The Beat Goes On

Clinical Insights in Heart Valve Research

Vol 1 Issue 1 – July 2024

Edwards

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Contents

Over 1 million severe symptomatic aortic stenosis patients have been treated with TAVR*

***Millions more remain untreated*[1–4]**

You are dedicated to ensuring that patients with symptomatic severe aortic stenosis have access to lifesaving therapy. For the millions of eligible patients still untreated,[1–4] your accurate, early diagnosis and urgent referral to a TAVR heart team are crucial.

#ForTheMillionsMore

*Edwards data on file

Introduction

Welcome to the first edition of 'The Beat Goes On' – a clinical compendium bringing you the latest data on aortic stenosis (AS) detection, diagnosis and the patient treatment journey. This publication aims to provide concise, thoughtfully curated clinical summaries for the use of both the general and the referring cardiology community.

To optimize patient care, early and accurate diagnosis of AS is essential to avoid undertreatment. In this issue we highlight the factors that may contribute to diagnostic ambiguity and bring you the latest published advice on resolving these issues. Also discussed here are factors influencing the rate of disease progression and rehospitalization to help identify patients who may benefit from closer monitoring as part of an individualized treatment plan.

This edition features insights from five recent publications covering the topics of diagnostic considerations, reintervention, 5-year outcomes for low-risk patients from the PARTNER 3 trial, and more.

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The Mortality Burden of Untreated Aortic Stenosis

Généreux P *et al. J Am Coll Cardiol.* 2023; **82:** 2101–9

Background

Both European and US guidelines recommend referral for an evaluation for aortic valve replacement (AVR) for patients with severe symptomatic aortic stenosis (AS), or for asymptomatic patients with severe AS and left ventricular dysfunction.[5,6] However, challenges in assessing AS can result in underestimation of severity and undertreatment, impacting the prognosis of patients.[7] Généreux *et al.* 2023 assessed mortality across the severity spectrum of untreated AS from a large, real-world database.

Aim[7]

To assess mortality rates across all severity categories of untreated AS from a large contemporary real-world database.

Study Population

24
centers

1,669,536
deidentified echocardiograms

595,120
patients met inclusion criteria

Primary endpoint: All-cause mortality

Secondary endpoint: Time to treatment with aortic valve replacement for AS

Results

70,778 (11.9%) patients were diagnosed with some degree of AS, according to documented echocardiographic reports (Figure 1), of whom:

- 86.6% of patients were diagnosed with mild, moderate, or severe AS
- 13.4% of patients received an intermediate diagnostic classification (mild-to-moderate and moderate-to-severe AS)

Diagnostic severity discordance in AS and severe AS echocardiographic criteria was found in at least 22.8% and 59.8% of moderate and moderate-to-severe AS patients, respectively.

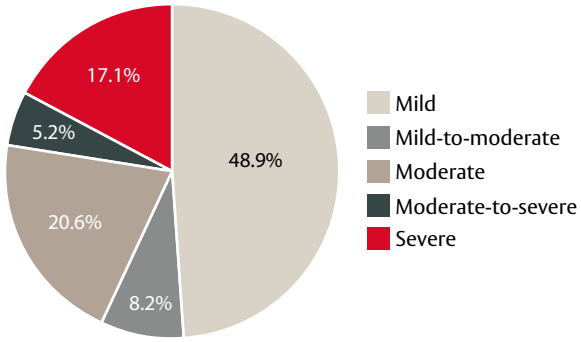

Figure 1. Classification of AS, including intermediate diagnoses

4-year mortality without AVR (Figure 2)

- Mortality rates for moderate-to-severe (45.7%) and severe (44.9%) were almost twice as high as those for mild AS (25.0%)[7]
- Mortality rates for intermediate classifications were similar to the rates for the next-higher classification[7]

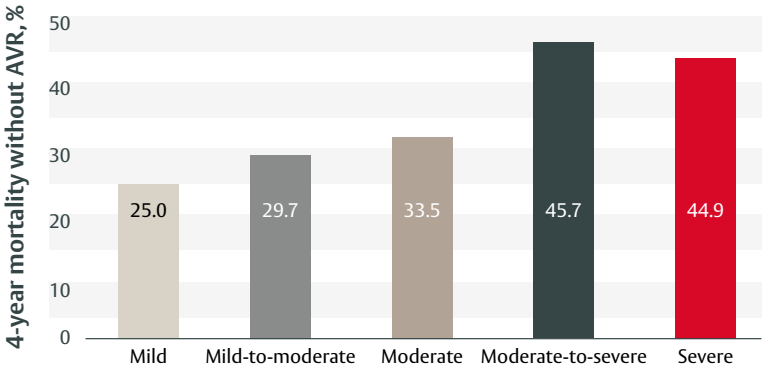

Figure 2. Mortality rates at 4 years without AVR[7]

Rates of AVR demonstrate undertreatment of patients with AS

The 4-year treatment rate for patients with severe AS was only 60.7% – over 1/3 of patients remained untreated. For moderate-to-severe AS the treatment rate was just 36.7% – 2/3 patients remained untreated despite having the same 4-year mortality without AVR as patients with severe AS (Figure 3). Underappreciation of AS severity may lead to undertreatment and potentially impact prognosis.

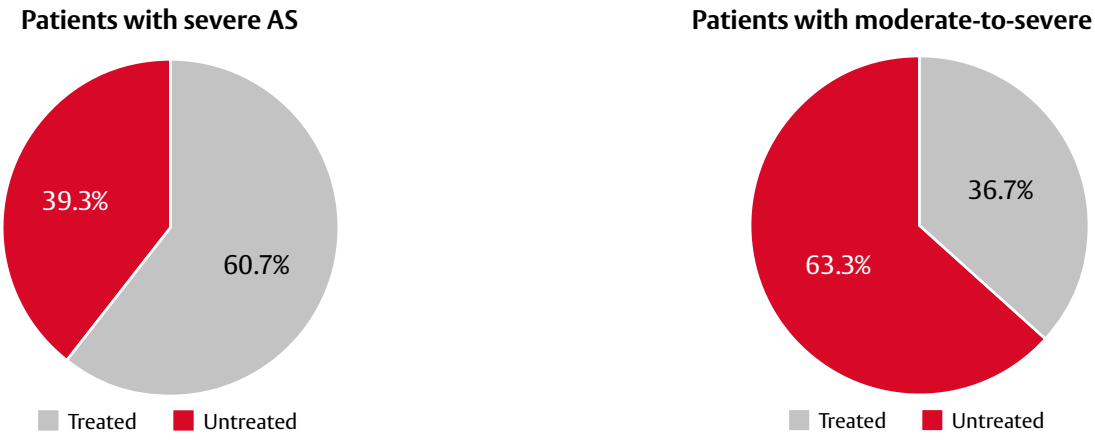

Figure 3. Treatment rates for patients with severe and moderate-to-severe AS

Underdiagnosis of AS is likely attributable to multiple factors, including:

- Difficult image acquisition
- Patient echogenicity
- Variability in image quality
- Challenging clinical situations such as discordant AS with/without low flow states

Patients presenting with moderate-to-severe AS may warrant referral to a multidisciplinary Heart Team for further evaluation and folllow-up.

Underdiagnosis of AS severity was common, with echocardiographic criteria for severe AS present in:

~1 in 5 (22.8%) patients diagnosed with moderate AS[7]

~3 in 5 (59.8%) patients diagnosed with moderate-to-severe AS[7]

Conclusion[7]

Treatment of severe AS remains low, with high unmet patient need – over 1/3 of patients remain untreated 4 years after initial diagnosis. Mortality risk increases incrementally across the spectrum of AS severity, highlighting the need for earlier diagnosis, closer follow-up, and earlier intervention where possible.

Intermediate diagnoses are common in real-world practice; however, American Heart Association/American College of Cardiology (AHA/ACC) guidelines only define AS as mild, moderate or severe.

Intermediate diagnoses are associated with the mortality rates of the higher severity grade which may contribute to underdiagnosis and undertreatment of severe AS.

Clinical Insights

- AS should be diagnosed as mild, moderate, or severe.[5]
- Accurate diagnosis is essential - where there is discordance, patients should be referred to the Heart Team for further diagnostic tests and evaluation.[7]
- Undertreatment of AS is associated with high mortality rates; 1 in 10 patients may die within 5 weeks while awaiting treatment – ensure timely referral of all patients with severe AS to the Heart Team.[8]

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Aortic Stenosis Progression: A Systematic Review and Meta-Analysis

Willner N *et al. JACC Cardiovasc Imaging*. 2023; **16:** 314–28

Background[9]

Degenerative aortic stenosis (AS) is a progressive disease with significant variation in the rate of progression. Currently, there are no medical therapies to prevent or slow the progression of AS, and aortic valve replacement (AVR) remains the only treatment.

The clinical factors influencing AS progression are largely unknown, and data on the impact of baseline AS severity and sex on the disease progression are scarce.

Aim[9]

To determine hemodynamic and anatomic AS progression rate and to assess whether baseline severity or sex impact rate of progression.

Study Population[9]

The authors identified prospective studies evaluating AS progression with the use of echocardiography or computed tomography (CT) from Medline, Embase and Cochrane Central Register of Controlled Trials.

24
studies included in the meta-analysis

5,450
unique patients

Results[9]

Annualized rate of progression

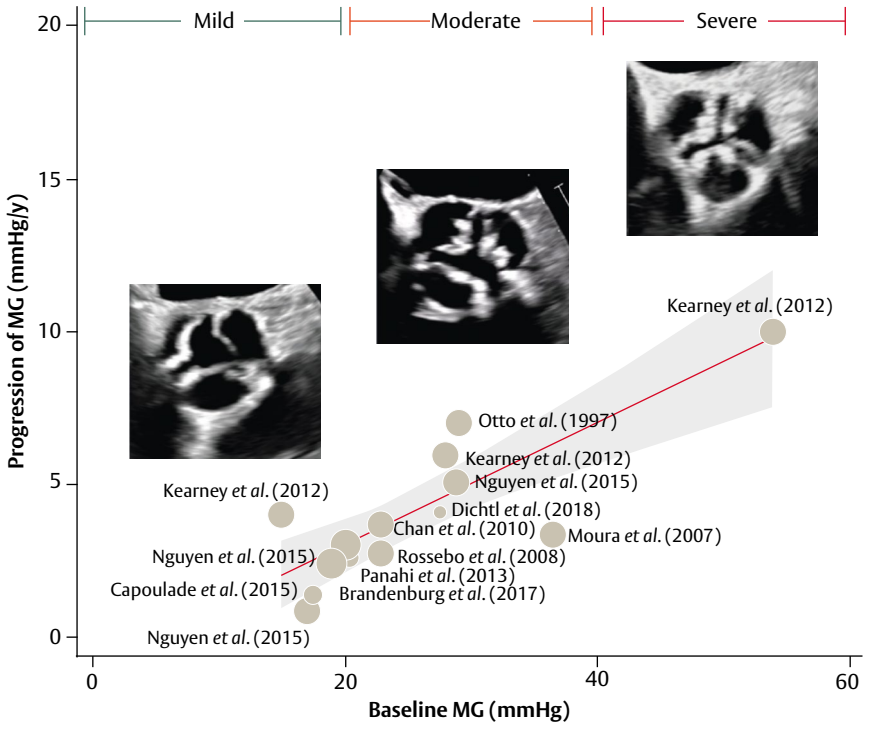
Pooled data from all studies reporting each outcome were used to determine the annual rate of progress of AS.

Increasing baseline mean gradient, peak velocity, and aortic valve calcification were predictive of increased rates of progression for mean gradient, peak velocity, and aortic valve calcification, respectively. No associations were found between baseline peak gradient or aortic valve area and their accelerated progression.

Table 1: Annualized rate of hemodynamic and anatomic progression of AS

Outcome	Annualized rate of progression
Mean gradient	+4.10 mmHg/year
Peak gradient	+7.86 mmHg/year
Peak velocity	+0.19 m/s/year
Aortic valve area	−0.08 cm^2/year
Aortic valve calcification	+158.5 AU/year

AU: arbitrary units



The upper 95% confidence interval for peak velocity progression was 0.23m/s/year suggests that the threshold for rapid progression may be lower than the threshold of 0.3 m/s/year previously reported,[9] and used in the AHA/ACC guidelines as a recommendation to refer for evaluation for intervention in asymptomatic patients.[5]

Only 4 of the 24 studies reported AS progression stratified by sex, and no differences in progression between males and females were found.

Increasing baseline AS severity was a predictor for accelerated AS progression (Figure 1).

Figure 1. Relationship between baseline aortic stenosis severity and disease progression

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Higher baseline severity of aortic stenosis is associated with faster progression. Bubble plot and meta-regression shows relationship between baseline aortic stenosis severity and rate of progression. MG = mean gradient.

Conclusion[9]

This systematic review and meta-analysis determined the most up-to-date and accurate annualized rates of AS progression and found that increasing baseline AS severity is associated with accelerated AS progression. No association was seen between sex and rate of AS progression, although these data are limited.

These data demonstrate that increasing baseline AS severity was associated with more rapid progression, which has important implications for individualized patient care. Using patient-specific baseline measures may help clinicians personalize the treatment plan and estimate the timing of valve intervention for individual patients by identifying those with more aggressive AS who may need more frequent follow-up and monitoring, and earlier intervention.

Clinical Insights

- Variation in diagnostic methodology, imaging, and interpretation is a major contributor to underdiagnosis and undertreatment of AS.[7]
- Using mean gradients, peak velocity, and aortic valve calcification to predict the rate of disease progression may help to personalize monitoring of patients.[9]
- A better understanding of factors affecting disease progression may benefit patients and may assist clinicians in better assessing time for referral and intervention.[9]
- Patients with more severe baseline AS may progress faster than previously thought and therefore earlier referral to the Heart Team may be necessary.[9]

Feature Article

Transcatheter Aortic Valve Replacement in Low-Risk Patients at Five Years

Mack MJ *et al*. *N Engl J Med* 2023; **389:** 1949–60

Background

The PARTNER 3 randomized controlled trial compares transcatheter aortic valve replacement (TAVR), using the Edwards SAPIEN 3 valve, with surgical aortic valve replacement (SAVR) in low-risk patients with severe, symptomatic aortic stenosis, with a planned follow-up of 10 years.[10]

Previous PARTNER 3 analyses have demonstrated that the rate of a composite of death, stroke, or rehospitalization at 1 and 2 years was lower for TAVR than for SAVR.[11,12] Here, Mack *et al*. report the 5-year outcomes.

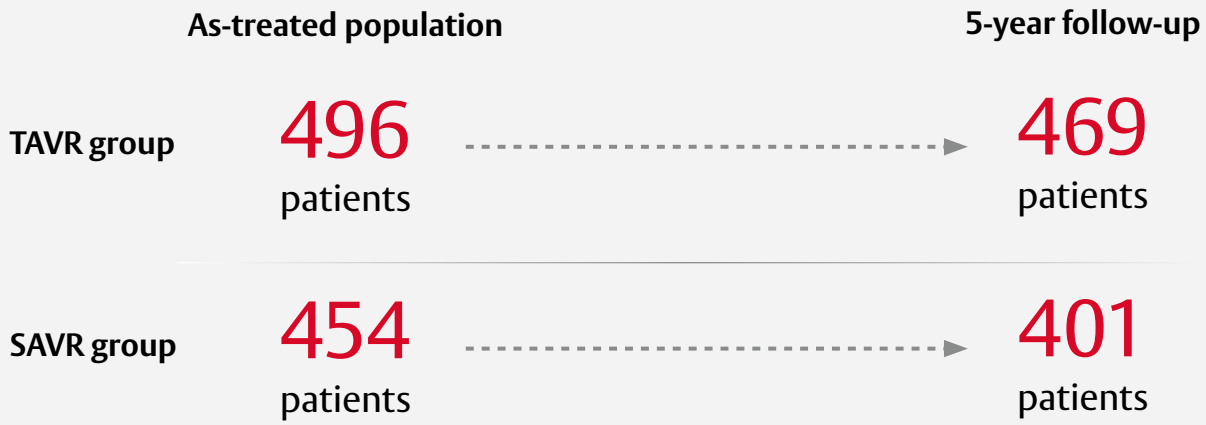
Objectives[10]

Primary endpoints: Non-hierarchical composite of all-cause mortality, stroke, or rehospitalization;* hierarchical composite including all-cause mortality, stroke, and number of rehospitalization days.

Summarized secondary endpoints†: Included mortality or disabling stroke, valve thrombosis (defined according to Valve Academic Research Consortium 3 criteria), reintervention, functional status and quality of life (Kansas City Cardiomyopathy Questionnaire – overall summary [KCCQ-OS]).

Study Population[10]

Patients were randomized 1:1 to undergo either TAVR with a SAPIEN 3 valve or SAVR with a commercially available bioprosthetic valve. Clinical outcomes and transthoracic echocardiography data were assessed at baseline, after implantation, at discharge, 30 days, 6 months, and then annually up to 5 years.



*Related to the procedure, the valve, or heart failure
†Please note that the secondary endpoints listed are those summarized. Please refer to the full publication for a complete list of endpoints

Results[10]

All-cause mortality, stroke, or rehospitalization at 5 years

The composite endpoint of all-cause mortality, stroke, or rehospitalization was similar in the TAVR and SAVR groups (−4.3%; 95% CI −9.9–1.3, p=0.07). The TAVR and SAVR groups had similarly low rates of cardiovascular mortality (5.1% vs 5.5%, hazard ratio 1.08 (95% confidence intervals 0.61–1.92) (Figure 1).

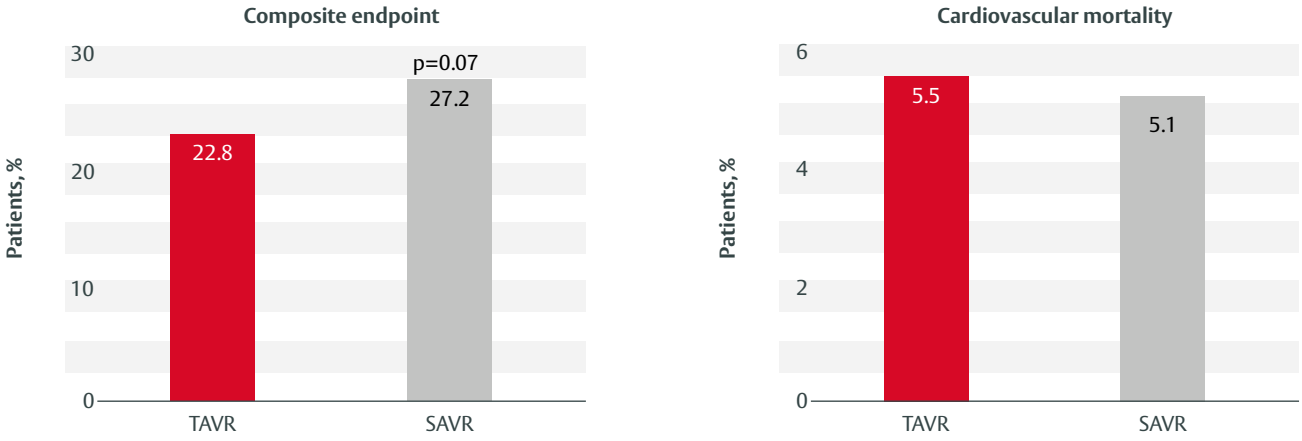


Figure 1. Composite endpoint and cardiovascular mortality at 5-year follow-up.

Valve durability

Kaplan–Meier estimates of all-cause valve failure at 5 years were similar for the TAVR and SAVR groups. Estimates of aortic valve reintervention were also similar, at 2.2% for the TAVR group and 2.6% for the SAVR group. Rates of irreversible Stage 3 hemodynamic valve deterioration, reintervention, and valve-related death were extremely low (Figure 2).

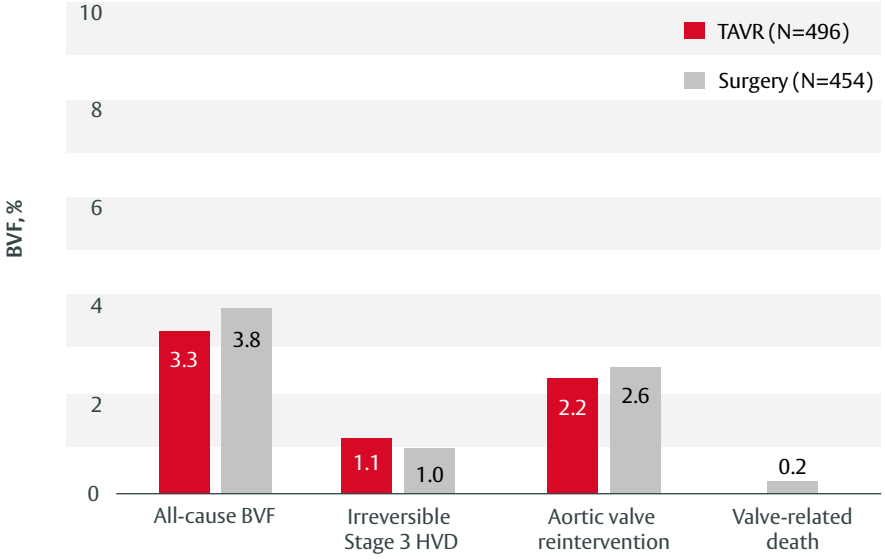


Figure 2. Valve durability at 5-year follow-up.

BVF: bioprosthetic valve failure; HVD: hemodynamic valve deterioration

Ultra-low rates of valve failure or reintervention at 5 years

Functional and health status

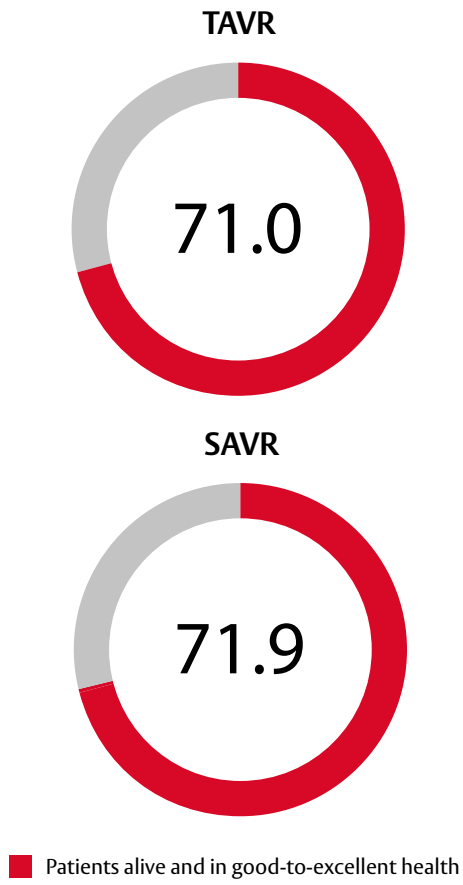
Functional outcomes were similar between the two groups, with a high percentage of patients alive and in New York Heart Association (NYHA) class I/II at 5 years (84.4% and 86.0% in the TAVR and SAVR groups, respectively).

The Kansas City Cardiomyopathy Questionnaire (KCCQ) measures patient-reported health status, taking into account symptom burden, physical and social limitations, and quality of life.

KCCQ-OS score[13]	Health status[13]
75–100	Good to excellent
50–74	Fair to good
25–49	Poor to fair
0–24	Very poor to poor

At 5 years, the mean KCCQ-OS scores were 86.2% in the TAVR group and 85.9% in the SAVR group. Furthermore, the majority of patients were alive with a KCCQ-OS score of 75 or greater (indicative of good to excellent health), with similar results in the TAVR and SAVR groups.

Mean KCCQ-OS scores ≥75 at 5 years



Conclusion[10]

At the 5-year follow-up, the composite endpoint was similar between the TAVR and SAVR groups. Valve durability is critically important, and this study reported low rates of bioprosthetic valve failure and reintervention in both the TAVR and SAVR groups.

The functional status and quality of life improvements seen at 1 year were sustained at 5-year follow-up, with the majority of patients in NYHA class I/II and reporting good health.

Overall, outcomes at 5 years were good in low-risk patients with severe symptomatic aortic stenosis, with similar results following both TAVR with the SAPIEN 3 valve and SAVR with contemporary bioprosthetic valves.

KCCQ-OS: Kansas City Cardiomyopathy Questionnaire overall summary

Clinical Insights[10]

- Valve durability is particularly important to consider for low-risk patients because they typically have longer life expectancies than high-risk patients. Longer-term results are critical to inform decision-making.
- This study highlights the low frequency of bioprosthetic valve failure with the SAPIEN 3 valve, showing encouraging signs for favorable durability and reinforcing it as a trusted alternative to SAVR.
- Rates of cardiovascular mortality were very low at 5.5% and 5.1% for TAVR and SAVR; this is particularly encouraging given the average patient age of 73 years at baseline.
- Longer-term data such as these should inform patient centered treatment for low risk patients.

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Rehospitalization Events After Aortic Valve Replacement: Insights From the PARTNER Trial

Huded CP *et al. Circ Cardiovasc Interv.* 2022; **15:** e012195

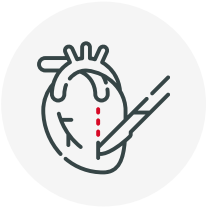
Background[14]

Heart failure is associated with poor prognosis in severe aortic stenosis, and a subset of patients continue to suffer from heart failure after AVR. Hospitalization for heart failure (either alone or as part of a composite) is a common endpoint in AVR trials; however, the prognostic impact of rehospitalization after valve replacement is unclear, particularly whether hospitalizations after AVR are transient events, or markers that identify patients at high risk for poor long-term outcomes.

Aim[14]

To use data from the PARTNER trials to evaluate the association between rehospitalization after AVR with 1-year survival and health status.

Study Population[14]



Surgical aortic valve replacement (SAVR) group:

1,395 patients from the SAVR arms of the PARTNER trials.[14]

Transcatheter aortic valve replacement (TAVR) group:

2,008 patients who underwent transfemoral TAVR and received an Edwards SAPIEN 3 valve.

Patients were stratified by status at 1 year:

Patient status	N (%)
Alive without heart failure hospitalization	2,929 (86.1)
Alive with heart failure hospitalization	183 (5.4)
Deceased	291 (8.5)

Endpoints: All-cause mortality, poor outcome (composite of death, Kansas City Cardiomyopathy overall summary [KCCQ-OS] score <60 or a ≥10-point decline from baseline), and disease-specific and general health status assessed by KCCQ-OS and Short Form 36 scores.

Results

Rehospitalization

Rehospitalization (composite of events due to heart failure, valve-related or procedure-related causes) rate was 9.7% at 1 year after AVR, with a heart failure hospitalization rate of 6.7% (Figure 1).

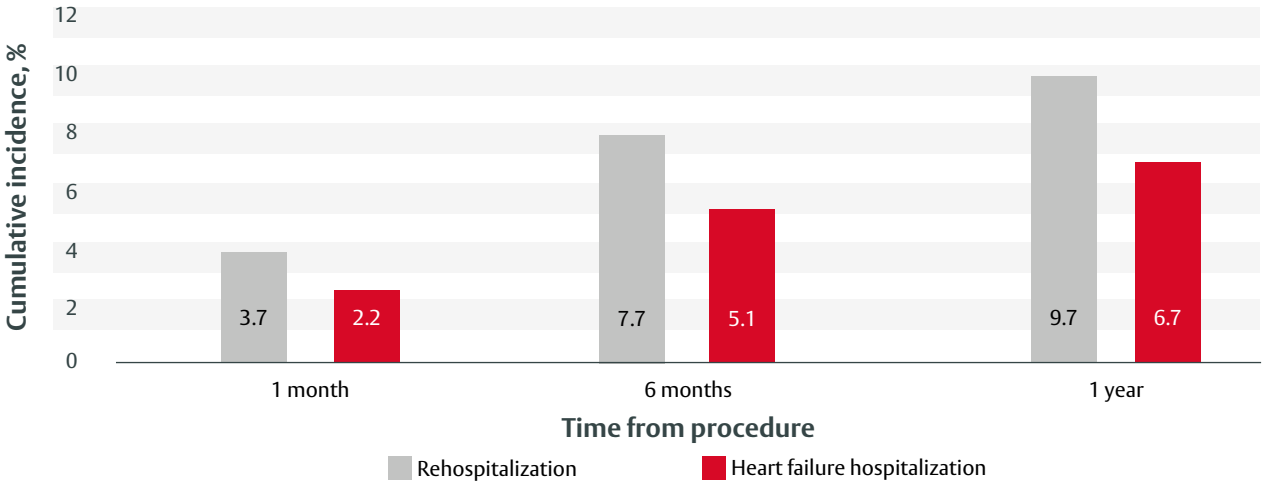


Figure 1. Hospitalization rates after AVR

Association of hospitalization with 1-year outcomes

Hospitalization for heart failure within 1 year of AVR was independently associated with an increased risk of mortality, poor outcome and worse health status, with similar associations seen for rehospitalization.

Hospitalization for heart failure increased the risk of:[14]

Mortality
Adjusted hazard ratio (HR):
4.0 (2.5, 6.4)
p<0.001

Poor outcome
Adjusted odds ratio:
2.8 (1.7, 4.4)
p<0.001

Worse health status
Adjusted difference in KCCQ-OS score:
–9.8 (–13.8, –5.8)
p<0.001

Values in brackets denote 95% confidence intervals

Risk factors for heart failure hospitalization:[14]

A multivariable model identified pre-procedural factors independently associated with an increased risk of heart failure hospitalization after AVR:

- Low baseline mean gradient; HR per 10 mmHg decrease 1.37 (1.15–1.61), p<0.001
- Pre-existing atrial fibrillation or flutter; HR 2.17 (1.42–3.31), p<0.001
- Prior percutaneous coronary interventions; HR 1.75 (1.06–2.91), p=0.03
- Prior coronary artery bypass graft (CABG); HR 1.72 (1.05–2.81), p=0.03

Conclusion[14]

By demonstrating the independent association of rehospitalization with mortality, poor outcomes, and worse health status, this data confirms the prognostic impact of rehospitalization events. Risk factors for heart failure hospitalization include lower baseline mean gradients, prior atrial fibrillation or flutter, prior coronary artery interventions, and prior CABG.

AVR via SAVR or TAVR is associated with low rates of heart failure hospitalization and rehospitalization. Prognostic associations of heart failure hospitalization and rehospitalization with mortality, poor outcome or decline of health status after AVR were equivalent for TAVR and SAVR.

Early identification of patients with an increased risk of heart failure hospitalization after AVR, and appropriate monitoring and management by the Heart Team, may improve outcomes in these patients.

Clinical Insights[14]

- Consider baseline risk factors when selecting patients for AVR.
- While risk of heart failure hospitalization following AVR should be considered, as TAVR has grown and devices have improved, the rate of poor outcomes has decreased, so this should not deter from the referral of AS patients for TAVR evaluation.
- Ensure patients with a high risk of future heart failure hospitalization, or who remain symptomatic after AVR are closely monitored.

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Long-Term Risk of Reintervention After Transcatheter Aortic Valve Replacement[15]

Baron S *et al*. *Am Heart J*. 2024; **267:** 44–51

Background[15]

TAVR has overtaken SAVR as the main mode of intervention for patients with severe, symptomatic aortic stenosis. This growth has been fuelled by the expansion of TAVR indications to include younger, healthier patients at lower surgical risk.

Aim[15]

To estimate the risk of reintervention up to 10 years after TAVR using Medicare claims data.

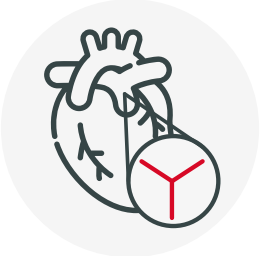
Study Population[15]

All patients in the Medicare claims database who underwent TAVR in 2011–2020 were included. Of those, patients who underwent valve reintervention up to the end of 2021 were identified. The cumulative probability of valve reintervention over time was estimated using a competing risk regression model.

Primary endpoint: Cumulative probability of valve reintervention over time.

Summarized secondary endpoints:* Risk of reintervention each year after the index procedure; change in reintervention rates over time.

Medicare claims database



Patients who underwent aortic valve reintervention

* Please note that secondary endpoints listed are those summarized. Please refer to full publication for complete list of endpoints.

Results[15]

Patients who underwent valve reintervention had significantly higher rates of chronic obstructive pulmonary disease, diabetes, and liver disease.

The risk of reintervention after TAVR seems to be improving over time: patients treated later in the TAVR era (2017–2021) had a significantly lower risk of reintervention than patients treated earlier (2011–2016; $p<0.001$). This may be attributed to improved TAVR valves and/or improved technical proficiency of implanters.

230,644
TAVR patients studied

1,880
patients underwent reintervention

1.63%
adjusted* cumulative incidence of reintervention at 10 years after TAVR (Figure 1)

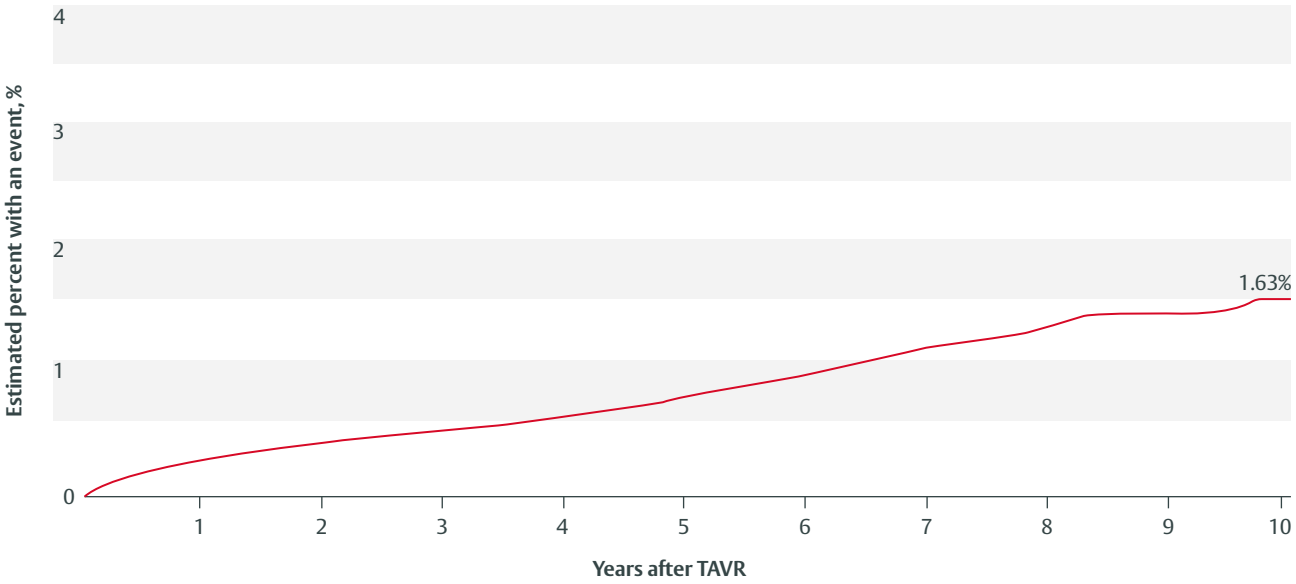


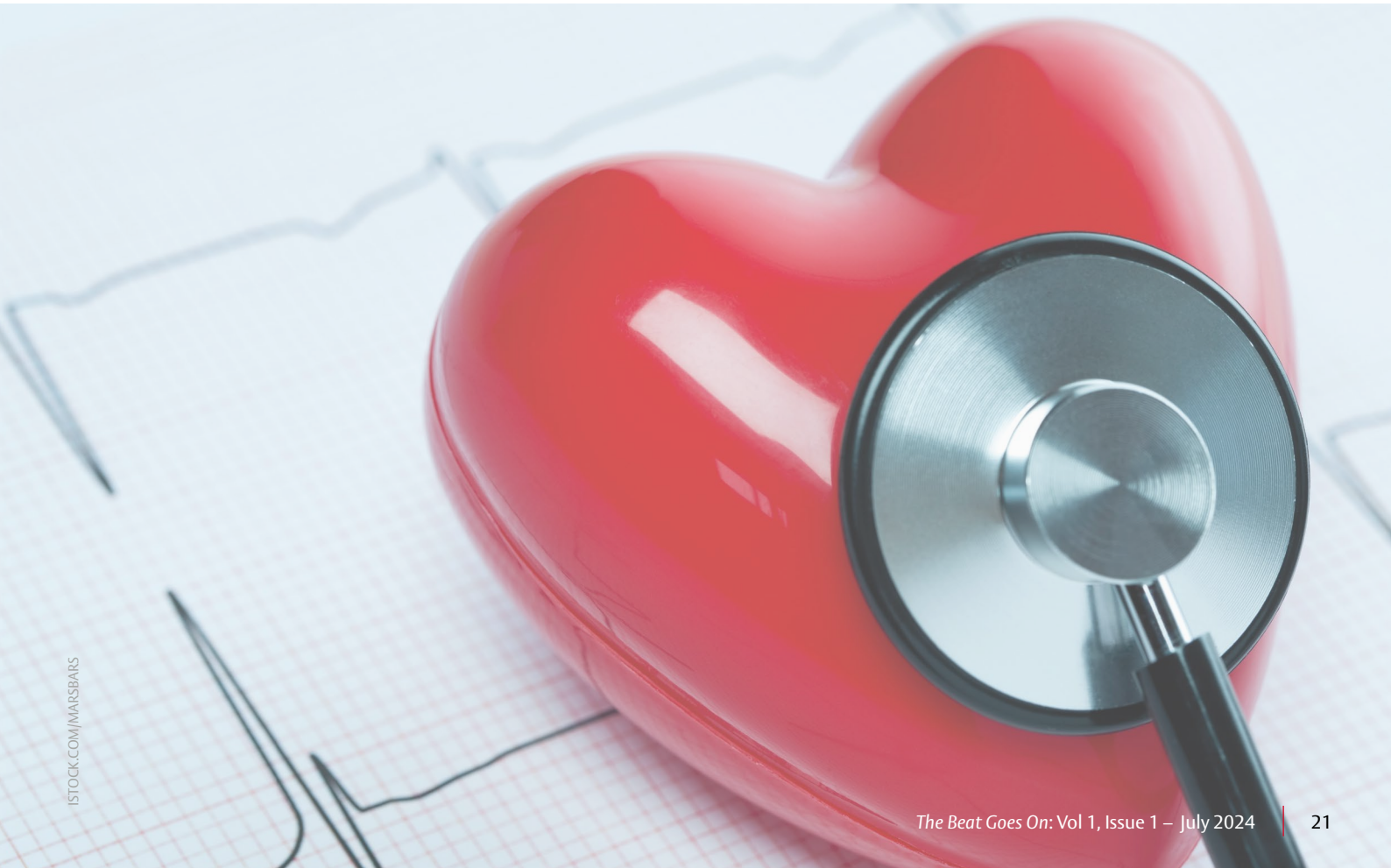
Figure 1. Adjusted cumulative risk of reintervention over time, accounting for the competing risk of death, as determined by Fine-Gray subdistribution hazard model

Conclusion[15]

This is the first real-world study assessing the risk of reintervention up to 10 years following TAVR. Results demonstrate that the risk of reintervention at 10 years is low and has improved over time, with over 98% TAVR patients not requiring reintervention. Additionally, the risk of reintervention for TAVR is at least comparable to the risk of reintervention after SAVR.

Clinical Insights[15]

- The durability of TAVR is an important consideration for shared decision-making, and reintervention rates are part of that decision.
- The growing body of evidence for long-term TAVR outcomes and improved transcatheter valves points to reduced rates of reintervention over time and will support shared decision-making conversations.
- Transcatheter valves and implantation techniques have improved – the risk of reintervention at 10 years after TAVR is at least comparable to the risk after SAVR (1.9–10.3%), making this a trusted option for patients.



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Edwards Lifesciences planned exhibits at upcoming cardiac conferences

Have questions about aortic stenosis or TAVR outcomes? Visit Edwards at these conferences:

JTVT	**July 19–20, 2024:** Fukuoka, Japan
CSANZ	**August 1–4, 2024:** Perth, Australia
ESC	**August 30–September 2, 2024:** London, UK
EACTS	**October 9–12, 2024:** Lisbon, Portugal
TCT	**October 27–30, 2024:** Washington, DC, USA
AHA	**November 16–18, 2024:** Chicago, IL, USA
PCR London Valves	**November 24–26, 2024:** London, UK
SCAI Fall Fellows	**December 13–17, 2024:** Miami, FL, USA
STS	**January 24–26, 2025:** Los Angeles, CA, USA
Tokyo Valves	**February 7–9, 2025:** Tokyo, Japan
CRF	**February 28–March 1, 2025:** New York, NY, USA
ACC	**March 28–30, 2025:** Chicago, IL, USA
SCAI	**May 1–3, 2025:** Washington, DC, USA
AATS	**May 3–6, 2025:** New York, NY, USA

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Any Edwards LIfesciences support, financial or otherwise, for the studies cited above is disclosed in the associated publication.

Abbreviations:

ACC:	American College of Cardiology
AHA:	American Heart Association
AS:	aortic stenosis
AVR:	aortic valve replacement
CABG:	coronary artery bypass graft
CT:	computed tomography
HR:	hazard ratio
HVD:	hemodynamic valve deterioration
KCCQ:	Kansas City Cardiomyopathy Questionnaire
KCCQ-OS:	Kansas City Cardiomyopathy Questionnaire - overall summary
NYHA:	New York Heart Association
SAVR:	surgical aortic valve replacement
TAVR:	transcatheter aortic valve replacement

US: Please see enclosed Important Safety Information

EU: Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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