**TCTAP 2018** 

Update of 2017 AHA/ACC and EACTS/ESC guidelines for management of patients with valvular heart disease

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Physician Name	Company/Relationship
Speaker Bureau/Advisory E	oard: Medtronic: C, SB, AB, OF LivaNova: C, SB, AB Highlife: AB, SB Boston Scientific: C, SB, AE Millipede: SB, C Pipeline: SB,C
Equity Interest:	InSeal Medical: E, AB, Valtech: E, SB, Claret: E, AB Shockwave: E, AB Valve Medical: E, AB Mitra/Trialign E, AB, SB
Key G – Grant and or Research Support E – Equity In C – Consulting fees, Honoraria R – Royalty Income SB – Speaker's Bureau O – Ownership OF – (	I – Intellectual Property Rights

## Aortic Stenosis

#### **Aortic Stenosis**

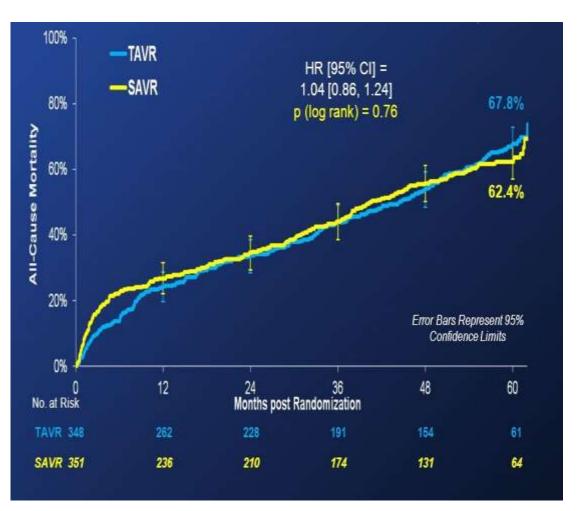
## COR updated from IIa to ILOE updated from B to A.



### Class I, LOE A

*SAVR or TAVR* is recommended for symptomatic patients with *severe AS (Stage D) and high risk for surgical AVR*, depending on patient-specific procedural risks, values, and preferences

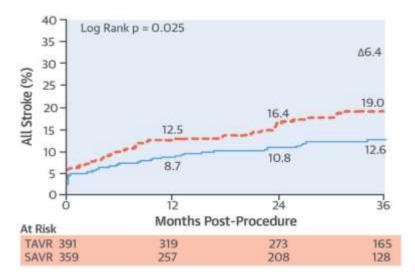
## Five Year Outcomes PARTNER I



- TAVR (N=)348 vs. SAVR (N=351)
  - Mean Age: 84.1 yr
  - Mean STS: 11.7%
  - Device Type: SAPEIN
- All-Cause Mortality (p=0.76)
  - TAVR 67.8%
  - SAVR 62.4%
- Stroke (p=0.35)
  - TAVR 14.7%
  - SAVR 15.9%
- PPM Rate
  - TAVR 9.7%
  - SAVR 9.1%

## **Three Year Outcomes**





- Multi-center, 1:1 Randomized
- SAVR (n=359)vs TAVR (n=391)
  - Mean age 83 yr
  - STS score 7 3%

Device Type: CoreValve Self Expanding

- All-cause Mortality
  - TAVR 32.9%
  - SAVR 39.1%
- Stroke
  - TAVR 12.6%
  - SAVR 19.0%
- PPM rate
  - TAVR 28%
  - SAVR 14.5%

#### **Aortic Stenosis**

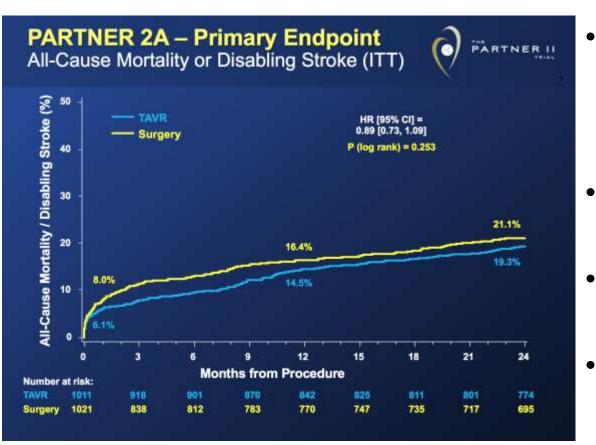
**New Addition to Guidelines** 



#### **Class IIa, LOE B-R**

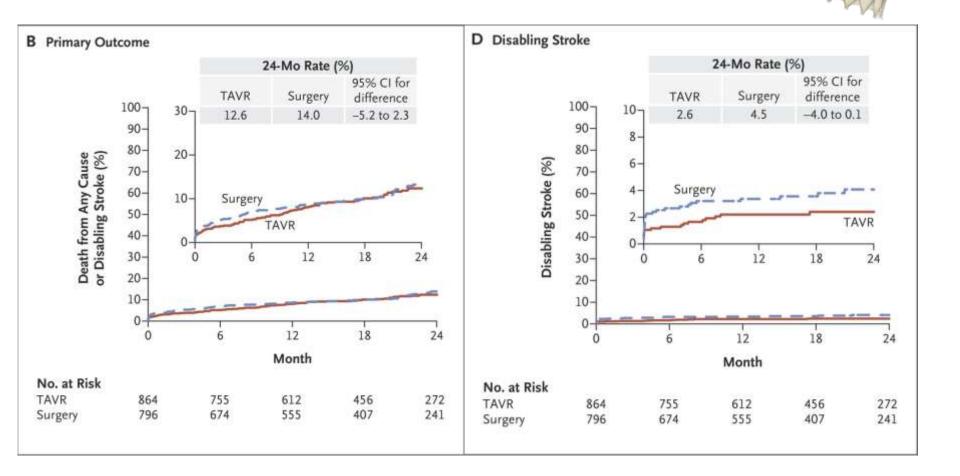
 TAVR is a reasonable *alternative* to surgical AVR for symptomatic patients with *severe AS (Stage D) and at intermediate surgical risk,* depending on patient-specific procedural risks, values, and preferences

### TAVR vs SAVR Intermediate Surgical Risk – PARTNER IIA Trial

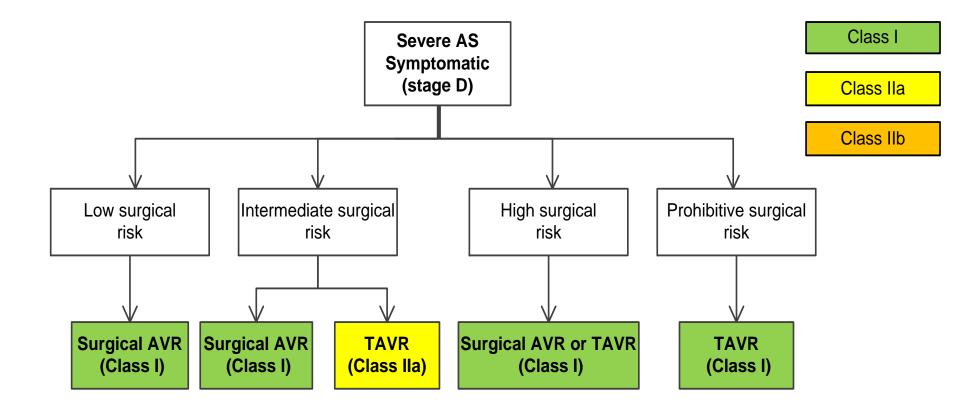


- TAVR (n=1011) with SAPIEN XT vs. SAVR (n=1021)
  - Mean age: 82 years
  - STS Score: 5.8
- All-cause mortality
  - TAVR 19.3%
  - SAVR 21.1%
- Disabling Stroke
  - TAVR 6.2%
  - SAVR 6.4%
- PPM Rate
  - TAVR 11.8%
  - SAVR 10.3%

### TAVR vs SAVR Intermediate Risk - SURTAVI Trial



#### Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS (Modified)



# **EACTS** Indications for intervention in aortic stenosis and recommendations for the choice of intervention mode (continued)



Recommendations	Class	Level
The choice for intervention must be based on careful individual evalu- ation 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.	1	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).	1	в
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	1	В

www.escardio.org/guidelines

2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

### **ΕΔ<u>CTS</u>**

#### Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk



	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I<10%)		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	2

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

#### Aspects to be considered by the Heart **EACTS** Team for the decision between SAVR and **ESC TAVI in patients at increased surgical risk** (continued)

www.e



	Favours TAVI	Favours SAV R
Clinical characteristics (continued)		
Frailty	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		4. ///
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+

#### Sectors Aspects to be considered by the Heart Team for the decision between SAVR and ESC TAVI in patients at increased surgical risk (continued)



	TAVI	SAVR
Anatomical and technical aspects (continued)	- 11 - 11 - 12 - 12	
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient-prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+

2017 ESC/EAC IS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

## Asymptomatic Aortic Stenosis

#### Asymptomatic Aortic Stenosis



#### class I



- Surgical AVR is recommended in asymptomatic patients with LV EF < 50% (Stage C2)
- Surgical AVR is recommended in asymptomatic patients undergoing other cardiac surgery

#### class lla

- AVR is reasonable for asymptomatic patients with very severe AS (stage C1, aortic velocity ≥5 m/s) and low surgical risk
- AVR is reasonable in asymptomatic patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in BP

## **EACTS** What is new in the 2017 Valvular Heart Disease Guidelines?



#### 2017 New recommendations

Diagnosis of severe aortic stenosis

See new recommendations for the diagnosis of severe aortic stenosis (Figure and Table).

Indications for surgery in asymptomatic aortic stenosis

New IIa C recommendation:

Severe pulmonary hypertension (systolic pulmonary artery pressure at rest >60 mmHg confirmed by invasive measurement) without other explanation.

Indications for intervention in asymptomatic severe primary mitral regurgitation

New additional statement:

If pulmonary hypertension (SPAP >50 mmHg at rest) is the only indication for surgery, the value should be confirmed by invasive measurement.

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)



## What is new in the 2017 Valvular Heart Disease Guidelines?



Changes in red	commendations
2012	2017
Indications for surgery in asymptomatic aor	tic stenosis
IIb C Markedly elevated BNP levels.	IIa C Markedly elevated BNP levels (>threefold age- and sex-corrected normal range) confirmed by repeated measurements without other explanations.
IIb C Increase of mean pressure gradient with exercise by >20 mmHg.	Taken out
IIb C Excessive LV hypertrophy in the absence of hypertension.	Taken out

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## **Prosthetic Aortic** Valve Failure

#### **Prosthetic Aortic Valve Failure**

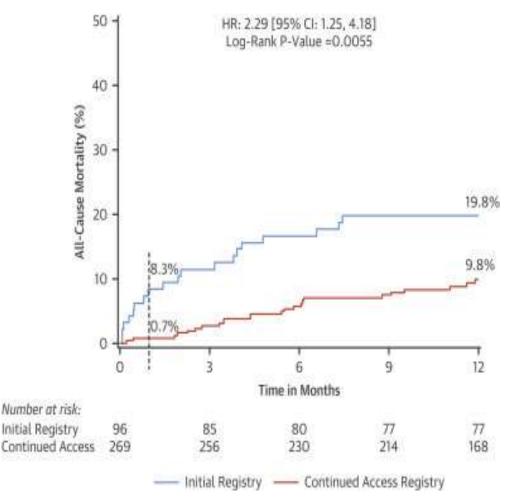


#### **New Addition to Guidelines**

#### **Class IIa, LOE B-NR**

For severely symptomatic patients with bioprosthetic aortic valve stenosis or regurgitation judged by the heart team to be at high or prohibitive risk for surgical therapy, in whom improvement in hemodynamics is anticipated, a
 transcatheter valve-in-valve procedure is reasonable

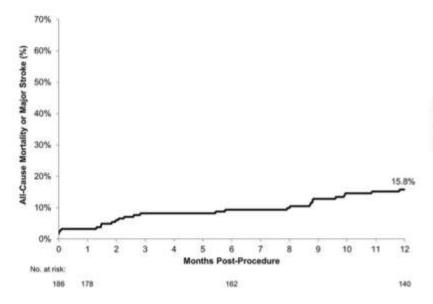
#### TAVR for Bioprosthetic Stenosis/Regurgitation Symptomatic



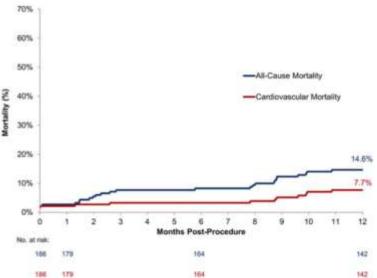
- Failed SAVR (n=365)
  - Initial Registry (n=96)
  - Continued Access (n=269)
  - Mean age: 78.9
  - Mean STS score: 9.1%
  - Device Type: Sapien XT
- Surgical implant>10yr: 66.3%
- All-cause mortality
  - 30 days: 2.7%
  - 1 year: 12.4%
- Major stroke:
  - 30 days: 2.7%
  - 1 year: 4.5%
- New PPM at 30-days: 1.9%

Webb JG, et al. J Am Coll Cardiol. 2017 May 9;69(18):2253-2262

### TAVR for Bioprosthetic Stenosis/Regurgitation



- N=233
- Mean age: 76.7 yr
- Mean STS: 9.0 ± 6.7%
   Surgical implant>10yr: 55.9%
   CoreValve U.S Study



- All-cause mortality
  - 30 days: 2.2%
  - 1 year: 14.6%
- Major stroke:
  - 30 days: 0.4%
  - 1 year: 1.8%
- PPM rate:

30 days: 8.1%

1 year: 11.0%

Deeb GM, et al. JACC Cardiovasc Interv. 2017 May 22;10(10):1034-1044

## **EACTS** Management of prosthetic valve dysfunction (continued)

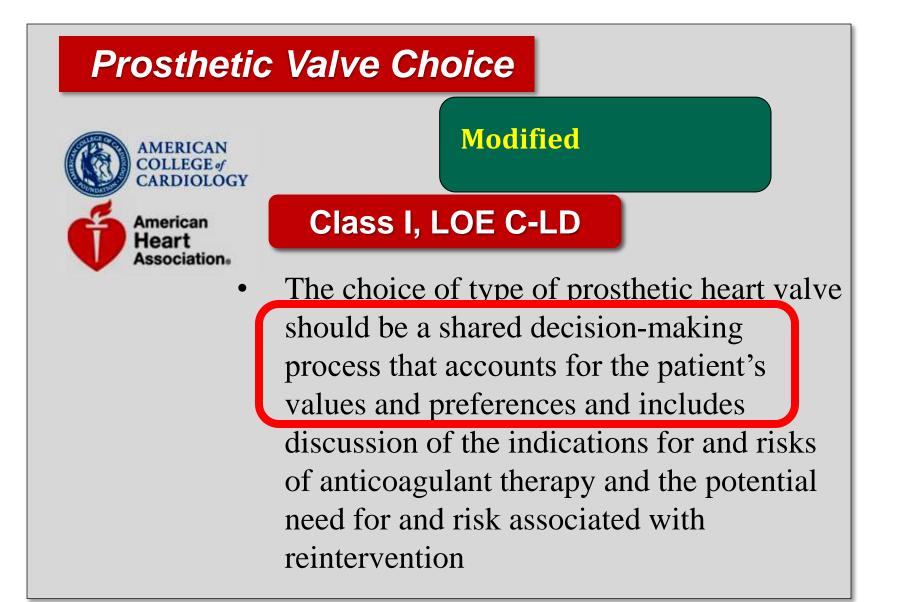


Recommendations	Class	Leve
Bioprosthetic failure	8	
Reoperation is recommended in symptomatic patients with a significant increase in transprosthetic gradient (after exclusion of valve thrombosis) or severe regurgitation.	I	C
Reoperation should be considered in asymptomatic patients with significant prosthetic dysfunction, if reoperation is at low-risk.	lla	с
Transcatheter valve-in-valve implantation in aortic position should be considered by the Heart Team depending on the risk of reoperation and the type and size of prosthesis.	lla	С

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

## **Prosthetic Aortic** Valve Choice



#### **Prosthetic Valve Choice**



#### **Age Range Modified**

#### **Class IIa, LOE B-NR**

For patients between 50 and 70 years of age, it is reasonable to individualize the choice of either a mechanical or
bioprosthetic valve prosthesis on the basis of individual patient factors and preferences, after full discussion of the trade-offs involved

### **ΕΔ<u>CTS</u>**

#### Choice of the aortic/mitral prosthesis in favour of a mechanical prosthesis (continued)



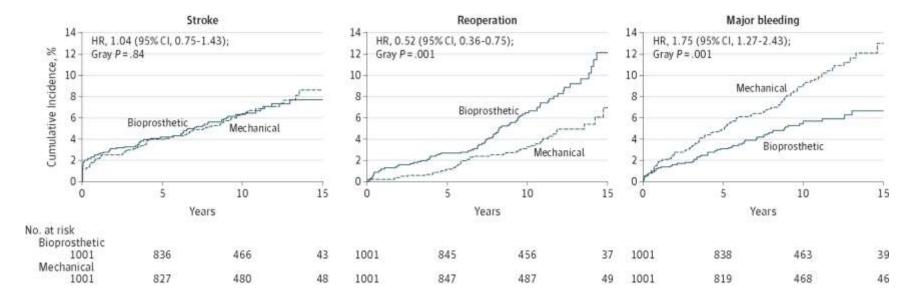
Recommendations	Class	Leve
A mechanical prosthesis should be considered in patients aged <60 years for prostheses in the aortic position and <65 years for prostheses in the mitral position*.	lla	¢
A mechanical prosthesis should be considered in patients with a reasonable life expectancy, for whom future redo valve surgery would be at high-risk.	lla	С
A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to high-risk for thrombo- embolism.	llb	C

\* Between 60 and 65 (aortic prosthesis) / 65 and 70 years (mitral prosthesis), both valves are acceptable and the choice requires careful analysis of factors other than age

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2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

### Prosthetic Valve Choice Mechanical vs. Bioprosthetic



- Incidence of Stroke
  - tAVR 7.7%
  - mAVR 8.6%

- Incidence of re-op
  - tAVR 12.1%
  - mAVR 6.9%

- Incidence of Bleed
  - tAVR 6.6%
  - mAVR 13.0%

## Anticoagulation

#### Anticoagulation – Bioprosthetic AVR

AMERICAN COLLEGE of CARDIOLOGY

#### **Class IIa, LOE B-NR**

Anticoagulation with a VKA to achieve an INR of 2.5 is reasonable for at least 3 months and for as long as 6 months after surgical bioprosthetic AVR in patients at low risk of bleeding.

**Guidelines Modified** 

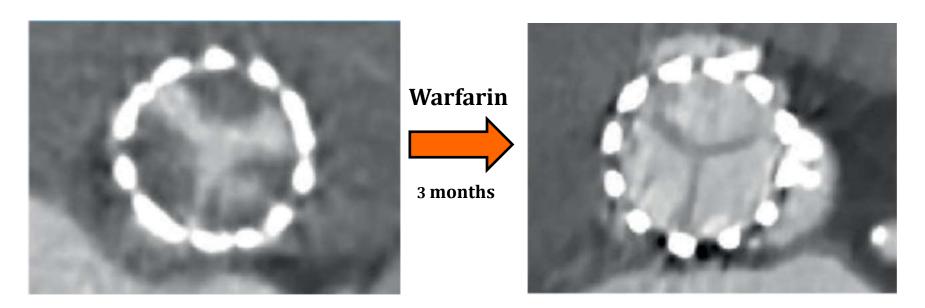
LOE from C to B-R

Anticoagulation for all surgical tissue prostheses was combined into 1 recommendation, with extension of the duration of anticoagulation up to 6 months.

#### Anticoagulation – TAVR New Recommendation New Recommendation Scarbiology American Heart Association

• Anticoagulation with a VKA to achieve an INR of 2.5 may be reasonable for at least 3 months after TAVR in patients at low risk of bleeding

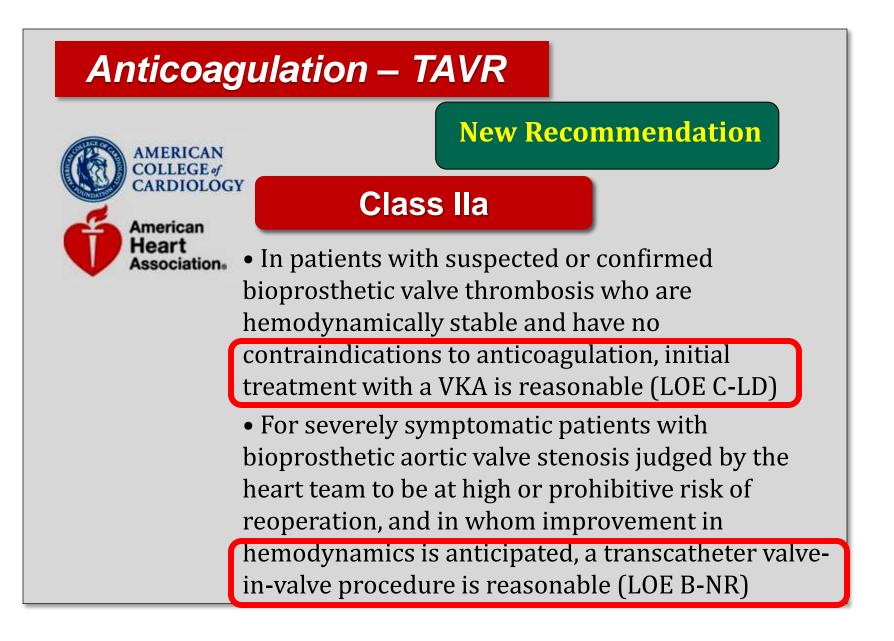
### Anticoagulation TAVR (New)



- N=460 TAVR, SAPIEN 3 or XT
- N=405 with MDCT and TEE at 1-3 mon
  - Median Age: 83
  - Median STS: 5.3
- Valve Thrombosis
  - Total: 28 pts (7%)

• Complete Resolution 85%

Hansson N et al. J Am Coll Cardiol. 2016 Nov 8;68(19):2059-2069



## **EACTS** What is new in the 2017 Valvular Heart Disease Guidelines?



#### 2017 New recommendations

#### Management after valve intervention

#### New recommendations:

After transcatheter as well as surgical implantation of a bioprosthetic valve, echocardiography – including the measurement of transprosthetic gradients -should be performed within 30 days (preferably around 30 days for surgery) after valve implantation (i.e. baseline imaging), at 1 year after implantation, and annually thereafter.

## Thank you!