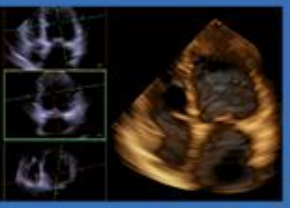

EuroValve
April 26-27, 2018

Translational aortic valve research. From biology to treatment

Standarized definition of bioprosthetic valve deterioration and failure

Anna Sonia Petronio, MD, FESC
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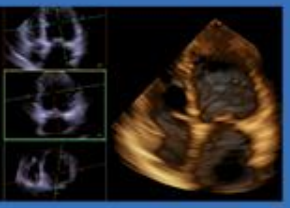

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Faculty disclosure

A.S.Petronio

I disclose the following financial relationships:

Consultant ,Advisory board and
Paid speaker for ABBOTT, Medtronic, Boston

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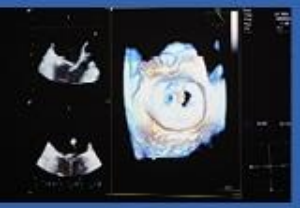
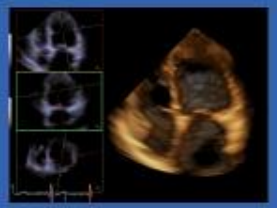

Long-term durability after SAVR/TAVI

Treatment	Year of pubblication	Number of patients	Types of prostheses	Rate of events
SAVR	2010-2015	19,913	4 types of prostheses	Freedom from SVD at 20 years: 58-67%
TAVI	2012-2016	8,914	2 types of prostheses	Freedom from SVD at 2.8-5 years: 100 – 94.4%

SVD in TAVI patients

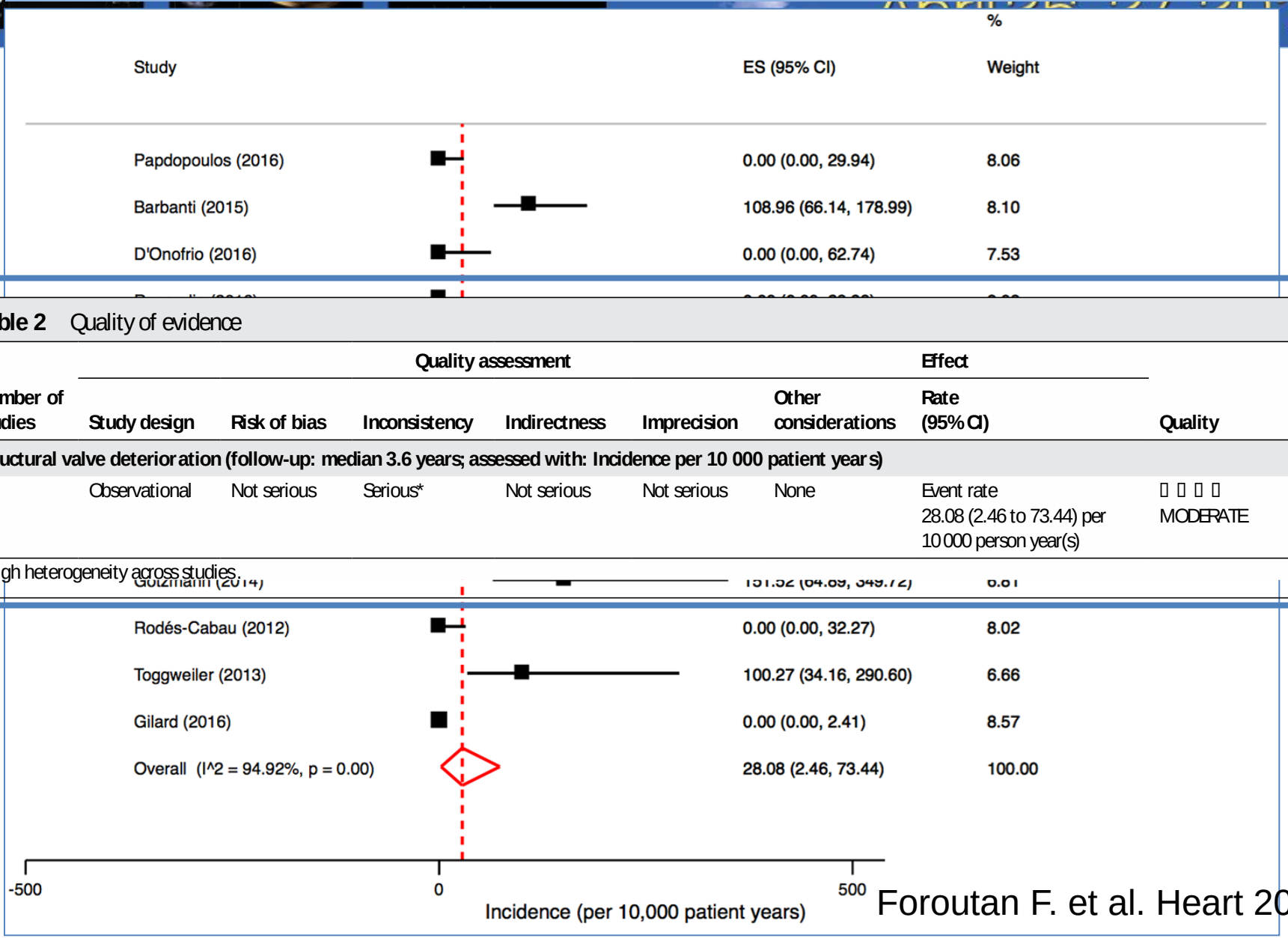

Table 2 Quality of evidence

Number of studies	Quality assessment: Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Effect: Rate (95% CI)	Quality
Structural valve deterioration (follow-up: median 3.6 years; assessed with: Incidence per 10 000 patient years)								
13	Observational	Not serious	Serious*	Not serious	Not serious	None	Event rate 28.08 (2.46 to 73.44) per 10 000 person year(s)	⨁⨁⨁◯ MODERATE

*High heterogeneity across studies

Foroutan F. et al. Heart 2017;

SVD and Long-term Durability After SAVR: Room for Confusion!

Bioprosthetic Valve Durability metrics in studies of SAVR

- Survival
- Valve-related survival
- Freedom from SVD
- Freedom from reoperation
- Freedom free from reoperation for SVD
- Freedom from / incidence of explant due to SVD

SVD and Long-term Durability After SAVR: Room for Confusion!

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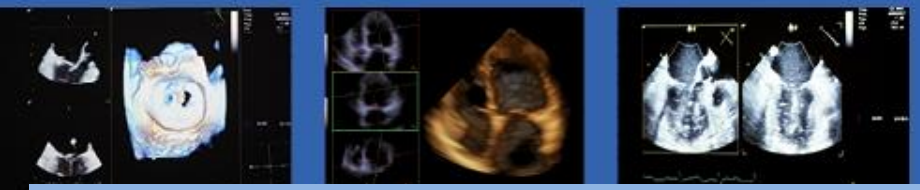
- Freedom from reoperation
- Freedom free from reoperation for SVD
- Freedom from / incidence of explant due to SVD

SAVR series	Prosthesis	Durability outcomes	SVD definition
David et al (2010)	Hancock II	● ● ●	Undefined
Mohammadi et al (2012)	Freestyle	● ● ●	Echocardiographic (1)
Forcillo et al (2013)	Carpentier-Edwards	● ●	-
Senage et al (2014)	Mitroflow	● ●	Echocardiographic (2)
Bourguignon et al (2015)	Carpentier-Edwards	● ● ●	Echocardiographic (3)
Johnstone et al (2015)	Carpentier-Edwards	●	Undefined



The Durability Issue: Structural Valve Deterioration (SVD) and Its Sisters

Bioprosthetic Valve Dysfunction

Structural Valve Deterioration	Nonstructural Valve Deterioration	Thrombosis	Endocarditis
Intrinsic permanent changes of the prosthetic valve (i.e., calcification, leaflet fibrosis, tear or flail) leading to degeneration and/or dysfunction	Any abnormality not intrinsic to the prosthetic valve itself (i.e., intra- or para-prosthetic regurgitation, prosthesis malposition, patient-prosthesis mismatch, late embolization) leading to degeneration and/or dysfunction	Thrombus development on any structure of the prosthetic valve, leading to dysfunction with or without thrombo-embolism	Infection involving any structure of the prosthetic valve, leading to perivalvular abscess, dehiscence, pseudo-aneurysms, fistulae, vegetations, cusp rupture or perforation

Standardised Definitions of SVD and Valve Failure: A EAPCI/ESC/EACTS Consensus

Standardised Definitions of Structural Deterioration and Valve Failure in Assessing Long-Term Durability of Transcatheter and Surgical Aortic Bioprosthetic Valves

D. Capodanno, A. S. Petronio, B. Prendergast, H. Eltchaninoff, A. Vahanian, T. Modine, P. Lancellotti, L. Sondergaard, P. F. Ludman, C. Tamburino, N. Piazza, J. Hancock, J. Mehilli, R. A. Byrne, A. Baumbach, A. P. Kappetein, S. Windecker, J. Bax, M. Haude

Simultaneous Publication in EHJ and EJCTS

July 21, 2017

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SPECIAL ARTICLE

Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Davide Capodanno[1*†], Anna S. Petronio[2†], Bernard Prendergast[3], Helene Eltchaninoff[4], Alec Vahanian[5], Thomas Modine[6], Patrizio Lancellotti[7], Lars Sondergaard[8], Peter F. Ludman[9], Corrado Tamburino[1], Nicolò Piazza[10], Jane Hancock[3], Julinda Mehilli[11], Robert A. Byrne[12], Andreas Baumbach[13], Arie Pieter Kappetein[14], Stephan Windecker[15], Jeroen Bax[16], and Michael Haude[17]

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†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., R.A.B.), EAPCI Databases and Registries Committee (A.S.P., L.S., P.F.L.); Valve for Life Initiative (A.B., M.H., S.W.); PCR London Valves Course Directors (B.P., C.T., N.P., S.W., M.H.), ESC Board (J.B.), ESC representatives (A.V., M.H., S.W.), EORP representatives (A.V., A.S.P.), EACTS representative (A.P.K.), VARC representatives (A.P.K., N.P., S.W.), Other invited experts (H.H., J.H., J.M., P.L., T.M.).

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Keywords: Transcatheter aortic valve implantation • Surgical aortic valve replacement • Durability • Long-term outcomes • Structural valve deterioration • Bioprosthetic valve failure • Bioprosthetic valve dysfunction

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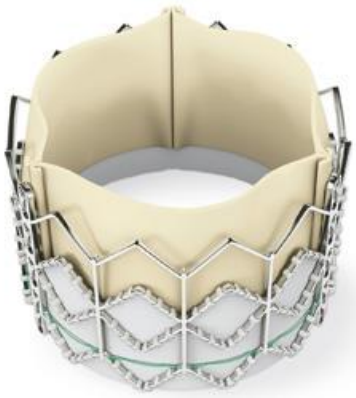
Endpoints for Durability Studies of TAVI or SAVR Bioprostheses

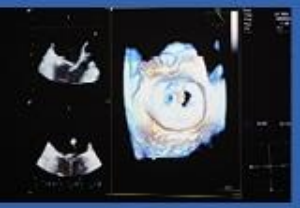
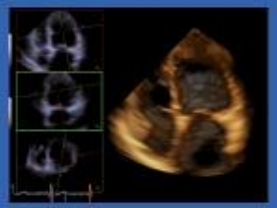
Structural Valve Deterioration (SVD)



A valve-centered endpoint

Bioprosthetic Valve Failure (BVF)

A patient-centered endpoint

EAPCI/ESC/EACTS Definition of SVD

Haemodynamic SVD

- **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

Morphologic SVD

- **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)

Haemodynamic and morphological SVD

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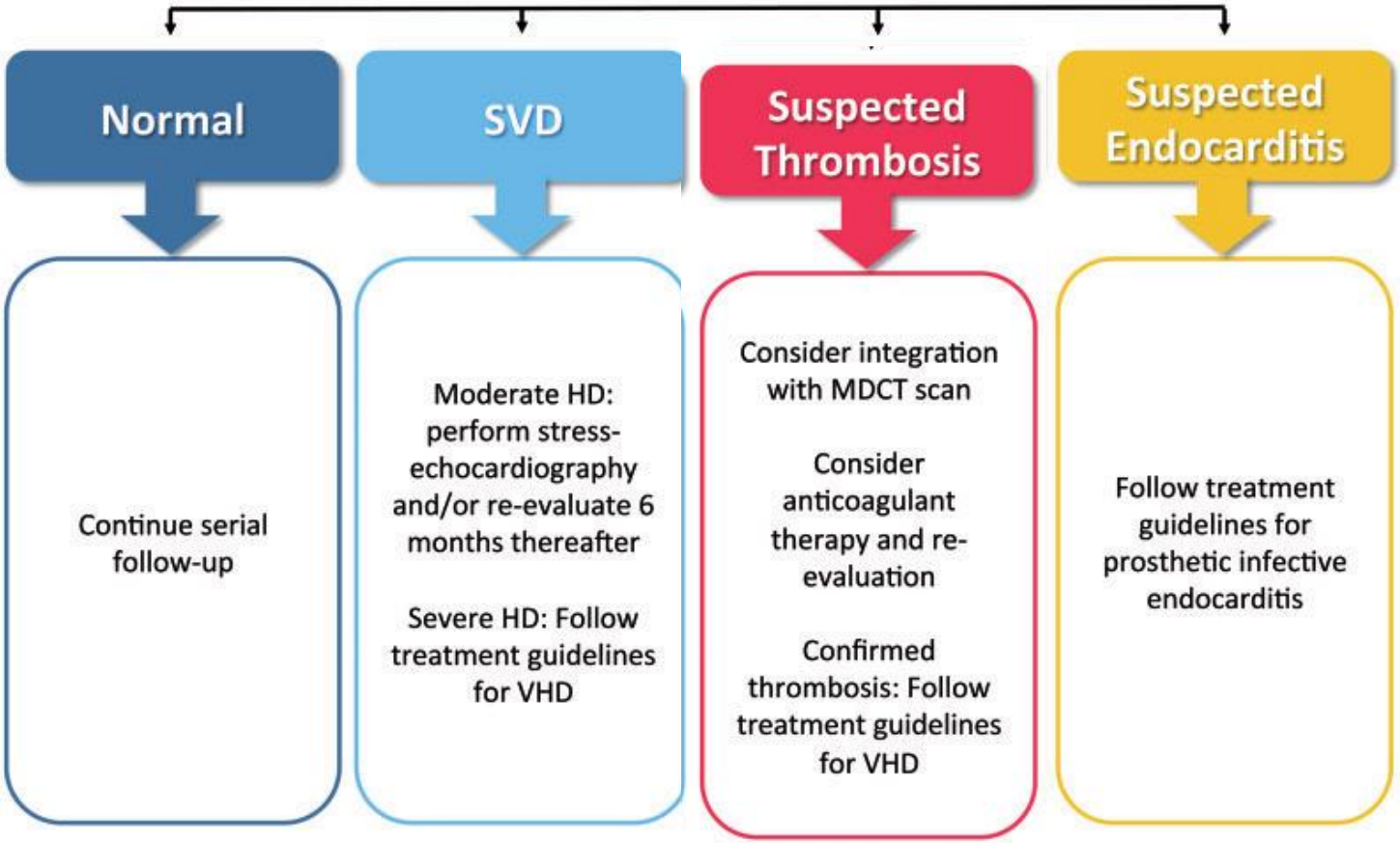
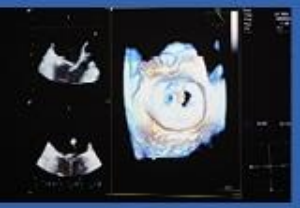
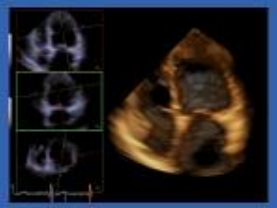
Capodanno et al. Eur J Cardiothorac Surg 2017 [ePub ahead of print] doi.org/10.1093/ejcts/ezx244

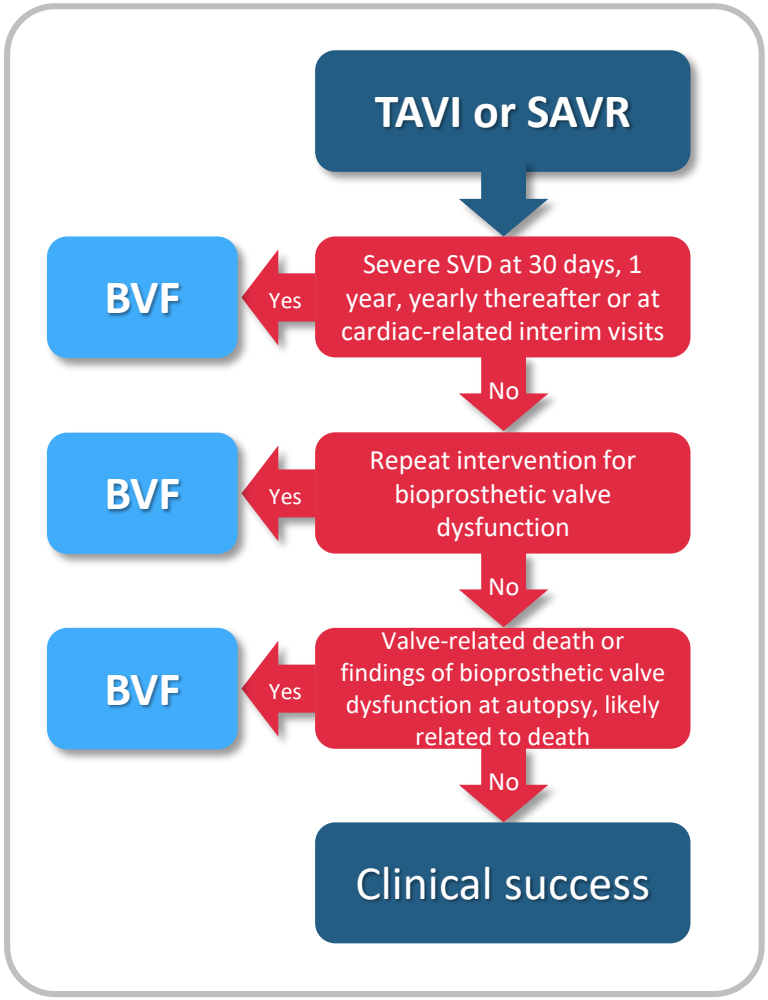
Echocardiographic follow-up (TTE and/or TOE)



Bioprosthetic Valve Failure (BVF)

- **Autopsy findings of bioprosthetic valve dysfunction, likely related to the cause of death, or 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 haemodynamic SVD**



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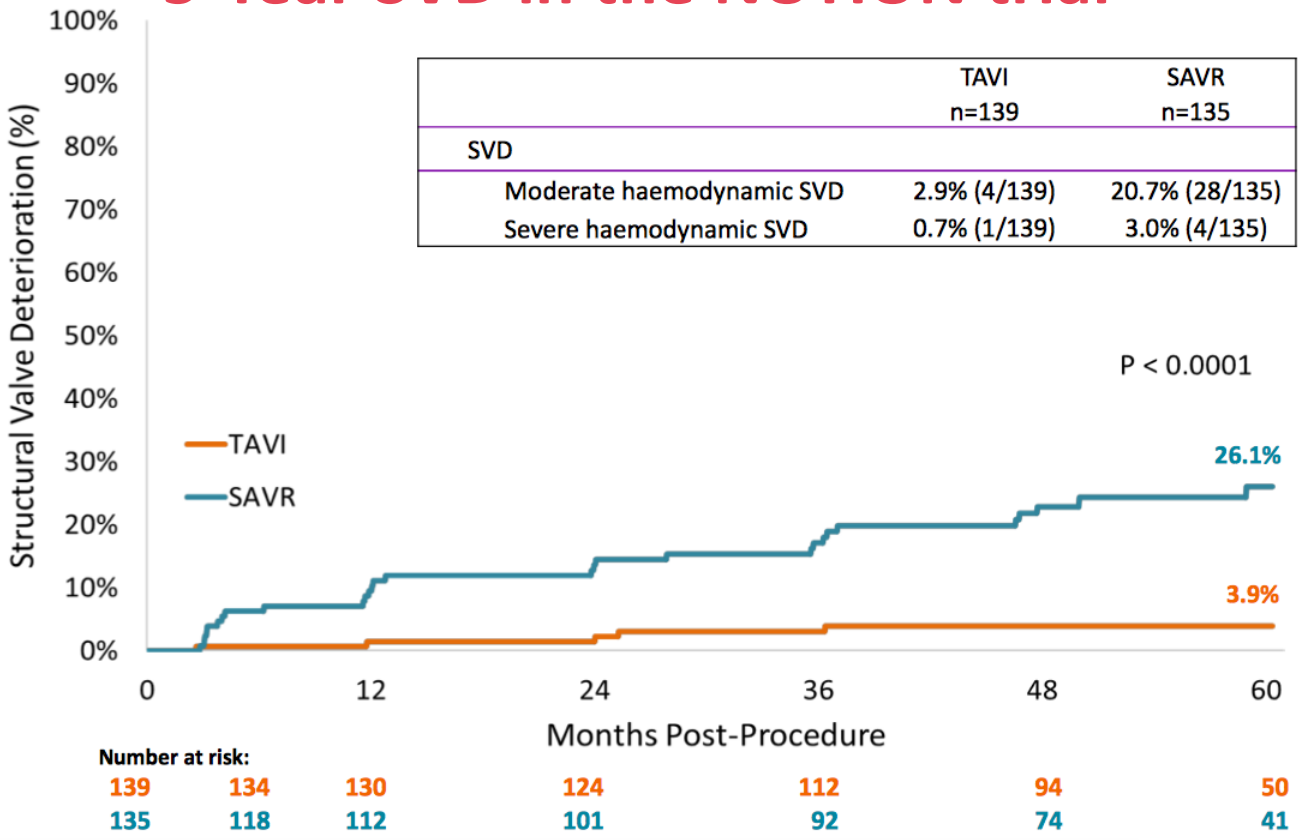
How Do The New EAPCI/ESC/EACTS Definitions Work in Practice?

5-Year SVD in the NOTION trial

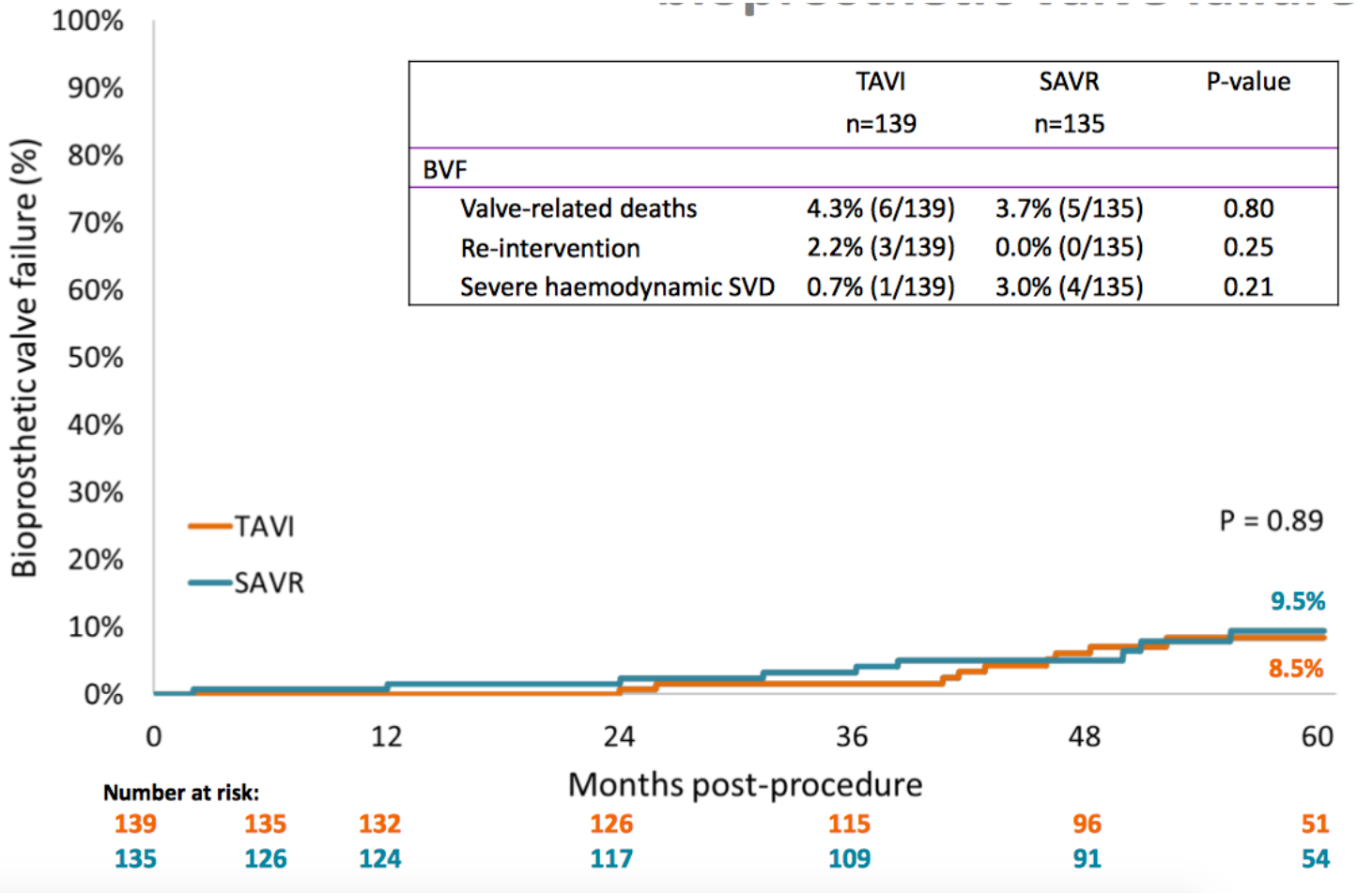
	TAVI n=139	SAVR n=135
SVD		
Moderate haemodynamic SVD	2.9% (4/139)	20.7% (28/135)
Severe haemodynamic SVD	0.7% (1/139)	3.0% (4/135)



Sondergaard L, EuroPCR 2017

5-Year BVF in the NOTION trial

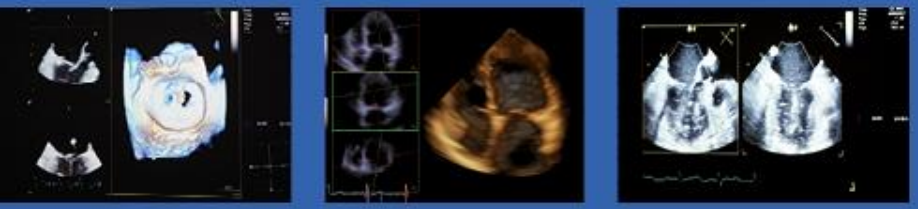
	TAVI n=139	SAVR n=135	P-value
BVF			
Valve-related deaths	4.3% (6/139)	3.7% (5/135)	0.80
Re-intervention	2.2% (3/139)	0.0% (0/135)	0.25
Severe haemodynamic SVD	0.7% (1/139)	3.0% (4/135)	0.21



Sondergaard L, EuroPCR 2017

EAPCI/ESC/EACTS Consensus Definitions: Key Points

- There should be clear distinction between SVD (the principal aetiology) and BVF (the clinical correlate).
- SVD causes irreversible dysfunction whereas other pathological causes of bioprosthetic valve dysfunction (i.e. thrombosis, endocarditis) are potentially reversible and should be identified and categorized separately.
- Echocardiography including the measurement of transprosthetic gradients should be performed within 30 days (preferably 30 days for surgery) after valve implantation (i.e. baseline imaging), at 1 year after implantation and annually thereafter.
- Considerations on reporting of SVD and BVF based on longitudinal vs. time-dependent outcomes, competing risk and actual vs. actuarial analyses.

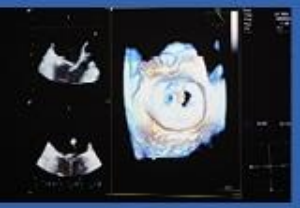
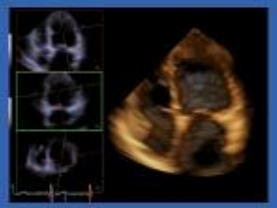


EAPCI/EORP TAVI DurabilityRegistry

European registry of TAVI patients treated >5 years ago.

The registry will focus on :

- Prevalence of BVF at latest follow-up
- Progression of SVD in patients treated at different time intervals.
- Subset analysis and follow-up of younger patients.

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April 26-27, 2018

Thank You