic performance compared to SAVR at the four-year milestone. Notably, both TAVI and SAVR exhibited similarly low rates of reintervention and clinical valve thrombosis, with 1.3% and 0.3% for TAVI and 1.7% and 0.2% for TAVI and SAVR, respectively. These results continue to support that Evolut™ TAVI may be a preferred strategy to surgery in the appropriate patients with severe AS at low surgical risk.

Key: primary device used

CoreValve™ TAV · Evolut™ PRO TAV · Evolut™ R TAV · Evolut™ PRO+ TAV · Evolut™ FX

Evolut™ R FORWARD Study[8]

Objective
The FORWARD Study was a prospective, single-arm, multicenter, observational study that assessed the safety and clinical performance of the Medtronic Evolut™ R system in patients with symptomatic native aortic stenosis or failed bioprosthesis in routine practice.
Specifics
Study status/duration 3-year outcomes reported/3-year follow-up
Sample size N = 1,038
30-day outcomes 1.9% All-cause mortality 1.8% Disabling stroke 17.5% New PPI 3-year outcomes 24.8% All-cause mortality 4.8% Disabling stroke 24.7% New PPI
Device Evolut™ R
Key takeaways
The FORWARD Study demonstrated excellent and reproducible results in real-world clinical practice. The high survival rate, low stroke rate, low permanent pacemaker rates, unsurpassed hemodynamics, and low rates of moderate/severe PVL confirmed the advantages of the Evolut™ R system.

Evolut™ R U.S. Study[9]

Objective
The Evolut™ R U.S. Clinical Study was a prospective, multicenter, controlled, nonrandomized, single-arm clinical study that evaluated the repositionable Evolut™ R system in patients deemed high risk or greater for surgery.
Specifics
Study status/duration 3-year outcomes reported/5-year follow-up
Sample size N = 241
30-day outcomes 2.5% All-cause mortality 3.3% Disabling stroke 16.4% New PPI 3-year outcomes 25% All-cause mortality 6.1% Disabling stroke 79.2% None/trace PVL
Device Evolut™ R
Key takeaways
Results from the Evolut™ R U.S. Study highlighted the safety and effectiveness of the Evolut™ R TAVI system. The 34 mm Appendix Study confirmed the performance of the Evolut™ R 34 mm valve in line with the Evolut™ platform.

Evolut™ R CE Mark Study[10]

Objective
The Evolut™ R CE Mark Clinical Study was a prospective, multicenter, controlled, nonrandomized, single-arm clinical study to evaluate the repositionable Evolut™ R system in patients with symptomatic aortic stenosis and heart team-assessed risk of operative mortality.
Specifics
Study status/duration 2-year outcomes reported/2-year follow-up
Sample size N = 60
30-day outcomes 0.0% All-cause mortality 0.0% Disabling stroke 11.7% New PPI 2-year outcomes 23.6% All-cause mortality 5.3% Disabling stroke 80% None/trace PVL
Device Evolut™ R
Key takeaways
The Evolut™ R CE Mark Study confirmed the safety and effectiveness of the Evolut™ R transcatheter aortic valve, a self-expanding bioprosthesis that provides a low-profile delivery system, conformable annular sealing, and the ability to reposition during deployment.

VIVA Study[11]

Objective
The VIVA study was a prospective, observational, single-arm, post-market, multicenter study to collect data regarding use of TAVI with the CoreValve and Evolut™ R devices in patients with failing surgical aortic bioprostheses at high risk for redo open-heart surgery.
Specifics
Study status/duration 2-year outcomes reported/2-year follow-up
Sample size N = 202
30-day outcomes 2.5% All-cause mortality 0.0% Disabling stroke 8.0% New PPI 2-year outcomes 16.5% All-cause mortality 1.7% Disabling stroke 12.0% PPI
Devices Evolut™ R 91%/CoreValve 9%
Key takeaways
Results from the VIVA Study confirmed the feasibility, safety, and effectiveness of the TAV-in-SAV intervention using the CoreValve/Evolut™ R devices in high-risk patients with failing surgical aortic bioprostheses.

Key: primary device used

CoreValve™ TAV Evolut™ PRO TAV Evolut™ R TAV Evolut™ PRO+ TAV Evolut™ FX

SURTAVI Continued Access Study[12]

Objective

Prior to intermediate risk approval, the SURTAVI Continued Access Study (CAS) enrolled patients in the U.S. who underwent attempted TAV implant under the same inclusion and exclusion criteria and trial procedures as the SURTAVI Trial with no randomization to surgery.

Specifics

Study status/duration
5-year outcomes reported/5-year follow-up

Sample size
N = 275

30-day outcomes	5-year outcomes
0.0% All-cause mortality 0.4% Disabling stroke 17.2% PPI	29.2% All-cause mortality 3.4% Disabling stroke 27.6% PPI

Devices
Evolut™ R 93%/CoreValve 7%

Key takeaways

For patients with severe symptomatic AS at intermediate surgical risk treated with TAVI, five-year data from SURTAVI CAS showed favorable clinical outcomes, with excellent valve hemodynamics, low reintervention rates (1.1%), and no clinical valve thrombosis. These data demonstrated the longer-term safety and effectiveness of TAVI in this risk population.

SURTAVI Trial[13]

Objective

The SURTAVI Trial was a prospective, randomized, multicenter, noninferiority study to assess the safety and efficacy of the Medtronic TAVI system to SAVR in patients with symptomatic severe aortic stenosis at intermediate surgical risk.

Specifics

Study status/duration
5-year outcomes reported/10-year follow-up

Sample size
N = 864 TAVI, N = 796 SAVR

30-day outcomes	5-year outcomes
2.2% All-cause mortality 3.4% All stroke 0.9% Aortic valve reintervention	31.3% All-cause mortality or disabling stroke 3.5% Aortic valve reintervention 3.0% ≥ Mild PVL

Devices
CoreValve 84%/Evolut™ R 16%

Key takeaways

Among intermediate-risk patients with symptomatic severe aortic stenosis, major clinical outcomes at five years were similar for TAVI and surgery. Bioprosthetic valve performance was consistent through five years. TAVI was associated with superior hemodynamic valve performance at five years and had significantly better hemodynamics than surgery at each follow-up. Clinical valve thrombosis and endocarditis were infrequent through five years with both TAVI and SAVR. Rates of heart failure or valve-related rehospitalization were similar as well. Reintervention rates between two and five years were equally low for TAVI and surgery. Health status improved similarly after TAVI or surgery, and was maintained at five years.

Key: primary device used

CoreValve™ TAV · Evolut™ PRO TAV · Evolut™ R TAV · Evolut™ PRO+ TAV · Evolut™ FX

NOTION Study[14]

Objective

The Nordic Aortic Valve Intervention (NOTION) Trial randomized all-comers with severe native aortic valve stenosis to either TAVI or SAVR, including a lower-risk patient population from three centers in Denmark and Sweden.

Specifics

Study status/duration
10-year outcomes reported/10-year follow-up

Sample size
N = 145 TAVI, N = 135, as-treated SAVR

30-day outcomes	10-year outcomes
2.1% All-cause mortality 1.4% All stroke 34.1% New PPI	62.7% All-cause mortality 9.7% All stroke SVD§: 20.2% (TAVI), 37.7% (SAVR); p = 0.0008 Severe SVD: 1.5% (TAVI), 10.0% (SAVR); P = 0.02

Device
CoreValve

Key takeaways

The NOTION trial 10-year results constitute the longest follow-up data from a prospective, randomized trial between TAVI and SAVR available to date. The NOTION Trial results demonstrate the strong clinical performance of CoreValve in lower risk patients (80% of patients had an STS < 3%) versus surgery. After 10 years of follow up, there was no difference between CoreValve TAVI and SAVR with regards to all-cause mortality, stroke, or myocardial infarction. At 10 years follow-up, the TAVI arm had less severe SVD, defined according a modified VARC-3 endpoint§, compared to SAVR, whereas there was no difference in bioprosthetic valve failure between arms (9.7% TAVI and 13.8% SAVR {HR 0.7; 95% CI 0.4–1.5; P = 0.4}).

§ Modified VARC-3 definition: Mean gradient ≥ 30 mmHg; AND increase in mean gradient ≥ 20 mmHg, Severe intraprosthetic AR.

BVD Pooled analysis
from the CoreValve U.S. Pivotal trial, SURTAVI trial, and CoreValve CAS[15]

Objective

The purpose of the BVD pooled analysis was to evaluate the five-year incidence, outcomes, and predictors of bioprosthetic valve dysfunction (BVD) in patients undergoing supra-annular, self-expanding TAVI or surgery from the CoreValve U.S. High-Risk and SURTAVI randomized clinical trials, and the CoreValve Extreme Risk and CoreValve CAS non-randomized trials.

Specifics

Study status/duration
5-year BVD rate and outcomes reported

Sample size
N=5,485 (TAVI RCT = 1,209, TAVI non-RCT = 3,190, SAVR RCT = 1,086)

Devices
CoreValve 89.0%, Evolut™ R 11.0%

	5-year incidence		
	CoreValve/ Evolut™ TAVI	**SAVR**	**P value**
BVD, %◊,¶	**9.6**	**15.4**	**< 0.001**
SVD◊	2.1	4.5	0.007
NSVD◊	5.5	9.6	< 0.001
Thrombosis	0.3	0.2	0.80
Endocarditis	1.6	1.8	0.67

Key takeaways

The CoreValve/Evolut™ supra-annular, self-expanding bioprosthesis is the first and only transcatheter valve to demonstrate lower rates of BVD and significantly better five-year valve performance compared with surgery in randomized clinical trials. This difference in valve performance was driven by a two-fold lower SVD and three-fold lower severe PPM, and was more profound in patients with smaller (≤ 23 mm) annuli (8.7% TAVI vs. 19.5% SAVR, p < 0001). Development of BVD, regardless of aortic valve replacement therapy, is associated with a significantly increased risk for worsened clinical outcomes including a 58% relative increase in 5-year hazard of death, 85% relative increase in 5-year hazard of cardiovascular death, and 50% relative increase in 5-year hazard of hospitalization. This was the first analysis to validate clinical criteria for valve performance (BVD) and its association with clinical outcomes, as evaluated by a comprehensive, contemporary BVD definition and > 5,000 patient analysis.

◊ BVD was defined as: SVD# (mean gradient ≥ 10 mmHg increase from discharge/30 days AND ≥ 20 mmHg at last echo or new onset/increase of ≥ moderate intraprosthetic aortic regurgitation), NSVD (30-day severe PPM at 30-day/discharge or severe PVR through five years), clinical valve thrombosis, or endocarditis.

¶ Adapted from VARC-3 Writing Committee; Généreux P, et al. *Eur Heart J*. 2021;42:1825-1857. Capodanno D, et al. *Eur Heart J*. 2017;38:3382-3390.

CoreValve U.S. Pivotal Extreme Risk Trial[16]

Objective
The CoreValve U.S. Pivotal Extreme Risk Trial evaluated the safety and efficacy of the Medtronic CoreValve system for the treatment of patients with symptomatic severe aortic stenosis in whom the predicted risk of operative mortality or serious, irreversible morbidity was 50% or greater at 30 days.

Specifics	
Study status/duration 5-year outcomes reported/5-year follow-up	
Sample size N = 489	
30-day outcomes 8.4% All-cause mortality 2.3% Major stroke 21.6% New PPI	**5-year outcomes** 71% All-cause mortality 10.7% Major stroke
Device CoreValve	

Key takeaways
Results from the CoreValve U.S. Pivotal Extreme Risk Trial achieved the primary endpoint, confirming the safety and efficacy of the CoreValve system in patients with symptomatic severe aortic stenosis at prohibitive risk for surgical valve replacement. The five-year results showed sustained hemodynamics with low gradients and large EOAs.

CoreValve U.S. Pivotal High Risk Trial[17]

Objective
The CoreValve U.S. Pivotal High Risk Trial was a prospective, randomized, multicenter, noninferiority study that compared the safety and efficacy of the Medtronic CoreValve system to SAVR in patients with symptomatic severe aortic stenosis at increased surgical risk.

Specifics	
Study status/duration 5-year outcomes reported/5-year follow-up	
Sample size N = 795 (TAVI = 390, SAVR = 357, as treated)	
30-day outcomes 3.3% All-cause mortality 3.9% Major stroke 19.8% New PPI	**5-year outcomes** 55.3% All-cause mortality 12.3% Major stroke 3% Reintervention
Device CoreValve	

Key takeaways
Study achieved one-year all-cause mortality primary endpoint showing the CoreValve system is superior to SAVR for patients with an increased surgical risk. The CoreValve system is the only TAVI valve to show patient survival superiority versus SAVR in a randomized controlled study at one year. At the five-year mark, all-cause mortality was similar for TAVI and SAVR. The significantly better hemodynamic performance was sustained for TAVI over SAVR. Additionally, TAVI showed less moderate structural valve deterioration$^{\Delta}$ (SVD) than SAVR.

CoreValve Expanded Use Study[18]

Objective
The purpose was to evaluate the safety and effectiveness of the CoreValve system in a subset of subjects excluded from the U.S. Extreme Risk Pivotal Trial population due to one or more additional comorbidities: • Severe mitral valve regurgitation (MR) • Severe tricuspid valve regurgitation (TR) • End stage renal disease (ESRD) • Low gradient low output (LGLO) • Failed bioprosthetic surgical aortic valve (TAV-in-SAV) • Two or more conditions (listed above)$^{\Delta}$

Specifics	
Study status/duration 5-year outcomes reported/5-year follow-up	
Sample size N = 782 (53 = severe MR, 54 = severe TR, 215 = LGLO, 133 = ESRD, 232 = TAV-in-SAV, 95 = 2 or more conditions)	
30-day outcomes for TAV-in-SAV 2.2% All-cause mortality 0.4% Major stroke 8.1% New PPI	**5-year outcomes for TAV-in-SAV** All-cause mortality: 46.8% Reintervention: 5.9% Major stroke: 6.7%
Device CoreValve	

Key takeaways
Primary endpoint results confirmed the safety and effectiveness of the CoreValve system in the EUS TAV-in-SAV, LGLO, severe MR, severe TR, and ESRD cohorts. The safety outcomes within each of the cohorts, to the extent which they differ from each other and previous trials in inoperable patients, were reasonable given the underlying disease states in these extreme-risk cohorts and the additional morbidity they introduced. Similarly, treatment with CoreValve was efficacious through the follow-up with improvements in QoL and hemodynamic performance being substantial, especially when considered within the context of the baseline characteristics of the cohorts (e.g., limitations in flow area with the TAV-in-SAV cohort and a very serious comorbidity limiting the potential to improve QoL in the ESRD cohort).

CoreValve ADVANCE Study[19]

Objective
The ADVANCE study was a multicenter, prospective, single-arm, observational study to evaluate safety and performance of the CoreValve system in a routine hospital setting.

Specifics	
Study status/duration 5-year outcomes reported/5-year follow-up	
Sample size N = 1,015	
30-day outcomes 4.5% All-cause mortality 1.2% Major stroke 26.3% New PPI	**5-year outcomes** 50.7% All-cause mortality 5.4% Major stroke 0.9% SVD
Device CoreValve	

Key takeaways
Five-year results in real-world, elderly, high-risk patients undergoing TAVI with a self-expanding bioprosthesis provided evidence for continued valve durability and sustained unsurpassed hemodynamics.

Key: primary device used

CoreValve™ TAV · Evolut™ PRO TAV · Evolut™ R TAV · Evolut™ PRO+ TAV · Evolut™ FX

ΔSVD definition reference: Capodanno D, et al. *Eur Heart J*. 2017;38:3382-3390.

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