

CardioEgypt 2018

TAVI Which Valve for which Patient?

27th February, 2018

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Disclosures

Presenter: Adam Witkowski

- Proctorship: Medtronic
- Speaker's Bureau: Boston Scientific, Edwards, Medtronic

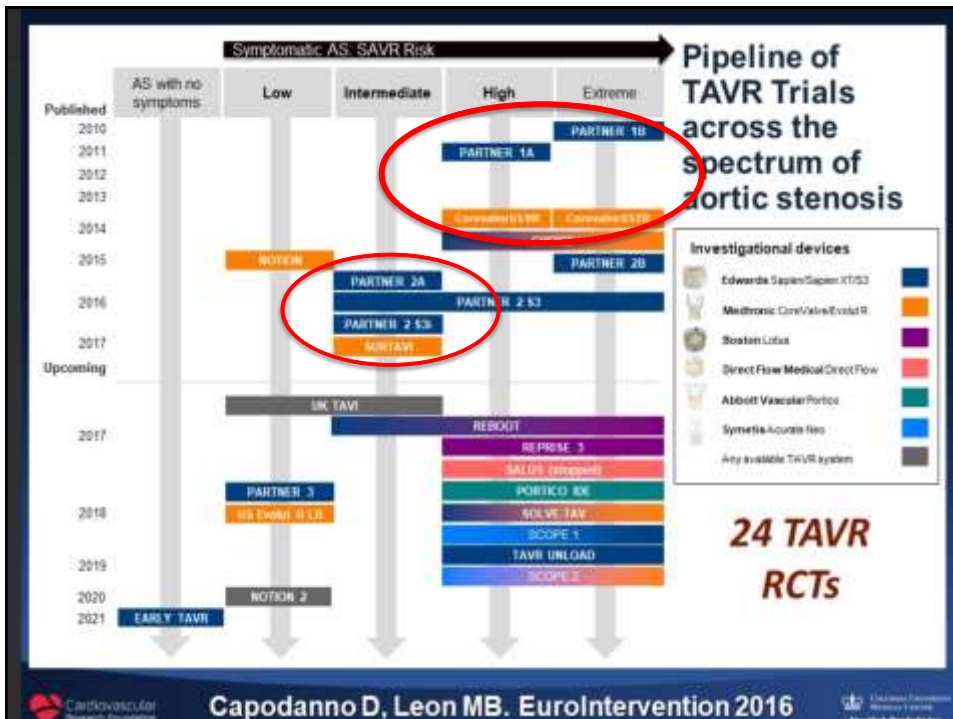
Estimated Global TAVR Growth



SOURCE: Credit Suisse TAVI Comment - January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

In the next 10 years, TAVR growth will increase X4!

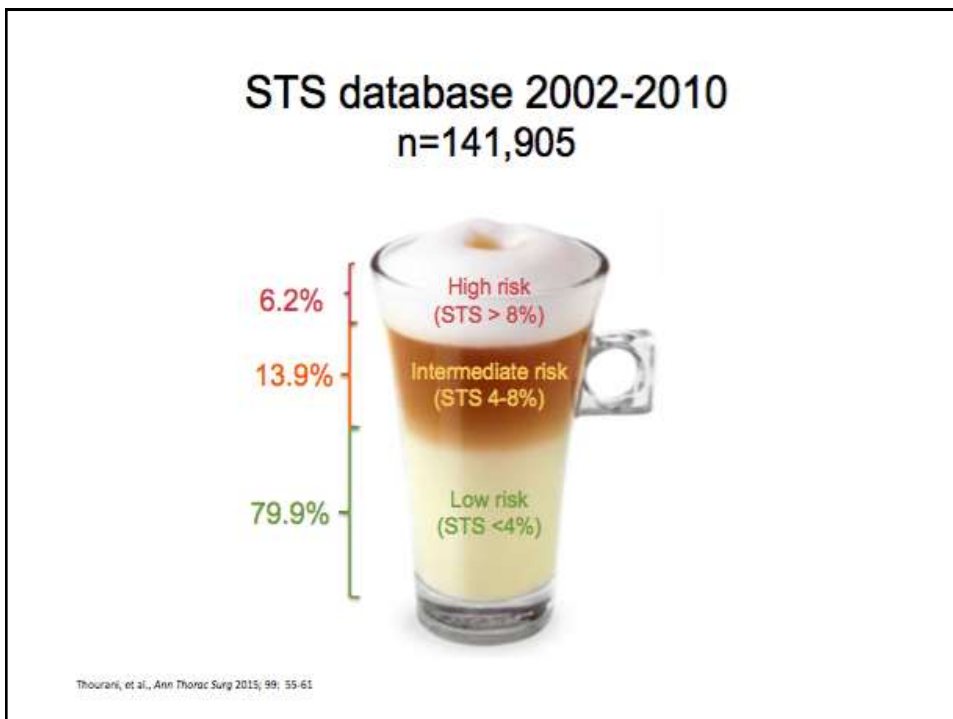
M. Leon @ TVT 2017



EACTS **Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode (continued)** **ESC** European Society of Cardiology

Recommendations	Class	Level
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in the according table). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic EuroSCORE I <10% and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	I	B

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx395) 51



4 Major Procedural TAVI Problems

SAFETY

- Bleedings and vascular complications
- Stroke

EFFICACY

- Paravalvular leaks
- Patient's frailty and futility of TAVI

Bleedings and Vascular Complications

- Femoral access is used in >90% of TAVI cases
- Despite ongoing miniaturization of TAVI delivery systems bleedings and vascular complications remain a source of problems in 2017 that are not much not different (however the incidence is lower) than in 2002
- *Major bleeding ($\approx 13\%$) and *vascular complications ($\approx 6\%$) strongly influence TAVI outcome

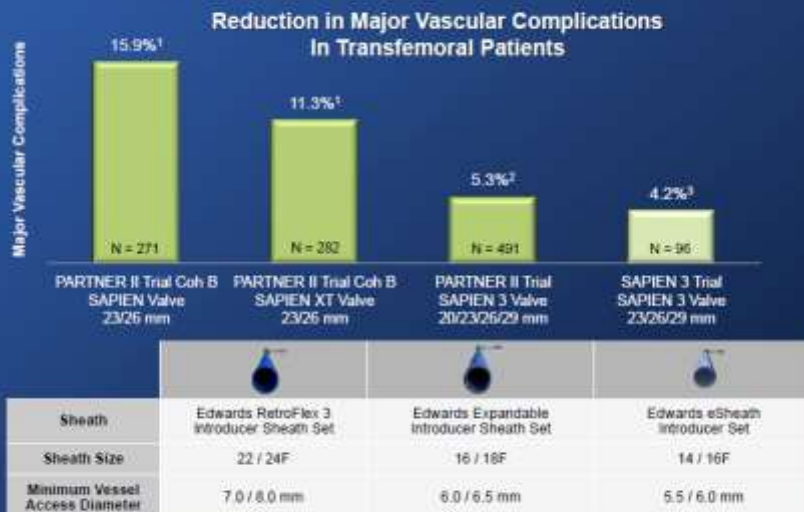


* CoreValve US Clinical Trials, ACC 2014

Impact of major vascular complications on 1-year mortality. Data from a pooled analysis of an as-treated TAVI cohort enrolled in PARTNER IA and IB



Ultra-low profile SAPIEN 3 system expands treatment possibilities while reducing complications

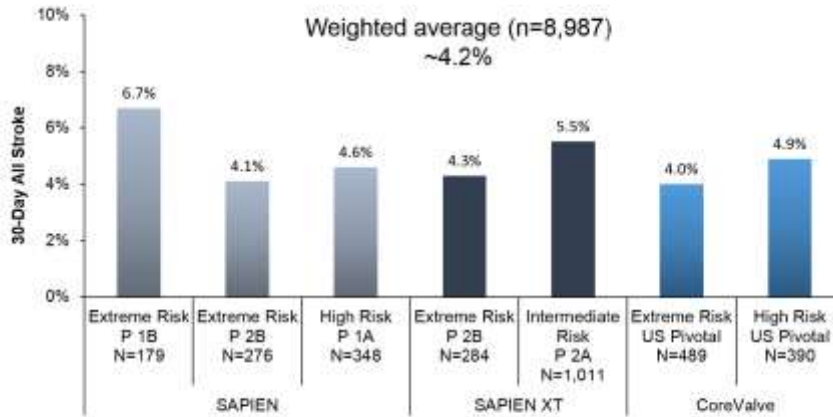


1. Data on file, Edwards Lifesciences

2. Kodali S. Clinical and Echocardiographic Outcomes at 30 Days with the SAPIEN 3 TAVR System in Inoperable, High-Risk and Intermediate-Risk Aortic Patients. Presented at ACC 2015, March 13, 2015; San Diego, California.

3. Webb J. Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve. JACC, VOL. 64 NO.21, pg 2236, 2014

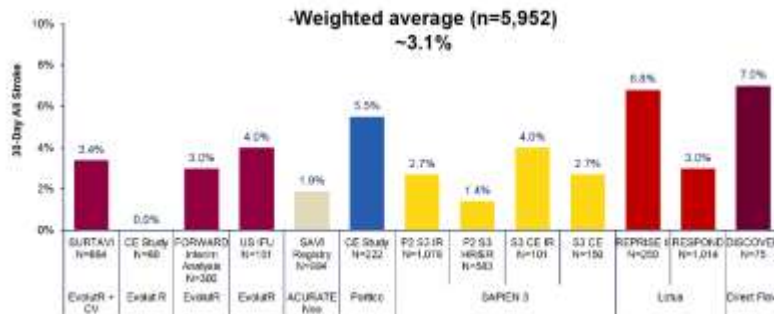
Stroke Rates in Randomized Trials



¹Loren, et al., *N Engl J Med* 2010;363:1907-1917; ²Webb, et al., *J Am Coll Cardiol Intv* 2015;5:1797-806; ³Serfaty, et al., *N Engl J Med* 2011;364:2187-94; ⁴Leon, et al., *N Engl J Med* 2016;374:1698-26; ⁵Hajek, et al., *J Am Coll Cardiol* 2014;63:1972-81; ⁶Kutsumi, et al., *N Engl J Med* 2014;370:1766-6;

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Stroke Rates with Contemporary Devices

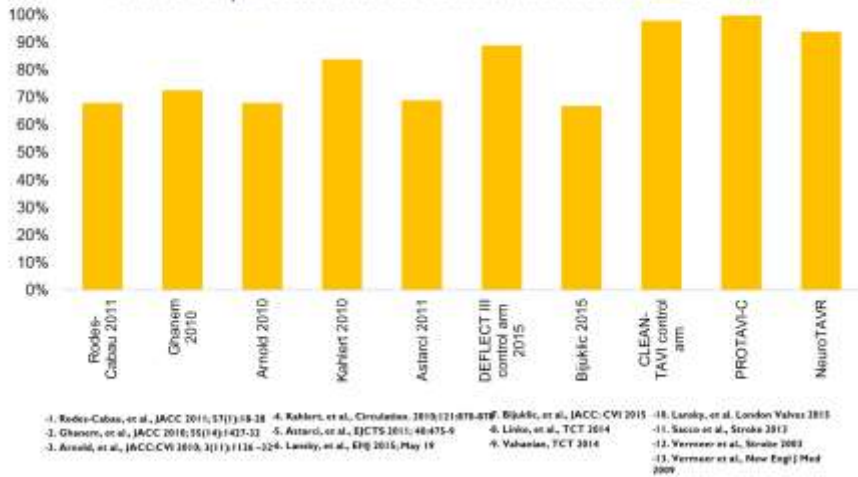


¹Mavroukas, et al., *J Am Coll Cardiol Intv* 2015;8:1358-67; ²Wadhvani, et al., presented at PCR London Values 2015; ³Linka, et al., presented at PCR London Values 2015; ⁴Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; ⁵Vahanian, et al., presented at EuroPCR 2015; ⁶Webb, et al., *J Am Coll Cardiol Intv* 2015;5:1797-806; ⁷DeMarco, et al., presented at TCT 2015; ⁸Mansoor, et al., presented at PCR London Values 2015; ⁹Falek, et al., presented at EuroPCR 2016; ¹⁰Kodali, presented at TCT 2016; Reardon, M. Published in NEJM March 2017

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MRI Lesions After TAVR

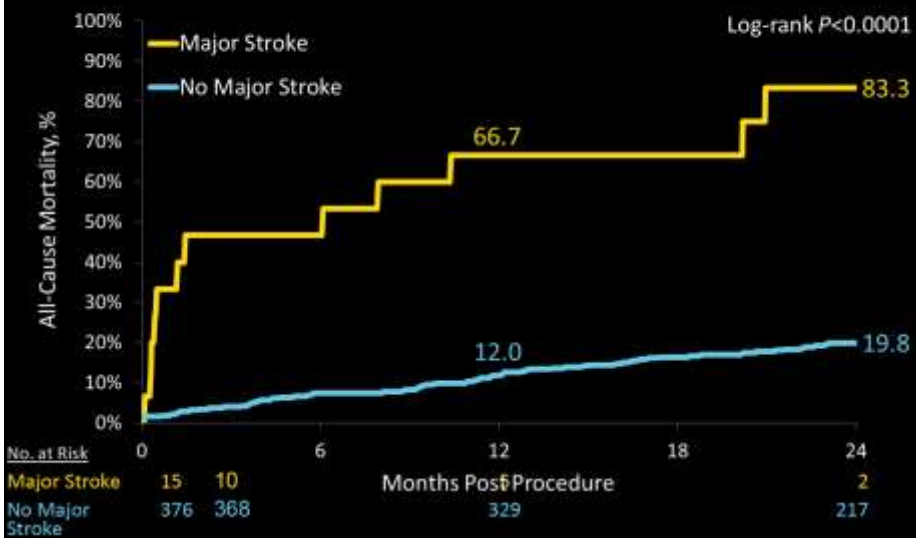
% of TAVI patients with new cerebral lesions on DW-MRI



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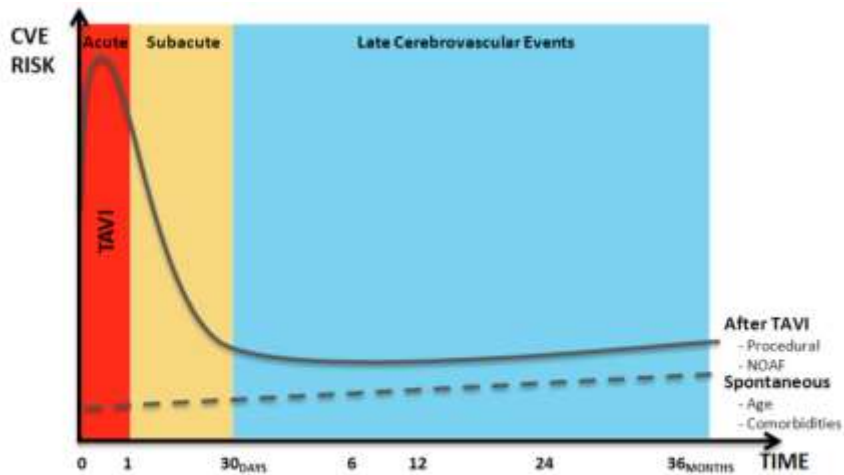
Mortality after Stroke

CoreValve High Risk Trial



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Risk of cerebrovascular events according to time after TAVI



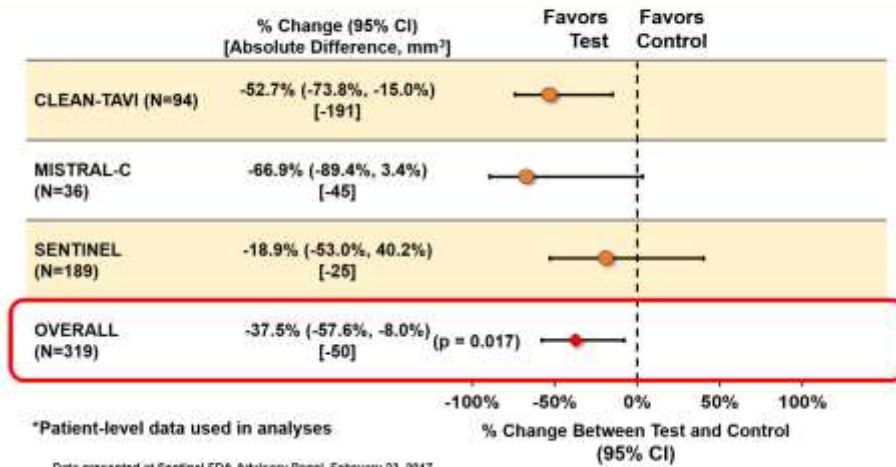
Ghanem A et al. Current Pharmaceutical Design

Cerebral Protection Devices

Company and Product	Ciaret Medical Sentinel	Keystone TriGuard	Edwards Embrella	iCS Emblok	Transverse Point-Guard
EU Status	CE Mark 97% market share	CE Mark 3% market share	CE Mark <3% market share	FIM first clinical case March 15, 2017	Pro-clinical/prototype
US Status	IDE study completed Positive FDA Panel Feb 23, 2017	IDE trial underway	No IDE yet	No IDE yet	No IDE yet
Access	8 Fr Right Radial	8Fr TF	Right Radial	12Fr TF sheath	TF
Debris	Captures and removes	Deflects downstream	Deflects downstream	Captures and removes	Deflects downstream
Placement and interaction with TAVR devices	Not in aortic arch	Sits in aortic arch. Devices must pass over and back across	Sits in aortic arch. Devices must pass over and back across	Sits in ascending aorta Devices must pass over and back across	Sits in aortic arch. Devices must pass over and back across

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Patient Level Meta-analysis: CLARET Lesion Volume in Protected Territories



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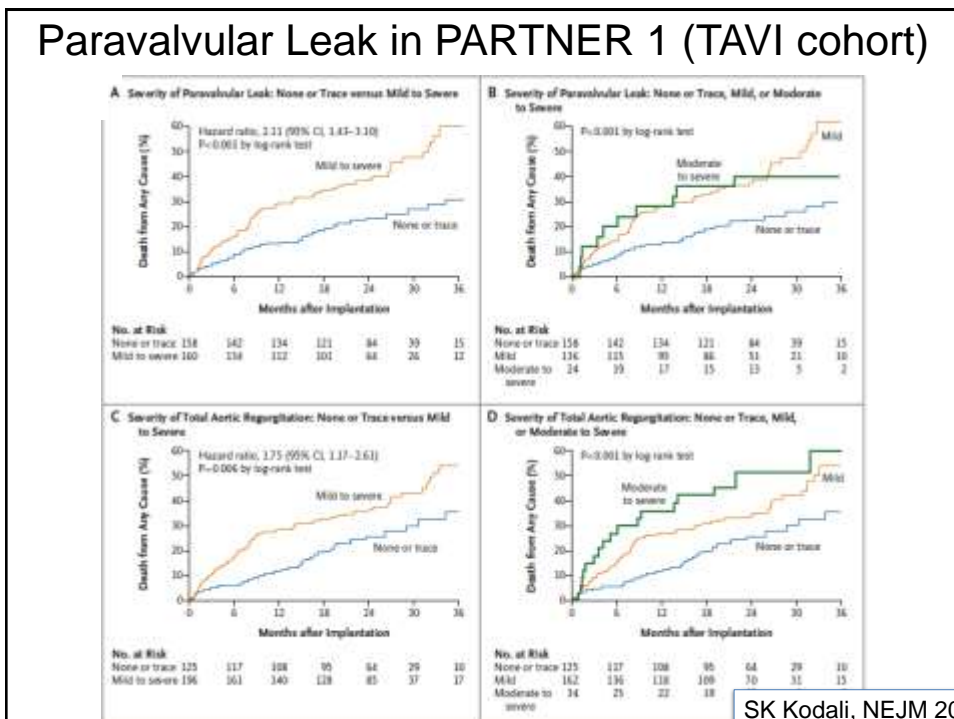
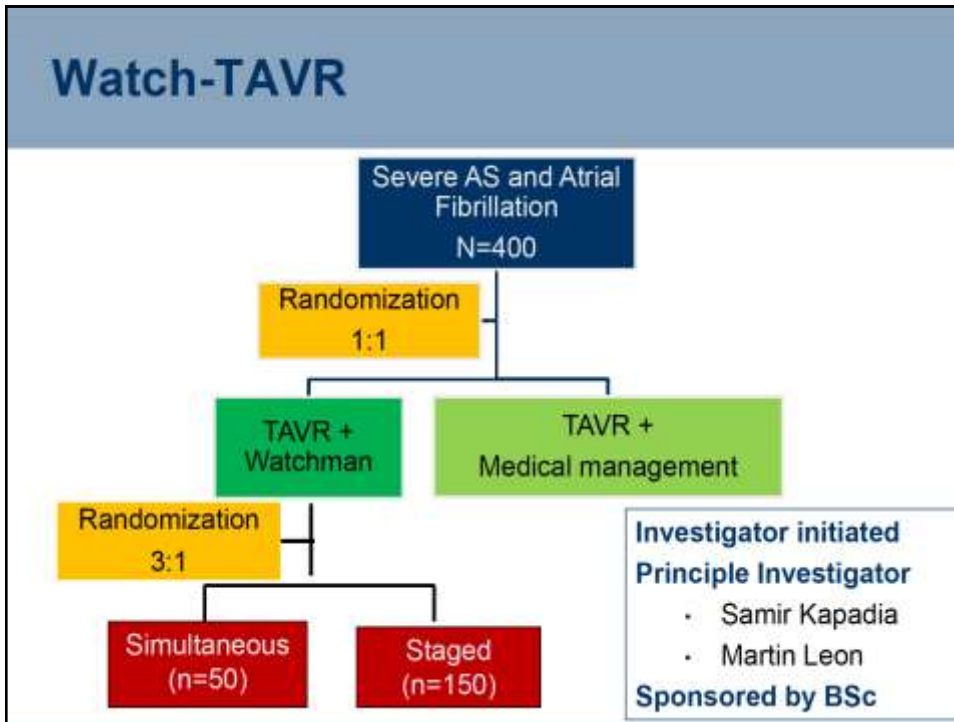
Ulm Sentinel study

- 802 all-comer consecutive TAVR patients at University of Ulm were prospectively enrolled
- A propensity-score analysis was done matching the 280 patients protected with Sentinel to 280 control patients



In multivariable analysis, TAVR without cerebral emboli protection (p=0.044) was the only independent predictor for stroke at 7-days
 TAVR without cerebral emboli protection (p=0.028) and STS score (<8 vs. ≥8) (p=0.021) were the only independent predictors for mortality and stroke at 7-days

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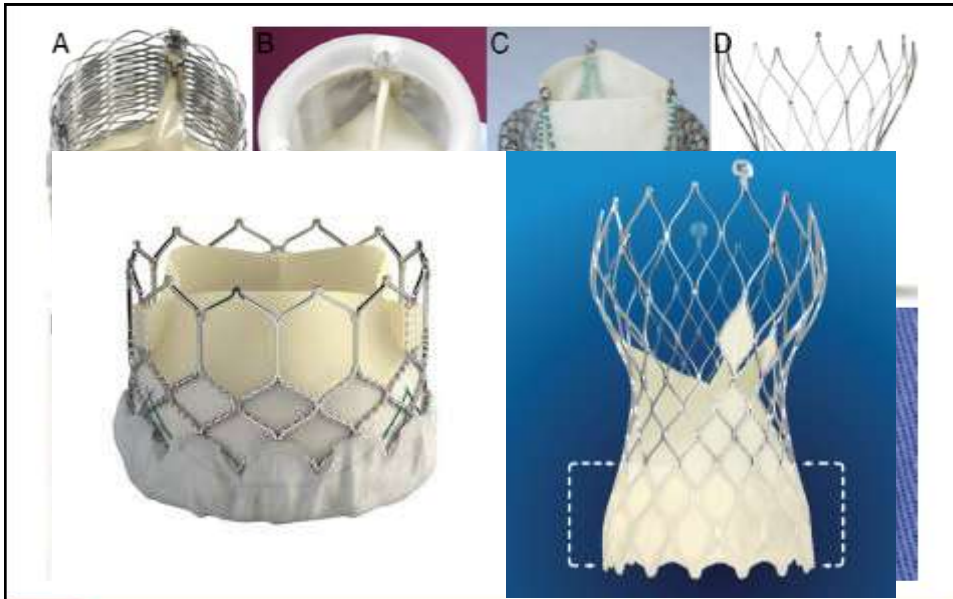
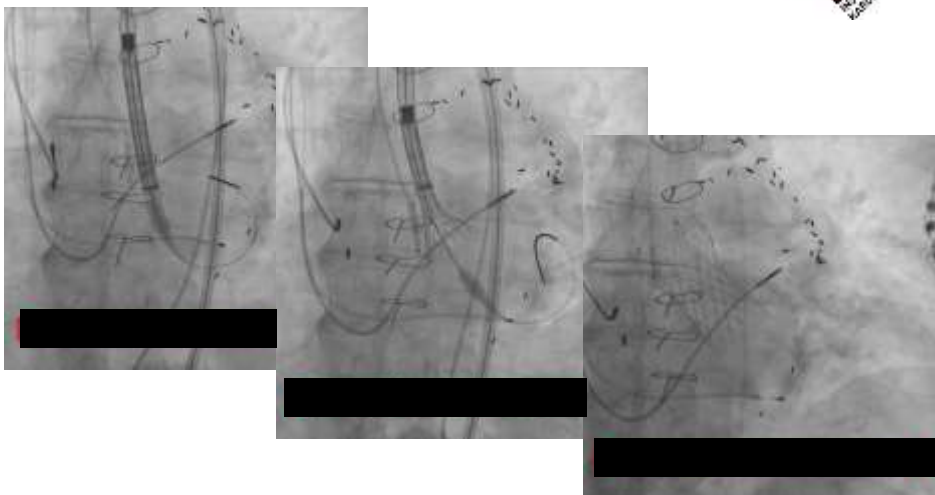


Figure 4 Valves Undergoing Early Evaluation

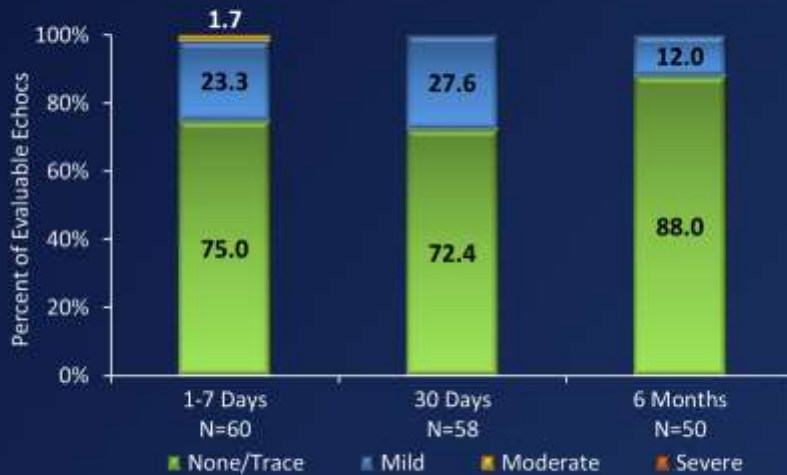
JG Webb, JACC 2012;60:483-92

(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), (B) Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), (C) HLT (Bracco Inc., Princeton, New Jersey), (D) Portico (St. Jude Medical Inc., St. Paul, Minnesota), (E) Engager (Medtronic Inc., Minneapolis Minnesota), (F) JenaClip (Jenavalve Inc., Munich, Germany), (G) Acurate valve (Symetis Inc., Ecublens, Switzerland), and (H) Inovare (Bralle Biomedica Inc., São José do Rio Preto, Brazil) valves.

TAVI, Evolute Pro 29



EVOLUT PRO PARAVALVULAR LEAK



Core laboratory assessments.
Similar results seen when only patients with data at all time were analyzed.

10

Frailty and Futility of Interventions

- Frailty is associated with increased morbidity and mortality after surgery and TAVI and futility of intervention
- The assessment of frailty should not rely on a subjective approach, such as the 'eyeball test', but rather on a combination of different objective estimates
- Poor mobility, as assessed by the 6-minute walk test, and oxygen dependency are the main factors associated with increased mortality after TAVI and other VHD treatments

They need to be separated regarding assessment,
appropriate clinical intervention and outcome evaluation



Should Clinical and Anatomic Factors Determine TAVI Device Selection to Achieve Best Result and Avoid Complications?

- YES – case planning is needed
- The landscape is rapidly evolving

4 Major Procedural TAVI Problems or How to Match Valve to patient?

- Bleedings and vascular complications: use smallest possible diameter of the delivery system
- Stroke: use neurprotective devices (as a routine?). Optimal antithrombotic treatment
- Paravalvular leaks: use valve with anti-leak external collar
- Frailty and futility of TAV: better patient selection!