

EgyValves @Alhyatt LIVE 2019

Patient Selection for TAVI in 2019

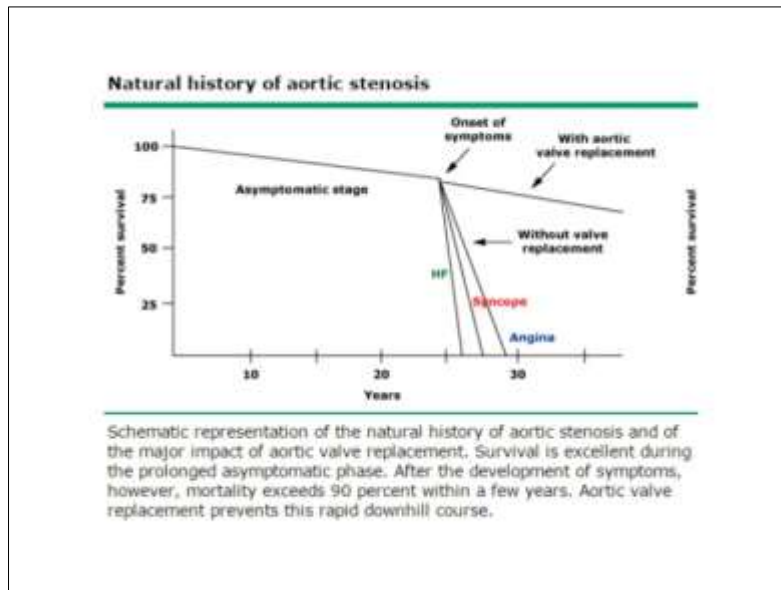
By

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Types of AS

- ***High-gradient aortic stenosis***
(valve area $<1 \text{ cm}^2$, mean gradient $>40 \text{ mmHg}$).
- ***Low-flow, low-gradient AS with reduced EF***
[valve area $<1 \text{ cm}^2$, mean gradient $<40 \text{ mmHg}$,
EF $< 50\%$, stroke volume index $< 35 \text{ mL/m}^2$]
- ***Low-flow, low-gradient AS with preserved EF***
(valve area $<1 \text{ cm}^2$, mean gradient $<40 \text{ mmHg}$,
EF $>50\%$, SVi $<35 \text{ mL/m}^2$)



- No medical therapy for aortic stenosis can improve outcome

Historical overview

- 1960s → SAVR
- 1985 → Alain Cribier performed the first BAV for a patient declined 3 times for SAVR due to very high surgical risk.

- But, 5 years later → data from registries started to show significant rates of restenosis

“I knew that if re-stenosis was occurring, then dilating the aortic valve with the balloon was not the best solution. I thought if we could place a stent around the balloon during the valvular angioplasty, the stent would be able to keep the valve open, and we would somehow need to place a prosthesis inside the stent”.

Dr. Alain Cribier.....



April 16, 2002

Circulation American Heart Association
Lippincott Williams & Wilkins

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD, Helene Eltchaninoff, MD, Assaf Bash, PhD, Nicolas Borenstein, MD, Christophe Tron, MD, Fabrice Bauer, MD, Genevieve Derumeaux, MD, Frederic Anselme, MD, François Laborde, MD, Martin B. Leon, MD

AHA; Nov, 2002

- At this point of time, there was the standard method of treatment (SAVR) vs. the new modality (TAVI) which gave new hope for patients unfit for surgery.

***Why are some patients
refused for SAVR?***

Cardiac Surgery Risk Models

Model	Region	Year of data collection	Year of publication	Number of patients (cases)	Risk variables
Azithiascore	Netherlands	1997-2001	2003	7 282 (3)	8
Cabdel	Finland	1990-1991	1996	386 (1)	7
Cleveland Clinic	USA	1986-1988	1992	5 051 (3)	13
EuroSCORE (additive)	Europe	1995	1999	13 302 (128)	17
EuroSCORE (logistic)	Europe	1995	1999	13 302 (128)	17
French score	France	1993	1995	7 181 (42)	13
Magovers	USA	1991-1992	1996	1 567 (1)	18
NYS	USA	1998	2001	18 814 (33)	14
NNE	USA	1996-1998	1999	7 290 (N/A)	8
Ontario	Canada	1991-1992	1995	6 213 (8)	6
Parsonnet	USA	1982-1987	1989	3 500 (1)	16
Parsonnet (modified)	France	1992-1993	1997	6 649 (42)	41
Pons	Spain	1994	1997	1 309 (7)	11
STS risk calculator*	USA	2002-2006	2007	774 881 (839)	49
isolated CABG				109 759	50
valve procedures				101 661	50
CABG and valve					
Toronto	Canada	1993-1996	1999	7 491 (2)	9
Toronto (modified)	Canada	1996-1997	2000	1 904 (1)	9
Trentfloy	Canada	1989-1990	1993	2 029 (1)	8
Tarum	USA	N/A	1992	3 156 (1)	10
UK national score	UK	1995-1996	1998	1 774 (2)	19
Veterans Affairs	USA	1987-1990	1993	12 712 (43)	10

DukeMedicine

STS Operative Risk Calculator

Online STS Risk Calculator
Dataset: 2.61

[Definitions](#)
[Support](#)

Help
More about Risk Calculator
New
Print

Today's Date 9/10/2009

Procedure

Coronary Artery Bypass Yes No Missing

Ventricular Assist Device Yes No Missing

Valve Surgery Yes No Missing

Aortic No
 Replacement
 Repair/Reconstruction
 Root Reconstruction with Valve Conduit
 Replacement + aortic graft conduit (not a valve conduit)
 Root Reconstruction with Valve Sparing

Calculations

Procedure Name	Isolated AVRepl
Risk of Mortality	7.6%
Morbidity or Mortality	30.2%
Long Length of Stay	15.8%
Short Length of Stay	13.7%
Permanent Stroke	3.1%
Prolonged Ventilation	20.5%
DSW Infection	0.2%
Renal Failure	13.1%
Reoperation	9.2%

Risk Calculator

Procedures

Date of birth

EuroSCORE

V 1.0 (c) Desktop Logic

Age:	<input type="text"/>	0
Gender:	<input type="text"/>	0
Chronic pulmonary disease:	<input type="checkbox"/>	0
Extracardiac arteriopathy:	<input type="checkbox"/>	0
Neurological dysfunction:	<input type="checkbox"/>	0
Previous Surgery:	<input type="checkbox"/>	0
Serum creatinine:	<input type="text"/> uMol/L	0
Active endocarditis:	<input type="checkbox"/>	0
Critical preop state:	<input type="checkbox"/>	0
Unstable angina:	<input type="checkbox"/>	0
LV:	<input type="text"/>	0
Recent myocardial Infarct	<input type="checkbox"/>	0
PAP:	<input type="text"/> mmHg	0
Emergency:	<input type="checkbox"/>	0
Other than CABG:	<input type="checkbox"/>	0
Surgery on thoracic aorta:	<input type="checkbox"/>	0
Postinfarct septal rupture:	<input type="checkbox"/>	0

Unfortunately, Many important risk factors that can affect patient's risk are not captured in the existing risk scores.

- Liver disease/cirrhosis
- Porcelain aorta
- Chest irradiation
- Injuring patent grafts
- Chest wall deformities
- Neurocognitive dysfunction
- Frailty

IDEAL MODEL DOES NOT EXIST

- So, How can we assess the surgical risk profile of the patient and consequently decide the best intervention ???

The HEART TEAM

- A multidisciplinary team responsible for taking decisions of treatment in cardiac patients.
- **Main players:** cardiologist, cardiac surgeon, vascular surgeon, anesthesiologist, intensivist.
- **Other players** join the team when needed: pulmonologist, hepatologist, neurologist, geriatrician,

Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on-site, and with structured collaboration between the two, including a Heart Team (heart valve centres).

www.escardio.org/guideLines

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

***Aspects taken into
consideration by the heart
team***

EACTS **Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk** **ESC** European Society of Cardiology

	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	+	

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391) 58

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

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

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391) 58

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

EACTS **ESC**
European Society of Cardiology

	Favours TAVI	Favours SAVR
Anatomical and technical aspects (continued)		
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		+

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehw395) 68

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

EACTS **ESC**
European Society of Cardiology

	Favours TAVI	Favours SAVR
Anatomical and technical aspects (continued)		
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehw395) 61

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

	Favours TAVI	Favours SAVR
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention (continued)		
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

www.escardio.org/guidelines 2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391) 82

Case 1

71 years old female

C/O progressive SOB over the past year– presented by NYHA III

Past Medical Hx and comorbidities:

- Paroxysmal atrial fibrillation
- HTN, Dyslipidemia
- Hodgkin's lymphoma with mediastinal surgery and chest irradiation 32 years ago
- Breast cancer → radical mastectomy and radiotherapy (25 sessions) 16 years ago

Echo

- Severe calcific AS
- EF = 60%
- Moderate pul HTN

- **Euroscore II 6.7, STS score 2.8**

Case 2

77 years old male

C/O SOB – currently NYHA III - recent hospital admission with acute pulmonary edema

Two episodes of exertional syncope

Past Medical Hx and comorbidities:

- Smoker
- COPD (FEV1 = 1.7 L - 55% of predicted)
- DM on insulin
- PVD
- CKD (serum Cr = 1.6 mg/dL)

Echo

- Severe calcific AS, mild AR
- Moderate MR, moderate TR
- EF = 55%
- Pul HTN (ePASP = 60 mmHg)

- STS 8.1, Euroscore II 11.2



- So, the main role of the heart team is to take the decision in each patient on individual basis according to the clinical scenario of each specific case

Guidelines help and decision is for the heart team

Evidence based selection criteria for TAVI

Inoperable & high risk patients

- ***PARTNER trial (cohort A):***
 - TAVI with balloon expandable Sapien valve *non inferior* to surgery in high risk patients
- ***PARTNER trial (cohort B):***
 - TAVI with balloon expandable Sapien valve *superior* to medical care in inoperable patients.

- ***The U.S. CoreValve pivotal trial (Extreme risk and high risk):***
 - TAVI with self expandable CoreValve is superior to SAVR.

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a "heart team" and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B


European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &
European Journal of Cardio-Thoracic Surgery 2012 -
doi:10.1093/ejcts/ezs455.

www.escardio.org/guidelines




Intermediate risk patients [STS score 4-8%]

- NOTION, SURTAVI, PARTNER 2A.
- TAVI noninferior to surgery and even superior when transfemoral access is possible



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 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/ehw395)

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- So; at that point, TAVI could be done for inoperable, high risk and intermediate risk patients after a decision from the heart team.

Is this enough?



2019 made his dream true

**TAVI in low risk
patients [STS <4%]**

PARTNER 3

- **Conclusion**: Among patients with severe aortic stenosis who were at low surgical risk, the composite of death, stroke, or rehospitalization at 1 year was **significantly lower** with TAVR than with surgery.

Evolut Low Risk

- **Conclusion:** In patients with severe aortic stenosis who were at low surgical risk, TAVR with a self-expanding bioprosthesis was **noninferior** to surgery with respect to the composite end point of death or disabling stroke at 24 months.

So, guidelines are expected to change soon to include patients with low surgical risk.

Risk
decreased
BUT
Age category
is still the
same



The Future

- NOTION 2 → enrolling younger patients
- DEDICATE → studying long term outcomes



Take Home Messages

- The very fast improvements in technology of transcatheter valves have expanded the risk profile of TAVI patients to include those at low surgical risk.
- With the data in our hands, younger patients with low risk are not yet TAVI candidates.

- Expanding the spectrum of TAVI to include younger patients if proved beneficial by future data will open the door for strong long term prosthesis durability studies.
- TAVI specific risk scores taking important data missed by conventional scores into consideration are strongly needed.

THANK YOU