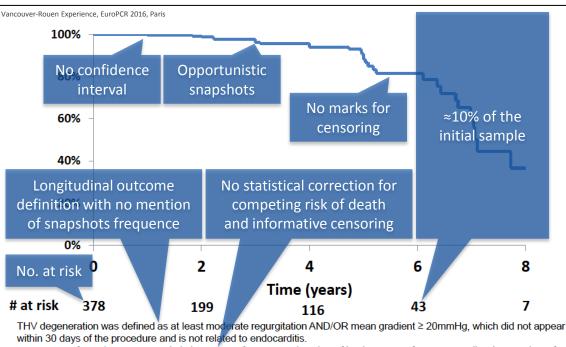


Durability of Transcatheter Aortic Valves: An Update

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STATISTICAL REPORTING OF TAVR DURABILITY IS COMPLEX



KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.

- 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"

 \sim 20 definitions of SVD using echocardiographic criteria since 2006

Definition	Reference	Journal, Year	
Leaflet calcification, leaflet tear	Amabile et al ¹¹	Journal of Thoracic and Cardiovascular Surgery, 2014	
Dysfunction or deterioration of the prosthesis (excluding infection or thrombosis) evident on echocardiography or at reoperation	Anselmi et al ¹²	Journal of Thoracic and Cardiovascular Surgery, 2014	
Echocardiographic evidence of SVD	Ashikhmina et al ¹³	Circulation, 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	Journal of Heart and Valve Disease, 2006	
Leaflet tear, leaflet prolapse, primary valve failure with significant regurgitation and increased NYHA class	Auriemma et al ¹⁵	Journal of Heart and Valve Disease, 2006	
Echocardiographic evidence of severe aortic stenosis (mean transvalvular gradient >40 mm Hg) 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}	Annals of Thoracic Surgery, 2015; European Journal of Cardio-Thoracic Surgery, 2016	
Severe hemodynamic SVD is defined as (1) mean gradient \geq 40 mm Hg or \geq 20 mm Hg 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	European Heart Journal, 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	Journal of the American College of Cardiology, 2017	
≥10 mmHg increase in transprosthetic mean gradient during follow-up compared with discharge assessment	Del Trigo et al ¹⁹	Journal of A	





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Task Force composition: IAPCI Security Board (AB, BP, MH, SW), IAPCI Scientific Documents and Initiatives Committee (IAC, RAB), EAPCI Databases and Registries Committee (IAS), ISS, IPSL, Valle for Etile Initiative (AB, MH, SW), PCR London Valles Course Directors (IBP, CT, NSW, DMR) Security (IAS), ISC representative (IAX), VARC Internatives (IAX), VARC Internatives (IAX), VARC Internatives (IAX), VARC Internatives (IAX), IPSC Internatives (IAX), VARC Internatives (IAX), IPSC Internatives (I

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Corresponding author, Tel: +39-095-7436103; fax: +39-095-362429; e-mail: dcapodarno@amail.com (D. Capodarno) Received 8 March 2017; received in revised form 21 March 2017; accepted 19 May 2017 Keywords: Transcatheter aortic valve implantation - Surgical aortic valve replacement - Durability - Long-term outcomes - Structural valve deterioration - Bioprosthetic valve failure - Bioprosthetic valve dysfunction

The first two authors contributed equally.

Task Force composition: EAPCI Executive Board (A.B., B.P., M.H., S.W.). EAPCI Scientific Documents and initiatives Committee (D.C., RA.B.). EAPCI Databases and persone control sectore double (Au, Br., M.H., SW), DATO Scientific Documents and initiatives committies (AP, K.J., RAAL, DATO, BARALESS, M.H., SW), EACT Scientific Concentration (B.P., CT., N.P., SW, M.H.), SEC Board (J.B.), initia (ASP, LS, PLJ, Walve for the initiative (AS, M.H., SW), PCR London Values Course Directory (B.P., CT, N.P., SW, M.H.), SEC Board (J.B.), es (A.V., M.H., SW), EDRP representatives (A.V., ASP), EACTS representative (A.P.K.), VARC representatives (A.P.K., N.P., SW), Other invited experts (HH IH IM PL TM)

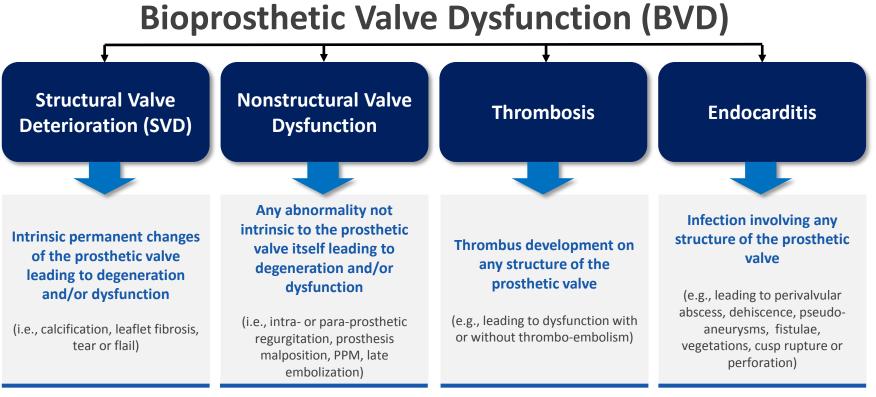
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durability outcomes based on longitudinal vs. time-dependent outcomes, competing risk and actual vs. actuarial analyses



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EUROPEAN CONSENSUS





Туре	Definition
Morphologic	 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	 Moderate 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 Severe Mean transprosthetic gradient ≥40 mmHg Mean transprosthetic gradient ≥20 mmHg change from baseline Severe intra-prosthetic AR, new or worsening (>2+/4+) from baseline

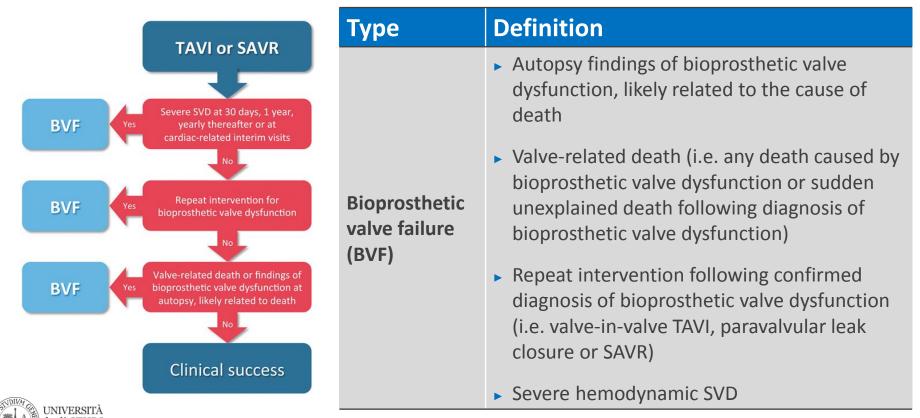


Criteria for SVD	EAPCI/ESC/EACTS	VIVID
No significant change from immediate post-implantation	No SVD	Stage 0
Morphological leaflet abnormality without significant hemodynamic changes	Morphological SVD	Stage 1
Moderate stenosis	Moderate H-SVD	Stage 2S
Moderate regurgitation	Moderate H-SVD	Stage 2R
Moderate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



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

ESC/EACTS DEFINITION OF BIOPROSTHETIC VALVE FAILURE



DURABILITY OF TRANSCATHETER AORTIC BIOPROSTHESES

Study	Ν	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%**



NIVERSITA Gleason TG, et al. JAC 2018; Didier R, et al. Circulation. 2018; Eltchaninoff H, et al. EuroIntervention 2018; Deutsch MA, et al. EuroIntervention. 2018; Barbanti et al. J Am Heart Assoc. 2018;

Durand E, et al. Circ Cardovasc Interv 2019;12; Holy EW, et al. EuroIntervention. 2018; Antonazzo Panico R, et al. EuroIntervention. 2018; Blackman DJ et al. JACC 2019.

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

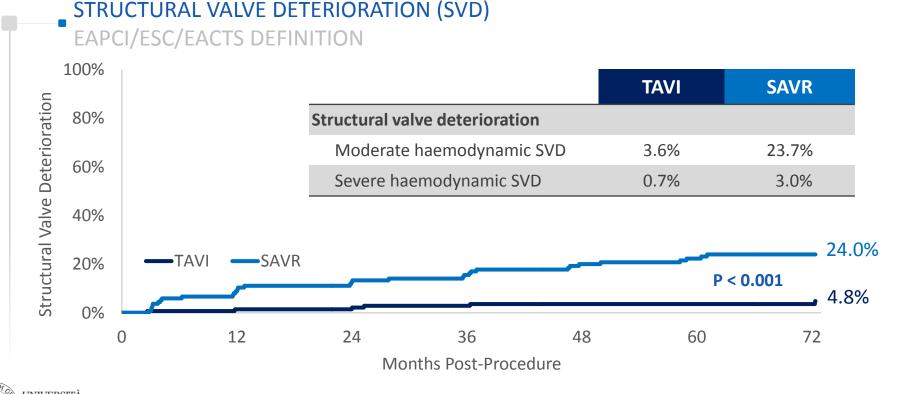
STRUCTURAL VALVE DETERIORATION (SVD)

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



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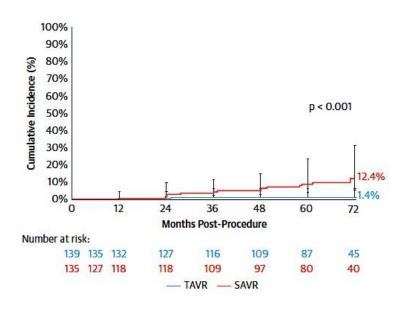
Sondergaard L, et al. J Am Coll Cardiol. 2019;74:546-53

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%
∆ 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

	50%			TAVI	SAVR	P value
Bioprosthetic Valve Failure	40%		Bioprosthetic valve failure			
			Valve-related deaths	5.0%	3.7%	0.59
	30%	Re-intervention	2.2%	0.7%	0.62	
	20% — TAVI		Severe haemodynamic SVD	0.7%	3.0%	0.21
		SAVR				
	10%				_	7.5%
	0%					P = 0.89 6.7%
	() 12	2 24 36 Months Post-Proce	48 edure	60	72

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Sondergaard L, et al. J Am Coll Cardiol. 2019;74:546-53

CLOSING REMARKS 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.



