



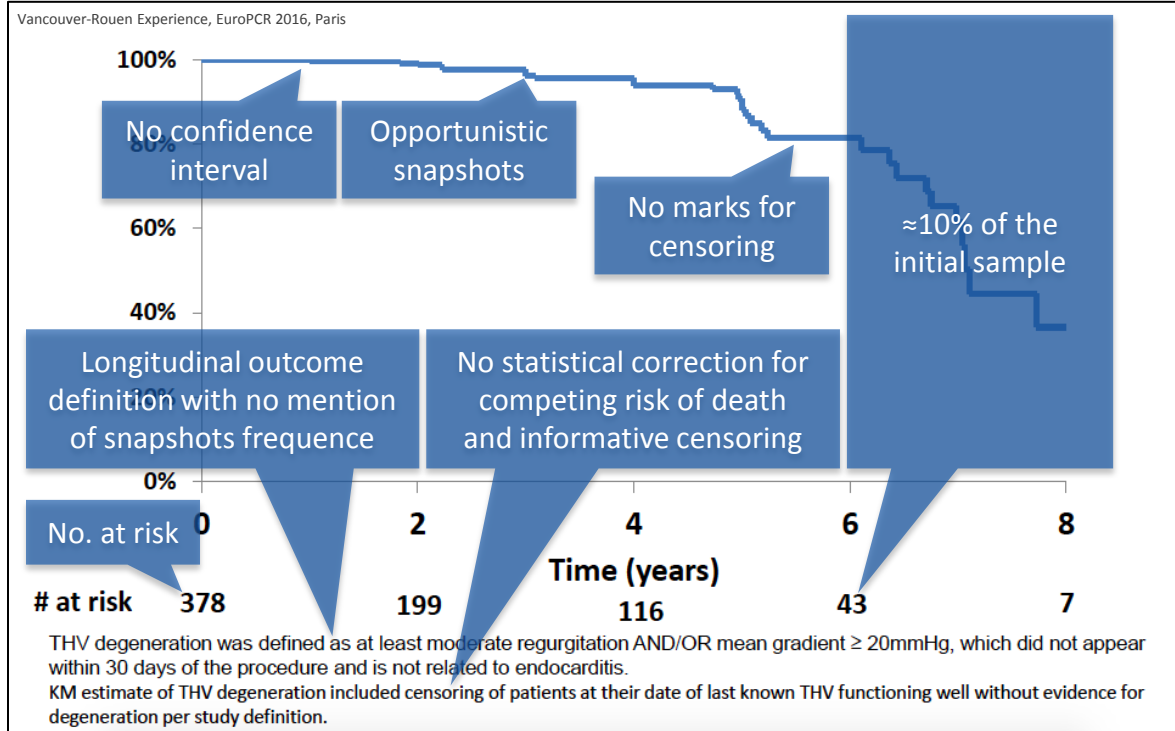
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Durability of Transcatheter Aortic Valves: An Update

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STATISTICAL REPORTING OF TAVR DURABILITY IS COMPLEX



- ▶ SVD evolves with time and does not occur at a precise instant
- ▶ Death exerts a competing risk against the risk of a valve to fail over time
- ▶ The typical assumption of non-informative censoring in old TAVI patients is false

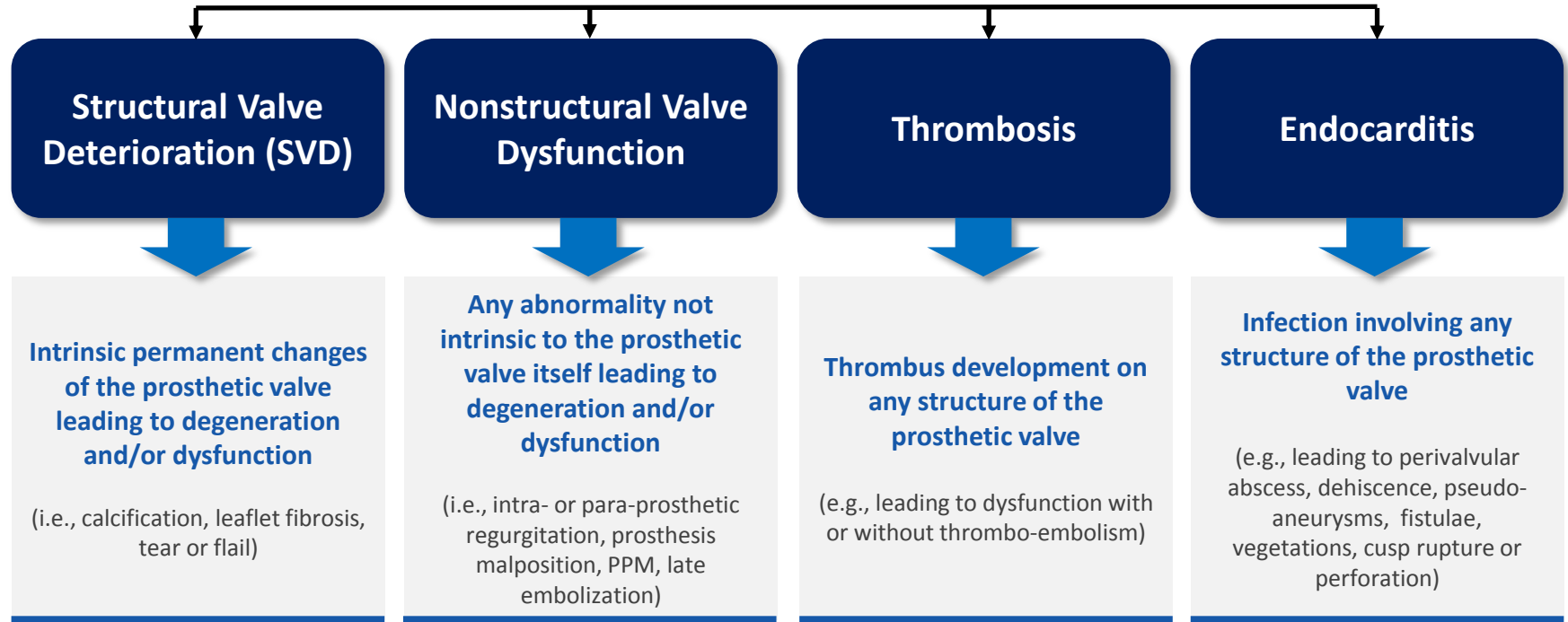
MANY DEFINITIONS OF STRUCTURAL VALVE DETERIORATION

Historically defined as “reoperation for SVD”

~ 20 definitions of SVD using echocardiographic criteria since 2006

Definition	Reference	Journal, Year
Leaflet calcification, leaflet tear	Amabile et al ¹¹	<i>Journal of Thoracic and Cardiovascular Surgery</i> , 2014
Dysfunction or deterioration of the prosthesis (excluding infection or thrombosis) evident on echocardiography or at reoperation	Anselmi et al ¹²	<i>Journal of Thoracic and Cardiovascular Surgery</i> , 2014
Echocardiographic evidence of SVD	Ashikhmina et al ¹³	<i>Circulation</i> , 2011
Echocardiographic criteria (mean gradient >40 mmHg or aortic insufficiency of grade 3 or 4 (based on a scale of 1 to 4)	Aupart et al ¹⁴	<i>Journal of Heart and Valve Disease</i> , 2006
Leaflet tear, leaflet prolapse, primary valve failure with significant regurgitation and increased NYHA class	Auriemma et al ¹⁵	<i>Journal of Heart and Valve Disease</i> , 2006
Echocardiographic evidence of severe aortic stenosis (mean transvalvular gradient >40 mmHg) or severe aortic regurgitation (effective regurgitant orifice area >0.30 cm ² , vena contracta >0.6 cm), even if the patient was asymptomatic	Bourguignon et al ^{16,17}	<i>Annals of Thoracic Surgery</i> , 2015; <i>European Journal of Cardio-Thoracic Surgery</i> , 2016
Severe hemodynamic SVD is defined as (1) mean gradient ≥ 40 mmHg or ≥ 20 mmHg change from baseline (before discharge or within 30 days of valve implantation), or (2) severe new or worsening (>2/4) intraprosthetic aortic regurgitation	Capodanno et al ¹⁰	<i>European Heart Journal</i> , 2017
Increase in mean gradient of >10 mmHg, decrease in Doppler Velocity Index <0.25, or development of new severe aortic regurgitation on consecutive aortic echocardiograms	Daubert et al ¹⁸	<i>Journal of the American College of Cardiology</i> , 2017
≥ 10 mmHg increase in transprosthetic mean gradient during follow-up compared with discharge assessment	Del Trigo et al ¹⁹	<i>Journal of the American College of Cardiology</i> , 2017
In accordance with 1996 guidelines (ie, a decrease of 1 NYHA functional class resulting from an intrinsic abnormality of the valve that causes stenosis or regurgitation) or a mean pressure gradient >40 mmHg was		

Bioprosthetic Valve Dysfunction (BVD)



EAPCI/ESC/EACTS STANDARDIZED DEFINITIONS OF SVD

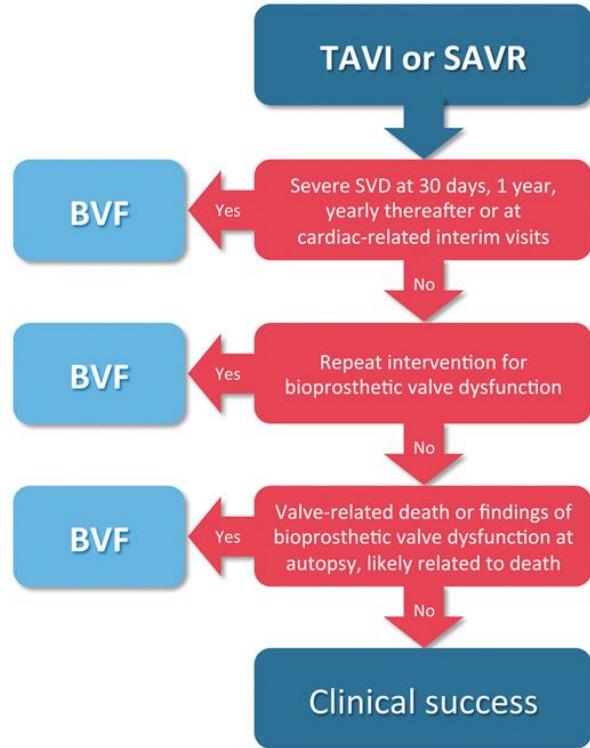
Type	Definition
Morphologic	<ul style="list-style-type: none"> ▶ Leaflet integrity abnormality (i.e. torn or flail causing intra-frame regurgitation) ▶ Leaflet structure abnormality (i.e. pathological thickening and/or calcification causing valvular stenosis or central regurgitation) ▶ Leaflet function abnormality (impaired mobility resulting in stenosis and/or central regurgitation) ▶ Strut/frame abnormality (i.e. fracture)
Hemodynamic	<p>Moderate</p> <ul style="list-style-type: none"> ▶ Mean transprosthetic gradient ≥ 20 mmHg and < 40 mmHg ▶ Mean transprosthetic gradient ≥ 10 and < 20 mmHg change from baseline ▶ Moderate intra-prosthetic AR, new or worsening ($> 1+/4+$) from baseline <p>Severe</p> <ul style="list-style-type: none"> ▶ Mean transprosthetic gradient ≥ 40 mmHg ▶ Mean transprosthetic gradient ≥ 20 mmHg change from baseline ▶ Severe intra-prosthetic AR, new or worsening ($> 2+/4+$) from baseline

“MORE ALIKE THAN DIFFERENT”

EAPCI/ESC/EACTS VS. VIVID DEFINITIONS OF SVD

Criteria for SVD	EAPCI/ESC/EACTS	VIVID
No significant change from immediate post-implantation	No SVD	Stage 0
Morphological leaflet abnormality without significant hemodynamic changes	Morphological SVD	Stage 1
Moderate stenosis	Moderate H-SVD	Stage 2S
Moderate regurgitation	Moderate H-SVD	Stage 2R
Moderate stenosis and regurgitation	Moderate H-SVD	Stage 2RS
Severe stenosis and/or severe regurgitation	Severe H-SVD	Stage 3

ESC/EACTS DEFINITION OF BIOPROSTHETIC VALVE FAILURE



Type	Definition
Bioprosthetic valve failure (BVF)	<ul style="list-style-type: none"> ▶ Autopsy findings of bioprosthetic valve dysfunction, likely related to the cause of death ▶ Valve-related death (i.e. any death caused by bioprosthetic valve dysfunction or sudden unexplained death following diagnosis of bioprosthetic valve dysfunction) ▶ Repeat intervention following confirmed diagnosis of bioprosthetic valve dysfunction (i.e. valve-in-valve TAVI, paravalvular leak closure or SAVR) ▶ Severe hemodynamic SVD

DURABILITY OF TRANSCATHETER AORTIC BIOPROSTHESES

Study	N	Valve	Follow-up	Survival*	Severe SVD	BVF
COREVALVE US HR trial	391	SE 100%	5 years	44.7%	0.8%	-
FRANCE-2 Registry	4,201	BE 68%, SE 32%	5 years	39.2%	2.9%	-
NOTION trial	139	SE 100%	6 years	57.5%	0.7%	7.5%***
UK-TAVI Registry	241	BE 25%, SE 64%	6 years	-	0.4%	-
Deutsch et al.	300	BE 29%, SE 71%	7 years	23.2%	- **	3.7%
Durand et al.	1,403	BE 84%, SE 16%	7 years	18.6%	4.2%	1.9%***
Eltchaninoff et al.	378	BE 100%	8 years	9.6%	3.2%	0.6%***
Barbanti et al.	288	BE 83%, SE 17%	8 years	29.8%	5.9%	4.5%***
Holy et al.	152	SE 100%	8 years	27.0%	0%	4.5%***
Antonazzo Panico, et al.	278	SE 100%	8 years	20.0%	3.6%	2.5%***

*Actuarial analysis ** 14.3% moderate or severe SVD (cumulative incidence function) ***Actual analysis (cumulative incidence function)

At a follow-up of 5 to 8 years, ESC/EACTS severe SVD is reported at **0 to 6%** and BVF at **1 to 8%**

5-YEAR DURABILITY OF TAVR VS SAVR IN HIGH RISK PATIENTS

STRUCTURAL VALVE DETERIORATION (SVD)

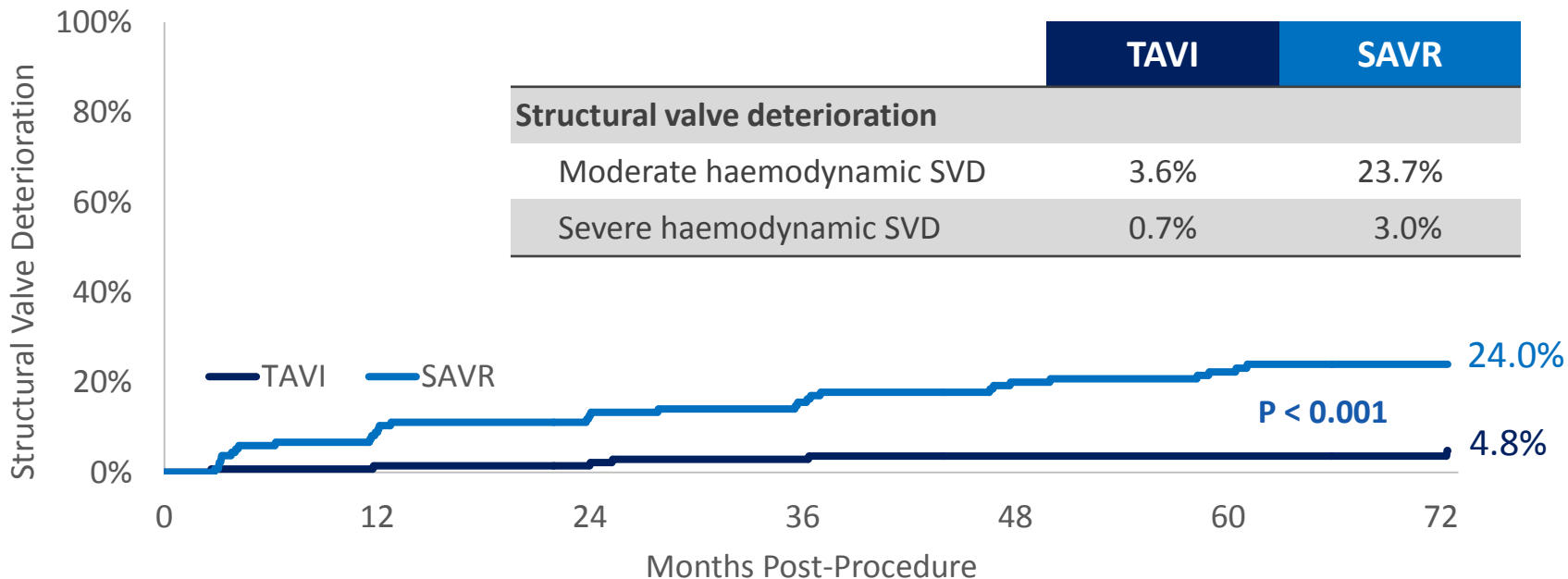
EAPCI/ESC/EACTS DEFINITION

	TAVR	SAVR	
Moderate hemodynamic SVD	9.2%	26.6%	<0.001
Mean gradient at any time of ≥ 20 mm Hg, but < 40 mm Hg	5.4%	25.7%	<0.001
Change in mean gradient from baseline of ≥ 10 , but < 20 mmHg	1.5%	5.4%	0.004
Moderate central AR (new from discharge)	3.3%	0.8%	0.022
Severe hemodynamic SVD	0.8%	1.7%	0.322
Mean gradient ≥ 40 mmHg	0.3%	1.1%	0.197
Change in mean gradient from baseline of ≥ 20 mmHg	0.5%	0.8%	0.673
Severe central AR (new from discharge)	0.3%	0.0%	>0.999

6-YEAR DURABILITY OF TAVR VS. SAVR IN LOW RISK PATIENTS

STRUCTURAL VALVE DETERIORATION (SVD)

EAPCI/ESC/EACTS DEFINITION



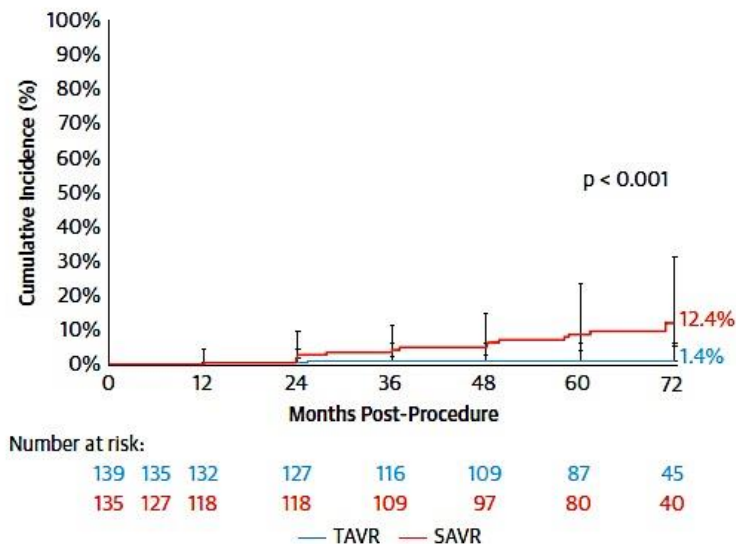
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6-YEAR DURABILITY OF TAVR VS. SAVR IN LOW RISK PATIENTS

STRUCTURAL VALVE DETERIORATION EAPCI/ESC/EACTS DEFINITION

	TAVR	SAVR
Moderate hemodynamic SVD	3.6%	23.7%
Mean gradient ≥ 20 mmHg	2.9%	22.2%
Δ in mean gradient ≥ 10 and < 20 mmHg	1.4%	11.1%
Moderate central AR	0.0%	0.0%
Severe hemodynamic SVD	0.7%	3.0%
Mean gradient ≥ 40 mmHg	0.0%	1.5%
Δ in mean gradient ≥ 20	0.7%	3.0%
Severe central AR	0.0%	0.0%

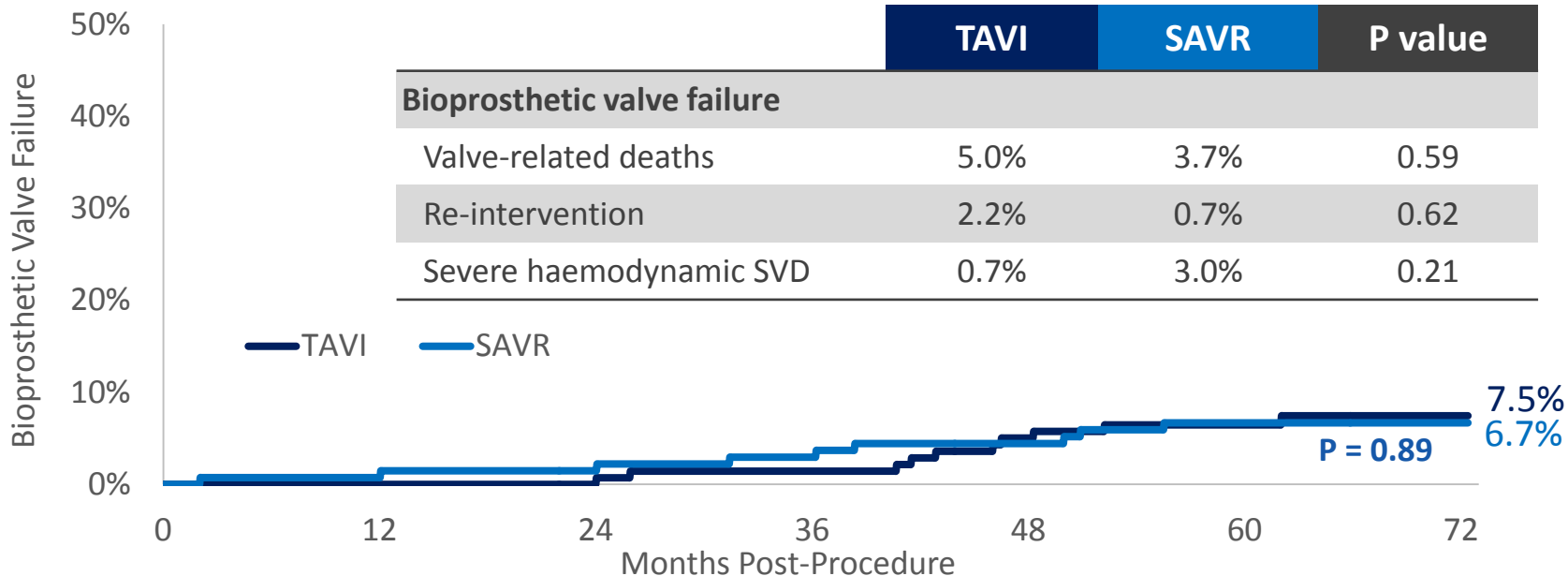
SVD AFTER EXCLUDING PATIENT-PROSTHESIS MISMATCH



6-YEAR DURABILITY OF TAVI VS SAVR IN LOW RISK PATIENTS

BIOPROSTHETIC VALVE FAILURE (BVF)

EAPCI/ESC/EACTS DEFINITION



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DURABILITY OF TRANSCATHETER HEART VALVES

- Assessing long-term SVD and BVF has become an important issue for patients and physicians making an informed decision between the choice of TAVI and SAVR bioprostheses, particularly for younger patients and those with few comorbidities who have many remaining expected years of life.
- TAVI durability data between 5 and 8 years using standardized definitions do not show safety concerns in comparison with historical SAVR data, and no difference in severe SVD or BVF at 6 years between TAVI and SAVR was shown in low risk patients from the NOTION trial.
- **Because what really matters is durability beyond 10 years, more meaningful durability data for TAVI are expected no sooner than 2020-2025.**