

10. KARDIOLOGIE-SYMPOSIUM DES HERZZENTRUMS HIRSLANDEN ZENTRALSCHWEIZ

Update TAVI



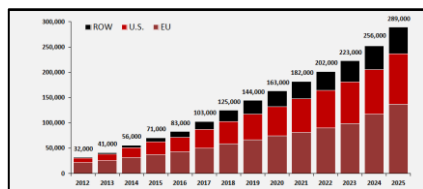
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Campus Virchow-Klinikum
Charité
Universitätsmedizin Berlin

•TAVI bei Patienten mit intermediärem oder niedrigem OP-Risiko?

•TAVI als Standardeingriff
Lebensqualität
Haltbarkeit der Klappen

•Komplikationsrate
Verbesserung der Technologie und Erfahrung der Zentren
Vaskuläre Komplikationen
Paravalvuläres Leck
Schlaganfall
Schrittmacherabhängigkeit

Estimated Global TAVI Growth



SOURCE: Credit Suisse TAVI Consensus – January 6, 2015. ASP assumption for 2015 and 2025 based on analyst model. Revenue split assumption in 2025 is 40% U.S., 35% EU, 25% ROW.

In the next 10 years, TAVI will grow X4

Indikation

Leitlinien

Datenlage

In 2016, TAVR indications are frozen in the past
European (2012) and US (2014) Guidelines

Recommendation	Class	Level
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

Table 11 Recommendations for the use of transcatheter aortic valve implantation

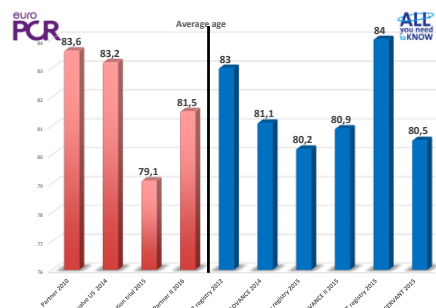
Recommendations	Class*	Level*	Ref*
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with 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	99
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	97

The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery
N Engl J Med. 2014;370:714-723. doi:10.1056/NEJMoa1302501.
ST5 11,2%

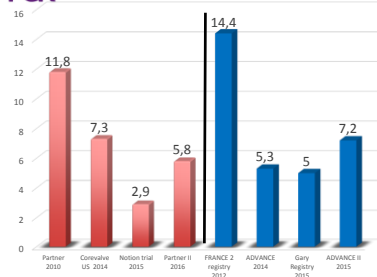
The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients
N Engl J Med. 2014;370:714-723. doi:10.1056/NEJMoa1302501.
ST5 11,8%

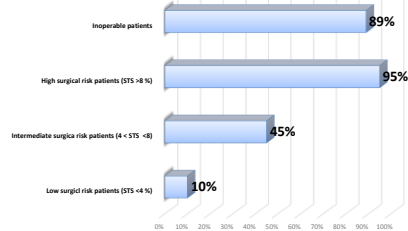


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STS

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to know
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EAPCI SURVEY

 ALL
you need
to know

 Petronio et al., in press
Eurointervention

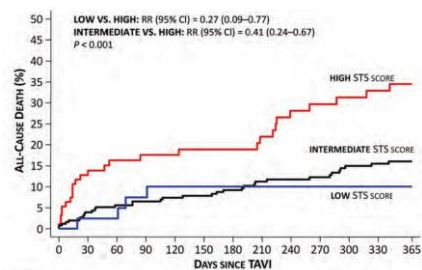
Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation

 Peter Wenaweser^{1,2}, Stefan Storteky^{1,2}, Sarah Schwander³, Dik Hegl⁴, Christoph Huber⁵, Thomas Nigrovi¹, Steffen Gloskeler⁶, Ciroshan J. O'Sullivan⁷, Bernhard Meier¹, Peter Juni¹, Thierry Carrel¹, and Stephan Windecker^{1,3}

Eur Heart Journal 2013

	All patients, N = 289	STS risk group			P-value
		Low, N = 61	Intermediate, N = 254	High, N = 91	
Age (years)	82.1 ± 5.8	78.2 ± 4.7	82.7 ± 5.7	83.7 ± 4.9	<0.001
Female gender, n (%)	126 (58)	30 (49)	146 (57)	50 (55)	0.01
Body mass index (kg/m ²)	26.2 ± 5.1	28.1 ± 4.1	26.3 ± 4.9	24.4 ± 4.6	<0.001
Risk assessment					
Logistic EuroSCORE (n)	24.3 ± 14.3	13.2 ± 7.5	22.1 ± 11.9	35.1 ± 16.7	<0.001
STS score (%)	4.8 ± 5.3	2.1 ± 3.3	5.7 ± 5.4	13.2 ± 7.1	<0.001
Access route					
Transcatheter, n (%)	258 (79)	51 (80)	208 (79)	71 (80)	0.94
Transapical, n (%)	76 (20)	8 (20)	66 (20)	18 (19)	
Transcatheter, n (%)	3 (1)	0 (0)	4 (2)	1 (1)	
Valve type					
Medtronic CoreValve, n (%)	124 (38)	21 (31)	148 (55)	51 (54)	0.72
Edwards Sapien valve, n (%)	145 (42)	14 (20)	106 (40)	41 (44)	

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to know


All-Comers NOTION Randomized Clinical Trial 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
STS Score	2.9 ± 1.6	3.1 ± 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 ± 4.0	8.9 ± 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61

J Am Coll Cardiol. 2015;65(20):2184-2194. doi:10.1016/j.jacc.2015.03.014

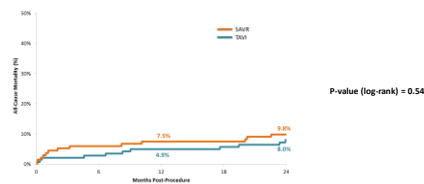
All-Comers NOTION Randomized Clinical Trial Primary Outcome Death from Any Cause at 2 Years

 Composite rate of
death from any cause, stroke or myocardial infarction
1 year after the procedure

TAVI 13.1% vs. SAVR 16.3%

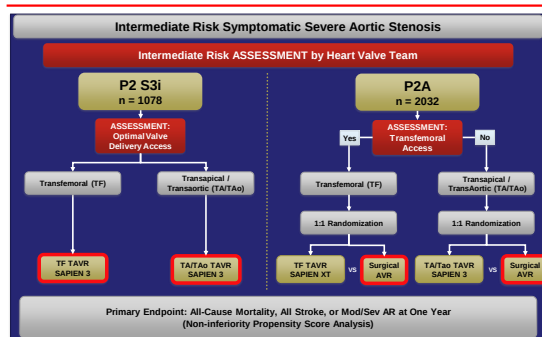
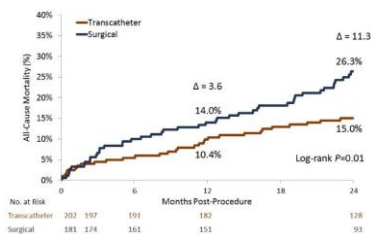
Absolute difference -3.2%; p=0.43 (for superiority)

*Intention-to-treat population



J Am Coll Cardiol. 2015;65(20):2184-2194. doi:10.1016/j.jacc.2015.03.014

Corevalve High Risk Pivotal Trial: subgroup analysis STS < 7

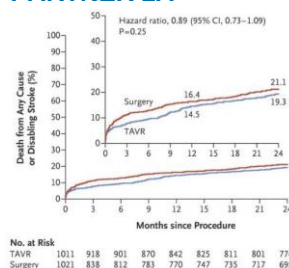


Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lutz G. Svensen, M.D., Ph.D., Stefan K. Kodali, M.D., Alvin H. Thomas, M.D., E. Murat Tuzcu, M.D., G. Craig Miller, M.D., Howard C. Herrero, M.D., Stephen Danks, M.D., David G. Cohen, M.D., Augustin D. Viebeck, M.D., Sybil Santhanam, M.D., Todd Green, M.D., Yoshitaka Kikawa, M.D., Willem T. Smeets, M.D., Norbert P. Williams, M.D., Dean DeFranco, M.D., Alan D'Agostino, M.D., Daniel J. Slom, M.D., Brian R. Williams, M.D., Robert H. Messer, M.D., Jeffrey M. Speck, M.D., Alvin H. Thomas, M.D., David L. Brown, M.D., William T. Frazier, M.D., Philippe Pibarot, O.D., Ph.D., Rebecca T. Pasterkamp, M.D., and A. John C. Webb, M.D., for the PARTNER 2 Investigators*

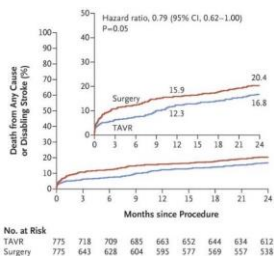
2032 Patienten mit schwerer Aortenstenose und intermediärem Risiko
TAVI vs SVR
Primärer Endpunkt: Gesamtmortalität, Schlaganfall oder moderate bis schwere Aorteninsuffizienz im 2 Jahres Follow-up
Device Sapien XT

PARTNER 2A

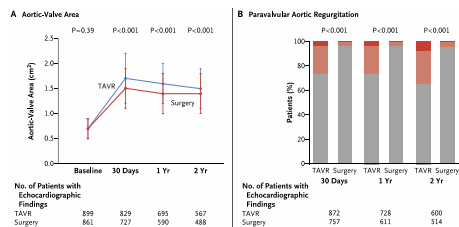


- Sapien XT
- CT imaging not universally used

PARTNER 2A – Transfemoral cohort

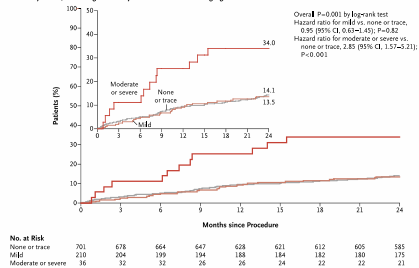


Echokardiographie



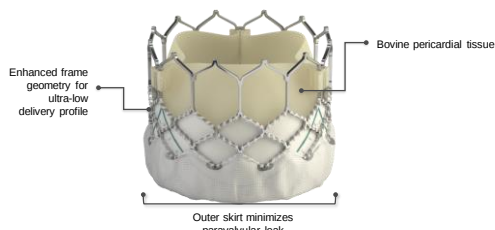
Echokardiographie

C. Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

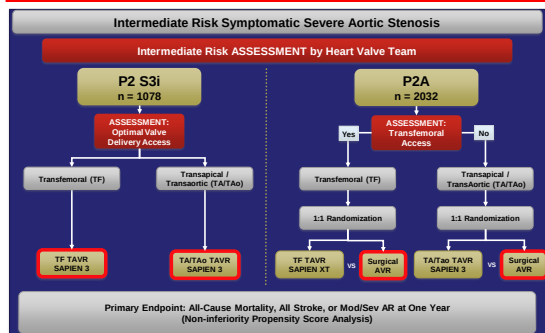


	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility	22-24F	16-20F	14-16F
Available Valve Sizes	23 mm, 26 mm	23 mm, 26 mm, 29 mm	20 mm, 23 mm, 26 mm, 29 mm

Edwards SAPIEN 3 Transcatheter Heart Valve



PARTNER 2A und S3i trial Studiendesign



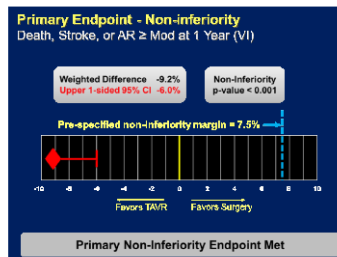
The PARTNER 2A and S3i Trial Lancet On-line

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

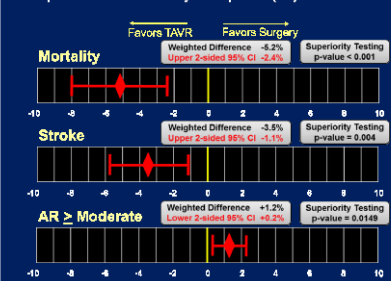
Vinod H Thevaranji, Sushant Kishor, Rajiv Malik, Howard C Hemmings, Matthew Williams, Vasili Babalunas, Richard Smalley, Scott Lin, S Chris Malvar, Samir Kapadia, Wilson Y So, Kevin J. Gerson, Dean Karam, Gerson Alkadi, Brian Whitman, Chandra Dinesh, Jonathan Lipson, Robert T. Hahn, Philippe Borent, Neil Wernsing, Ward Kibbe, David Cohen, Robert S. Kim, Michael T. Hahn, Len C. Green, John C. Webb, Jeffrey W. Moses, Michael J. Mack, D. Craig Miller, Craig R. Smith, Maria C. Ali, Roger Parvathaneni, Ralph B. D'Agostino Jr., Martin B. Leon

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S3i verglichen mit PARTNER 2 konventionell operierten Patienten in der Propensity Score Analyse



Superiority Analysis Components of Primary Endpoint (VI)



Partner 2A und S3i Trials

- Bei Patienten mit intermediärem Risiko:
Sapien-3 1-Jahres Raten nach TAVI:
Gesamt mortalität 7,4 %
Schlaganfall 4,6 %
Schwere Aorteninsuffizienz (Paravalvuläres Leck) 1,5 %
 - Beim Vergleich der Sapien3 mit dem Outcome der chirurgisch versorgten Patienten zeigen die 1-Jahresdaten:
Nicht-Unterlegenheit hinsichtlich des primären Endpunktes
Mortalität, Schlaganfall oder moderate - höhergradige Aorteninsuffizienz
- Überlegenheit der Prozedur mit der Sapien 3 für die Endpunkte
Gesamt mortalität und Schlaganfall
- Prozedur bedingter Effekt
Time-to-event Analyse findet sich dieser Vorteil in den ersten Monaten

•TAVI bei Patienten mit intermediärem oder niedrigem OP-Risiko?

•TAVI als Standardeingriff
Lebensqualität
Haltbarkeit der Klappen

•Komplikationsrate
Verbesserung der Technologie und Erfahrung der Zentren
Vaskuläre Komplikationen
Paravalvuläres Leck
Schlaganfall
Schrittmacherabhängigkeit

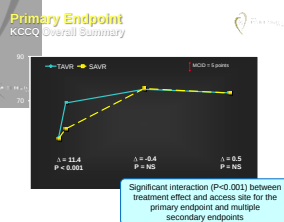
Haltbarkeit der Klappenprothesen

Health Status Benefits of Transcatheter vs. Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk
Results From The PARTNER 2 Trial

David J. Cohen, M.D., M.Sc.
On behalf of the PARTNER 2 Investigators
Saint Luke's Mid-America Heart Institute
University of Missouri-Kansas City
Kansas City, Missouri

TCT 2016 / Washington DC | November 8, 2016

Highlights from TCT 2016: Partner II Quality of Life



Mid-Term Hemodynamic Trends and Between Echo Changes in Transcatheter Aortic Valves in the PARTNER 1 Trial

Five Year Results

Patricia S. Douglas, MD
on behalf of the PARTNER Trial Investigators
and The PARTNER Publications Office

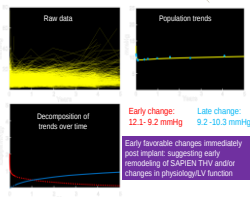
TCT 2016 / Washington DC | November 8, 2016

Highlights from TCT 2016: Partner I Eye Echo

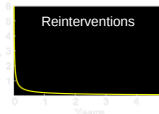
Get implantation success per procedure as approx. 70%, 80%, 90% and 1, 2, 3, 4, 5 yrs. Analyzed by a single core laboratory

Echocardiographic parameters
→ AV mean gradient
→ Doppler velocity index (DVI)
→ [Effective orifice area (EOA)]

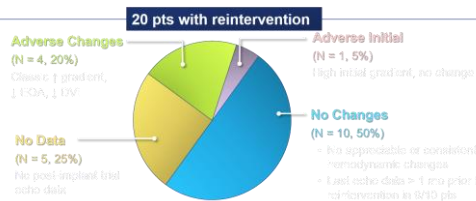
AV Mean Gradient Population Trends: Early Post Implant and Midterm to 5 Yrs



- VASC-2 'mL JAC' found in 3-48%
 - ⇒ Similar rates in SAVR and TAVR
 - ⇒ Impractical for case review
- AV mean gradient ≥ 20 mmHg
 - ⇒ N=10 (0.45%)
 - ⇒ 6 deaths (3 CV), no reintervention
- A.v. mea. gradia. ≥ 40 mmHg
 - ⇒ N=11 (0.46%)
 - ⇒ 8 deaths (2 CV), 1 reintervention



- 20 pts with reintervention
 - (9 SAVR, 8 late valve-in-valve, 3 BAV)
- Indication: Structural cause in 5 (25%)
 - AS: n=1; Valve thrombosis: n=1; Trans A/R: n=3



- This evaluation of 2404 TAVR patients in the PARTNER I trial, encompassing 6493 patient years of follow up, is the largest, core-lab based study of transcatheter heart valves to date
- Population hemodynamic trends show excellent durability of the SAPIEN THV without structural deterioration to 5 years
- Similarly, severely abnormal hemodynamics which might be suggestive of valve thrombosis or stenosis in individual patients were rare in this protocol-driven data base
- Together, these data demonstrate excellent mid-term durability of THV, suggesting that the low 5 year survival observed in this cohort is not related to adverse hemodynamics or THV deterioration

Valve Performance - Long-term -

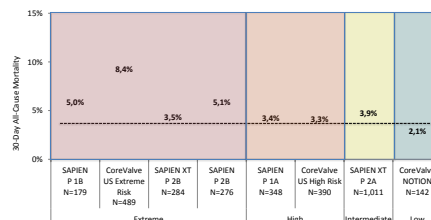
	Number of Patients with Available Echo at Follow-Up				
	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
CoreValve					
Italian Registry	274	246	211	175	108
CE Trial	45	38	22	17	
ADVANCE	576	488	353		
US Pivotal ER	336	261	184		
ANZ	278	172			
Edwards					
PARTNER B	91	71	46	31	15
PARTNER A	219	156	106	79	56
Vancouver	88	73	65	47	37
Canadian Experience	218	135	78	22	
SOURCE XT	1,362	835	568		
Prevail XT	187	151	104		
TOTAL	3,674	2,626	1,737	371	216

• TAVI bei Patienten mit intermediärem oder niedrigem OP-Risiko?

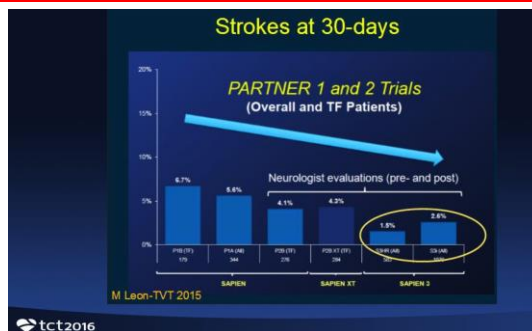
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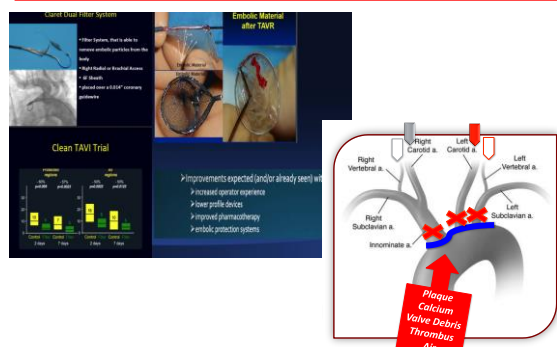
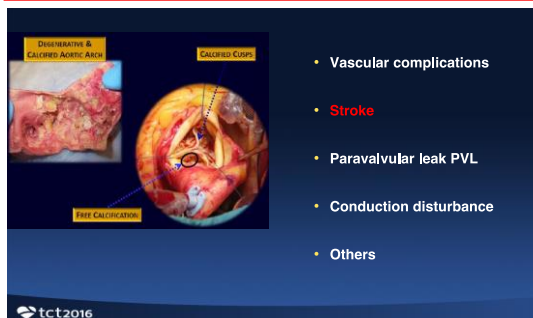
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Verbesserung der Technologie und Erfahrung der Zentren
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TAVR: All-Cause Mortality @ 30 days

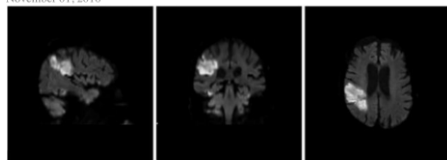


Tavris, et al., N Engl J Med 2010;363:1587-1597; Popma, et al., J Am Coll Cardiol 2014;63:1377-83; Webb, et al., J Am Coll Cardiol 2010;50:1797-806; Teresh, et al., N Engl J Med 2011;364:2387-96; Adams, et al., N Engl J Med 2014;370:1760-6; Tuzi, et al., N Engl J Med 2010;374:1009-20; Thompson, et al., J Am Coll Cardiol 2010;55:2338-44

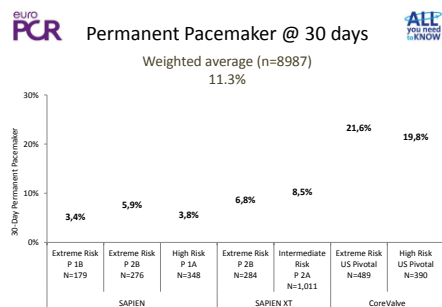




November 01, 2016



WASHINGTON, DC—Cerebral protection during transcatheter aortic valve replacement using the Sentinel filter device (Claret Medical) is safe and appears to trap embolic debris in almost every single procedure, but this does not translate into significant reductions in new brain lesion volume on MRI. Those are the findings from the SENTINEL randomized trial, presented here at TCT 2016



*Lewin, et al., N Engl J Med 2015;363:1357-1367; *Veldt, et al., J Am Coll Cardiol Intv 2015;8:1797-806; *Smith, et al., N Engl J Med 2015;364:2387-96; *Lewin, et al., N Engl J Med 2015;374:1500-10; *Higgins, et al., J Am Coll Cardiol 2015;65:1372-81; *Adams, et al., N Engl J Med 2014;370:1790-6.

Zusammenfassung:

Leitlinien

TAVI bei inoperablen Patienten oder Patienten mit hohem OP-Risiko

Diskussion um eine Indikationsausweitung

Entwicklung neuer Klappenprothesen
Verbesserte Implantationstechniken

Zunehmend Studiendaten zu „jüngeren Patienten“

Reduzierte Mortalitäts- und reduzierte Komplikationsraten

Dem chirurgischem Klappenersatz zumindest gleichwertig
Wenn nicht sogar überlegen

Haltbarkeit der Prothesen
Schrittmacherrate

Ideale Leitlinien für 2016 ??

Table 1. Recommendations for the use of transcatheter aortic valve implantation

Recommendations	Class ^a	Level ^b	Ref ^c
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	91
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with aortic stenosis (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/or have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with aortic stenosis (AS) who may still be suitable for surgery, but in whom TAVI is favored by a heart team based on the individual risk profile and systemic suitability.	IIa	B	97

Recommendations	TAVI	SAVR
High-risk patients	I (B)	IIb - B
Intermediate risk patients	I (A)	I - B
Low-risk patients	IIb (B)	I - B

- Partner 1 A-CoreValve US
- CoreValve US – Partner II
- Notion trial

MANAGEMENT OF SEVERE AORTIC STENOSIS FUTURE OUTLOOK

Vahl et al J Am Coll Cardiol 2016

FUTURE MANAGEMENT STRATEGIES FOR PATIENTS WITH SYMPTOMATIC SEVERE AORTIC STENOSIS			
Prohibitive risk patients	Extreme risk or Inoperable patients	High risk patients	Lower risk patients*
✗ Surgical aortic valve replacement (SAVR) ✗ Transcatheter aortic valve replacement (TAVR) Both SAVR and TAVR considered. Further focus on symptom relief and palliation.	✗ SAVR ✓ TAVR • SAVR suboptimal • TAVR expected to improve survival and quality of life (QoL)	✓ SAVR ✓ TAVR (preferred) • Both SAVR and TAVR expected to improve survival and QoL • TAVR preferred unless age, anatomical or other patient factors make SAVR the superior option	✓ SAVR (preferred) ✓ TAVR • Both SAVR and TAVR expected to improve survival and QoL • May consider TAVR in absence of anatomic or unfavorable clinical characteristics with emphasis on patient age and valve durability



2012 GUIDELINES FOR THE MANAGEMENT OF AORTIC VALVULAR HEART DISEASE



2014 GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH VALVULAR HEART DISEASE

UPDATE 2017

Vielen Dank für Ihre Aufmerksamkeit !

