



# Aortic stenosis: TAVI vs. SAVR



Dept. of Cardiology and Angiology

Hannover Medical School





#### Evidence for treatment decisions

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



Currently, 8 transcatheter aortic valve replacement (TAVR) systems are commercially available in Europe (A-H), whereas 2 TAVR systems are approved by the U.S. Food and Drug Administration in the United States (A, B). (A) Edwards Lifesciences Sapien 3 Valve (Edwards Lifesciences, Irvine, California); (B) Medtronic CoreValve Evolut R (Medtronic, Minneapolis, Minnesota); (C) Symetis Acurate *neo* Valve (Symetis, Ecublens VD, Switzerland); (D) JenaValve (JVT Research & Development Corporation, Irvine, California); (E) St. Jude Medical Portico Valve (St. Jude Medical, St. Paul, Minnesota); (F) Direct Flow Medical Valve (Direct Flow Medical, Inc., Santa Rosa, California); (G) Medtronic Engager Valve (Medtronic, Minneapolis, Minnesota); and (H) Boston Scientific Lotus Valve (Boston Scientific, Marlborough, Massachusetts).

#### Vahl Tet al JAm Coll Cardiol 2016;67:1472-87

#### Which patients should we treat:

- High risk
- Intermediate risk
- Low risk

5 randomized trials 1 meta-analysis Large registries





#### Key Message 1

# Intermediate risk patients have a good outcome post TAVI (better than high risk patients)





#### 2-Year all-cause mortality in the CoreValve ADVANCE Registry



CoreValve ADVANCE Study





#### **Outcome in the PARTNER 1A Trial**

	All-Cause	Death at 2			
Subgroup	Years K	M Rates	Hazard	P Value*	
	TAVR	SAVR			
Prior CABG					0.67
No	24.1	30.6	0.77 (0.55, 1.07)		•
Yes	17.6	24.5	0.66 (0.37, 1.18)		-
PVD					0.82
No	22.2	28.1	0.75 (0.51, 1.10)		-
Yes	21.2	29.1	0.70 (0.44, 1.11)	<mark>_</mark>	-
Hypertension					0.11
No	21.1	59.8	0.29 (0.09, 0.95)		
Yes	22.2	27.4	0.78 (0.58, 1.05)		
STS Score					0.11
≤7%	15.0	26.3	0.56 (0.35, 0.89)	<b>_</b>	
>7%	29.9	31.1	0.91 (0.63, 1.33)		
			0.125	0.25 0.50 1.	00 2.00
Favors TAVR Fa					Favors SAVR





#### Key Message 2

## In Intermediate risk patients, the outcome after TAVI is comparable to surgery











#### The Italian OBSERVANT registry







#### **PARTNER II Trial**

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

#### Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D.,

Table 1. Characteristics of the Patients at Baseline.*					
Characteristic	TAVR (N=1011)	Surgery (N = 1021)			
Age — yr	81.5±6.7	81.7±6.7			
Male sex — no. (%)	548 (54.2)	560 (54.8)			
Body-mass index†	28.6±6.2	28.3±6.2			
STS risk score‡	5.8±2.1	5.8±1.9			













## Main findings of SURTAVI

- TAVI had significantly less 30 day stroke, AKI, atrial fibrillation and transfusion use and a superior quality of life at 30 days.
- TAVI resulted in significantly improved AV hemodynamics with lower mean gradients and larger aortic valve areas than SAVR through 24 months.
- SAVR had less residual aortic regurgitation, major vascular complications and fewer new pacemakers.
- Need for a new pacemaker after TAVI was not associated with increased mortality.





#### Key Message 3

## TAVI is promising in low risk patients





# The **NOTION trial** was the first to randomize TAVI (CoreValve) with SAVR in Low and intermediate risk patients:

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY © 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER INC. VOL. 65, NO. 20, 2015 ISSN 0735-1097/\$36.00 http://dx.doi.org/10.1016/j.jacc.2015.03.014

## Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis



#### 1-Year Results From the All-Comers NOTION Randomized Clinical Trial

Hans Gustav Hørsted Thyregod, MD,\* Daniel Andreas Steinbrüchel, MD, DMSc,\* Nikolaj Ihlemann, MD, PHD,† Henrik Nissen, MD, PHD,‡ Bo Juel Kjeldsen, MD, PHD,§ Petur Petursson, MD,|| Yanping Chang, MS,¶ Olaf Walter Franzen, MD,† Thomas Engstrøm, MD, DMSc,† Peter Clemmensen, MD, DMSc,† Peter Bo Hansen, MD,# Lars Willy Andersen, MD, DMSc,# Peter Skov Olsen, MD, DMSc,\* Lars Søndergaard, MD, DMSc† *Thyregod et al., JACC 2015* 





#### The NOTION Trial Randomized Low-Risk Patients



#### NOTION Trial | Select Baseline Characteristics

Characteristic, %or mean ± SD	TAVI n=145	SAVR n=135	p-value
Age (yrs)	79.2 ± 4.9	79.0 ± 4.7	0.71
Male	53.8	52.6	0.84
STSScore	2.9±1.6	3.1 ± 1.7	0.30
STSScore < 4%	83.4	80.0	0.46
NYHA class III or IV	48.6	45.5	0.61





## The NOTION Trial aortic valve performance







## The NOTION Trial all-cause mortality, stroke or MI











	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)ª		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)ª	*	
Presence of severe comorbidity (not adequately reflected by scores)	÷	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty <sup>b</sup>	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure		
Suspicion of endocarditis		+







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	Favours TAVI	Favours SAVR
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
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		+
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		+







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	Favours TAVI	Favours SAVR
Cardiac conditions in addition to aort require consideration for concomitan	ic stenosi: t interven	s that Ition
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+



# **AORTIC STENOSIS: TAVI vs. SAVR**





#### **Choice of intervention:**



2017

## 2012

Recommendations	Class	Level			In patients who are at increased		
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	В	Not suiteble for SAVR	Increased Risk	surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥10% ,or other risk factors not included in these scores such as frailty , porcelain aorta , sequelae of chest radiation ), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics with TAVI being favoured in elderly	I	В
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	lla	В	High Risk only	Low Risk	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)	ı	в







Key learnings from emerging evidences :

- TAVI is equal to surgery and guideline indicated in intermediate risk patients.
- TAVI prostheses are proven to be durable up to five years and probably beyond.
- (Many examples of patients with functioning prosthesis up to 12 years)
- TAVI seems safe even in low-risk patients (5-year follow up)
- Remaining issues to solve before expanding indications to low risk patients (durability, pace maker rate)

# Yes we can > Yes we should!



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	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) <sup>a</sup>		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)ª	÷	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	÷	
Frailty <sup>b</sup>	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	÷	
Suspicion of endocarditis		+



	Favours TAVI	Favours SAVR
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
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		+
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		+







	Favours TAVI	Favours SAVR
Cardiac conditions in addition to aort require consideration for concomitan	ic stenosis t interven	s that ition
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+



## Conclusion



#### **Choice of intervention:**

2012



Recommendations	Class	Level			In patients who are at increased		
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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	lla	В	High Risk only	Low Risk	patients suitable for transfemoral accessaccessSAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic 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	в





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# ORTIC STENOSIS: TAVI vs. SAVR



#### Siontis GCM et al Eur Heart J 2016;37:3503-3512



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# ORTIC STENOSIS: TAVI vs. SAVR



#### Siontis GCM et al Eur Heart J 2016;37:3503-3512

www.escardio.org/guidelines







0.1 0. Favours TAVI

#### New-onset AF

PARINER 1A	42/348	60/351
US CoreValve	71/390	121/357
NOTION	32/145	80/135
PARTNER 2A	110/1011	273/1021
Overall (Hetero	geneity $\tau^2 =$	0.076, P = 0.004)

#### Major bleeding

PARTNER 1A	60/348	95/351
US CoreValve	123/390	135/357
NOTION	16/142	28/134
PARTNER 2A	169/1011	471/1021
Overall (Hetero	geneity $\tau^2 =$	0.212, P < 0.001

#### Major vascular complications

PARTNER 1A	40/348	13/351
US CoreValve	27/390	7/357
NOTION	8/142	2/134
PARTNER 2A	86/1011	55/1021
Overall (Hetere	ogeneity $\tau^2 =$	0.131, P = 0.089)

#### Valve endocarditis

PARTNER 1A	4/348	3/351
US CoreValve	3/390	5/357
NOTION	9/145	2/135
PARTNER 2A	11/1011	6/1021
Overall (Hetere	geneity 1	$e^2 = 0.128, P = 0.280)$

8			0.71 0.54 0.28 0.41 0.46	(0.49, (0.42, (0.18, (0.33, <b>(0.34</b> ,	1.02) 0.69) 0.43) 0.50) <b>0.63)</b>	<0.001
			0.64 0.83 0.54 0.36 0.57	(0.48, (0.68, (0.31, (0.31, <b>(0.35</b> ,	0.85) 1.02) 0.95) 0.42) <b>0.92)</b>	0.020
-	-		3.10 3.53 3.77 1.58 2.46	(1.69, (1.56, (0.82, (1.14, <b>(1.49</b> ,	5.70) 8.01) 17.46) 2.19) 4 <b>.05)</b>	<0.001
-		_	1.34 0.55 4.21 1.85 <b>1.56</b>	(0.30, (0.13, (0.91, (0.69, <b>(0.74,</b>	5.96) 2.28) 19.48) 4.99) 3.28)	0.244
2 0.5	1 2 5 Fav	I 10 vours SAVR				

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#### Siontis GCM et al Eur Heart J 2016;37:3503-3512







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# AORTIC STENOSIS: TAVI vs. SAVR



Disease (European Hei doi:10.1093/eurheartj/e







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	PARTN	IER 2A	SUR	TAVI	P. P.					I	
Age (years)	81.6	± 6.7	79.8	± 6.2	B Primary Out	come		1	24-Mo Rate (	%)	
STS Score	5.8 :	± 2.0	4.5 ±	£ 1.6		100 -	30-	TAVR	Surgery	95% CI differen	for
Frail (%)	44	l.4	52	2.3	e (6	90- 80-	20-	12.6	14.0	-3.2 to	2.3
	PARTNER Surgery	PARTNER TAVI	SURTAVI Surgery	SURTAVI TAVI	n Any Caus ig Stroke (%	70- 60- 50-	10-	Surgery	TAVE		
30-day mortality (%)	4.1	3.9	1.7	2.2	ath fron Disablir	40- 30-	0	6	12	18	24
2-year mortality (%)	18.0	16.7	11.6	11.4	or D	20- 10-					
Stroke 30-day (%)	6.1	5.5	5.6	3.4		0		6	12	18	24
Moderate/severeAR (%)		3.7	0.6	5.3	No. at Risk	864		755	Month	456	272
New PM (%)	6.9	8.5	6.6	25.9	Surgery	796		6/4	555	407	241

Reardon MJ et al New Engl J Med 2017 (epub March 17)

www.escardio.org/guidelines

Disease (European He doi:10.1093/eurhearti/e











© Consideration of TAVI as an alternative to SAVR in a wide range of patients with increased surgical risk ("intermediate" or "high risk")

80 Risk scores alone are insufficient to guide decision between TAVI and SAVR

- ScAvaliable data for TAVI mostly in population > 75 years !
  - Bicuspid valves more frequent in younger patients (few experience, worse results?)
  - Missing longterm durability data
  - Higher PM and PVL rates become more relevant in younger patients
- Solution with the second structure of patients are theoretically eligible for both, TAVI and surgery, a number of patient characteristics affect the individual risk / benefit ratio for both modalities (complex decision process)

schocal outcome data for both modalities require consideration









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

	Favou rs TAVI	Favou rs 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	+	







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

	Favou rs TAVI	Favou rs 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		+
escardio.org/guidelines	10101	10101







#### bects to be considered by the Heart Team the decision between SAVR and TAVI satients at increased surgical risk (continued)



	Favour s TAVI	Favour s SAVR
Anatomical and technical aspects (continued)		
	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Severe chest deformation or scoliosis	+	
cardio org/quidelines 2017 ESC/EACTS G		L







## ects to be considered by the Heart Team the decision between SAVR and TAVI



	Favour s TAV/I	Favour s
Anatomical and technical aspects (continued)		
Size of aortic valve annulus out of range for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Cardiac conditions in addition to aortic stenosis that require concomitant intervention	ire consideratio	n for

Disease (European He doi:10.1093/eurheartj/e







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

	Favou rs TAVI	Favou rs SAVR
Cardiac conditions in addition to aortic stenosis that require concomitant intervention <i>(continued)</i>	consideratio	n for
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+





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stenosis and recommendations for the choice of intervention mode *(continued)* 



17 ESC/EACTS Guidelines 1 Disease (European He doi:10.1093/eurhearti/e





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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.	I	С
SAVR is recommended in patients at low surgical risk (STSor 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	В
TAVI is recommended in patients who are not suitable for SAVRas assessed by the Heart Team.	I	В

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Management of Valvula Disease (European He doi:10.1093/eurheartj/e





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stenosis and recommendations for the choice of intervention mode *(continued)* 



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7 ESC/EACTS Guidelines Vianagement of Valvula Disease (European He doi:10.1093/eurhearti/e





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# stenosis and recommendations for the choice of intervention mode *(continued)*



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17 ESC/EACTS Guidelines Management of Valvula Disease (European He doi:10.1093/eurhearti/e



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# TAVI Similar to SAVRif STSscore>3

#### PARTNER II trial –Sapien XTvs. SAVR N= 2032, age 81.7, STSscore 5.8%



#### SURTAVItrial -C N= 1746, age 79.6



Reardon et al. New Engl JMed 201





# AVI Lower Mortality than SAVR if STSscore>3

Meta-analysis of RC n= 3806



Sionitis et al.. Eur Heart J2016





8.6%

4.3%

-

# TAVILOWERGETOKE Rates than SAVR 1 STSscore



Time in Months

TAVR

Number at risk:

TAVR

Surgery

Thourani et al., Lancet2016

4.6%

TE-TAVR

Time in Months

Number atrisk

Surgery - TF arm

TF-TAVR







Thourani et al., Lancet2016

# Only one randomized Trial with Follow-up at 5 yrs: PARTNER 1

Excellents Hemodynamic Results of both TAVI and SAVR



# 5-Years Durability in Registries



cohort) showed signs of SVD

5 definite SVD cases (1.4%) requiring Redo-TAVI in 2 + 10 (2.8%) with mild stenosis (20-40 mm Hg)



## LONG-TERM OUTCOMES IN EXTREME RISK PATIENTS





PARTNER 1B: 5-Year Follow-up

Kapadia SR et al. Lancet 2015

#### *CoreValve Exteme-Risk: 3-Year Follow-up*



#### Yakubov SJ et al. J Am Coll Cardiol 2015





# LONG-TERM OUTCOMES IN HIGH RISK PATIENTS









Deeb M et al. J Am Coll Cardiol 2016 All-cause Mortality







# OUTCOMES IN INTERMEDIATE RISK PATIENTS









Reardon MJ et al N Engl J Med. 2017 Apr 6;376:1321-1331

1,746 patients, mean STS score 4.5%, mean age 80 years







# TAVI vs. SAVR: LONG-TERM HEMODYNAMIC Data





Nedizinische Hochschule Hannover



#### *CoreValve High-Risk: 3-Year Follow-up*



Deeb M et al. J Am Co



































# Vielen Dank!



PURE

CANTOS

Ernährung

Antiinflammatorische Therapie der Atherosklerose

**STEMI** Guidelines

PAD Guidelines

CASTLE AF

**AFFIRM** 

Vorhofflimmerablation bei Herzinsuffizienz

Blutdruckvariabilität bestimmt Risiko bei VHF

