



31. Berliner Dialyseseminar 7./8.12.2018

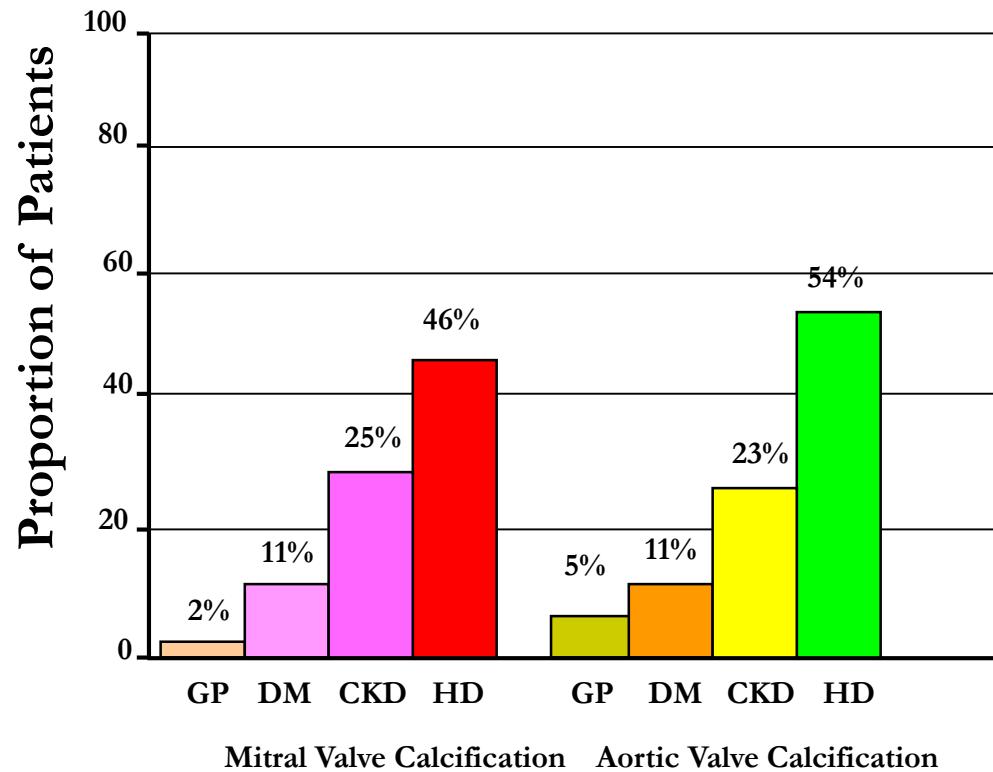
Klappenvitien bei Dialyse Patienten TAVI

Ulf Landmesser

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BIH Professor für Kardiologie

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Charité – Universitätsmedizin Berlin

Prevalence of Valve Calcification in the general population and in patients with chronic renal disease



Accelerated Progression of Calcific Aortic Stenosis in Dialysis Patients

Vlado Perkovic^{a,b} David Hunt^c Sian V. Griffin^a Moira du Plessis^c
Gavin J. Becker^b

^aDepartment of Nephrology, ^bUniversity of Melbourne Department of Medicine, and ^cDepartment of Cardiology,
Royal Melbourne Hospital, Parkville, Vic., Australia

Parameter	Cases	Controls	p
Annual change in valve area, cm ² /year (range)	-0.19 (-1.45 to 0.20) ^a	-0.07 (-1.1 to 0.37) ^a	<0.001
Annual change in mean gradient, mm Hg/year (range)	4.9 (-4.9 to 50)	2.5 (-7.4 to 16.7)	0.052

Prospective evaluation of aortic stenosis in end-stage kidney disease: a more fulminant process?

Dominica Zentner¹, David Hunt¹, William Chan¹, Federica Barzi², Leeanne Grigg¹ and Vlado Perkovic²

D. Zentner *et al.*

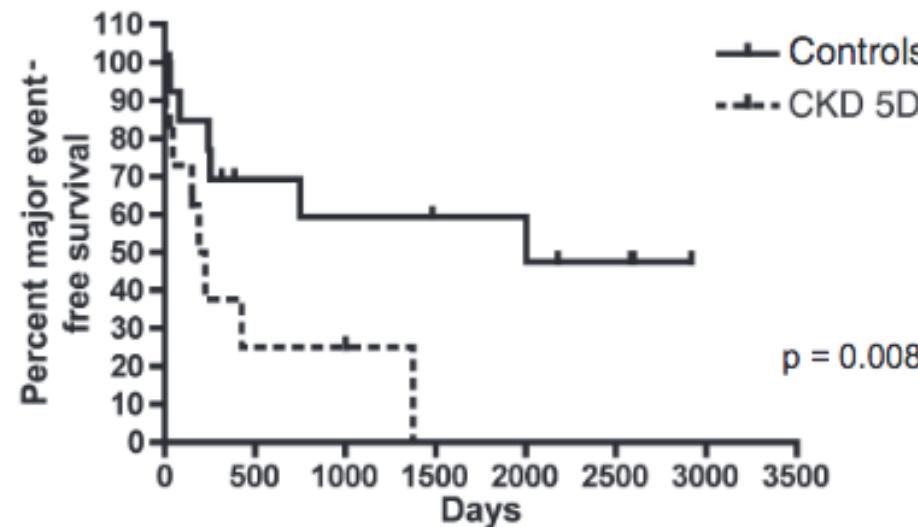


Fig. 2. Major event-free survival in the severe AS subgroups [HR and 95% CI: 3.26 (1.30–8.14)].

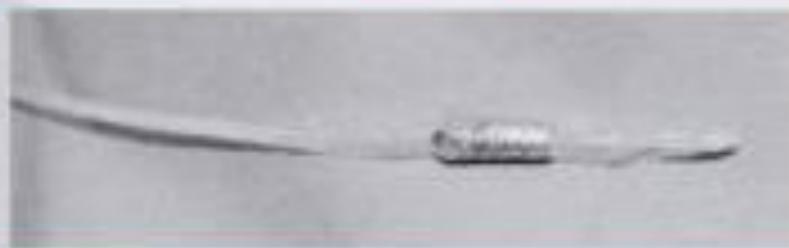
Klappenvitien bei Dialyse Patienten

TAVI

- 1) Entwicklung TAVI Global/Deutschland
- 2) TAVI vs. SAVR – Neue ESC/EACTS Guidelines
- 3) TAVI bei Dialyse Patienten

Special Report

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis First Human Case Description



Cribier A et al. Circulation 2002;106:3006-3008.

ESC CONGRESS
BARCELONA 2017

#esccongress

www.escardio.org/ESC2017

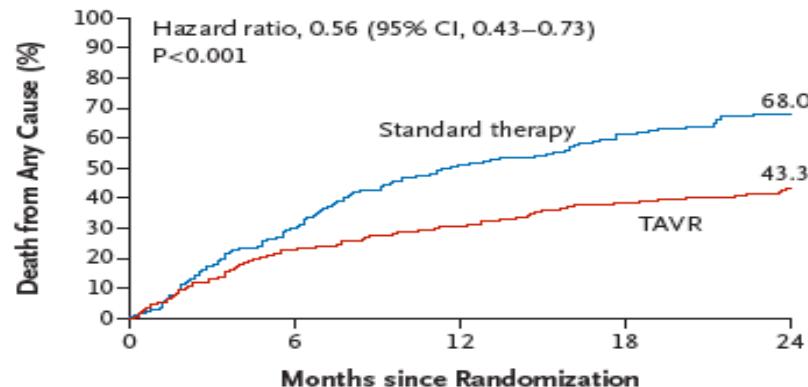
Katheter-basierter Aortenklappenersatz

Alain Cribier



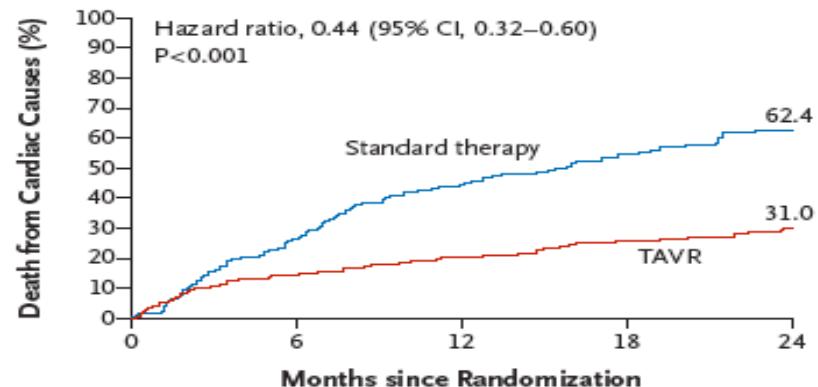
TAVI Markedly Reduced Mortality in Inoperable Patients - PARTNER 1 B

A



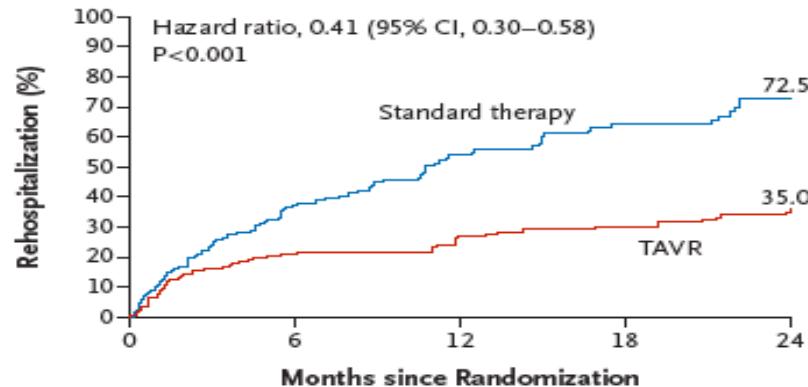
No. at Risk					
TAVR	179	138	124	110	83
Standard therapy	179	121	85	62	42

B



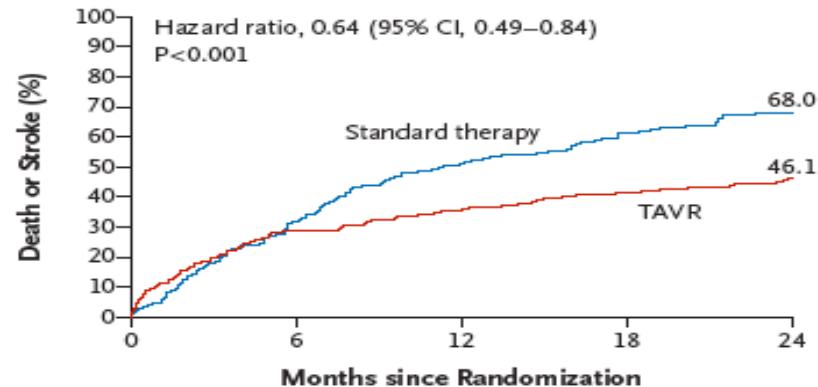
No. at Risk					
TAVR	179	138	124	110	83
Standard therapy	179	121	85	62	42

C



No. at Risk					
TAVR	179	115	100	89	64
Standard therapy	179	86	49	30	17

D



No. at Risk					
TAVR	179	128	116	105	79
Standard therapy	179	118	84	62	42



TAVI

An Established Simple Treatment
for Inoperable and High-Risk
Aortic Stenosis



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TAVI was non-inferior to SAVR in Intermediate Risk Patients

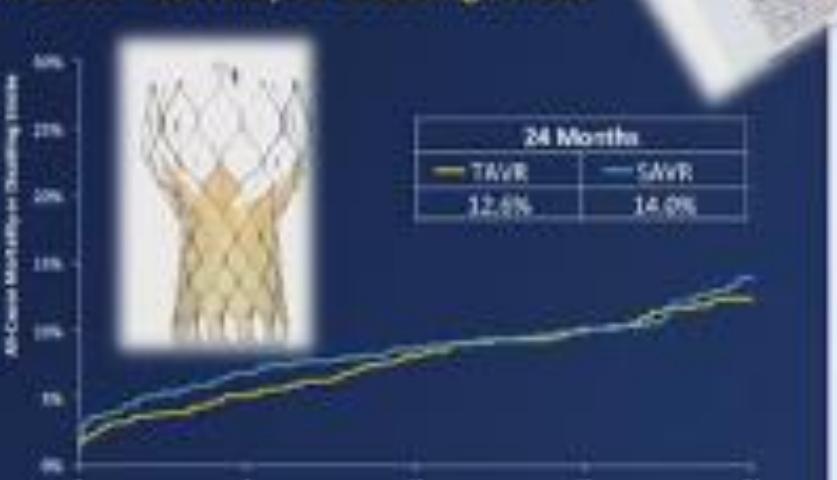
THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

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

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

All-Cause Mortality or Disabling Stroke



The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812

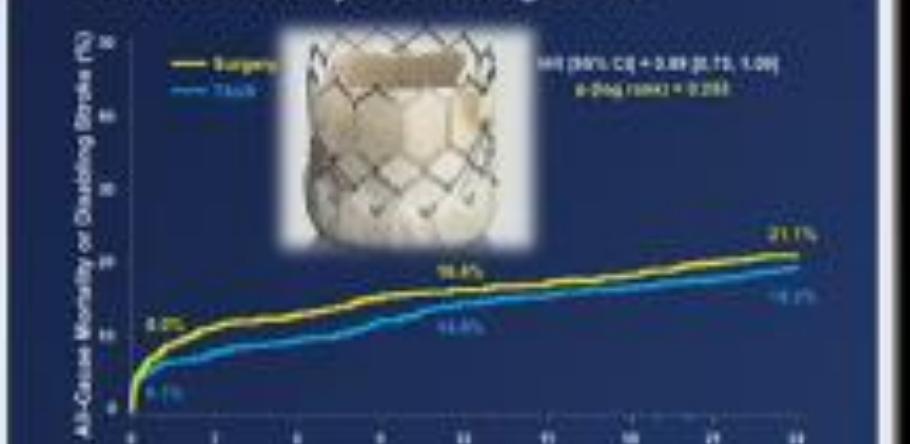
APRIL 28, 2016

VOL. 374 NO. 17

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., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babalarios, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

Primary Endpoint (ITT) All-Cause Mortality or Disabling Stroke



2017 ESC/EACTS Guidelines

B) Choice of intervention in symptomatic aortic stenosis

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).

I

C

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 Table 7). 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%^d and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).⁹³

I

B

TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.^{91,94}

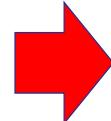
I

B

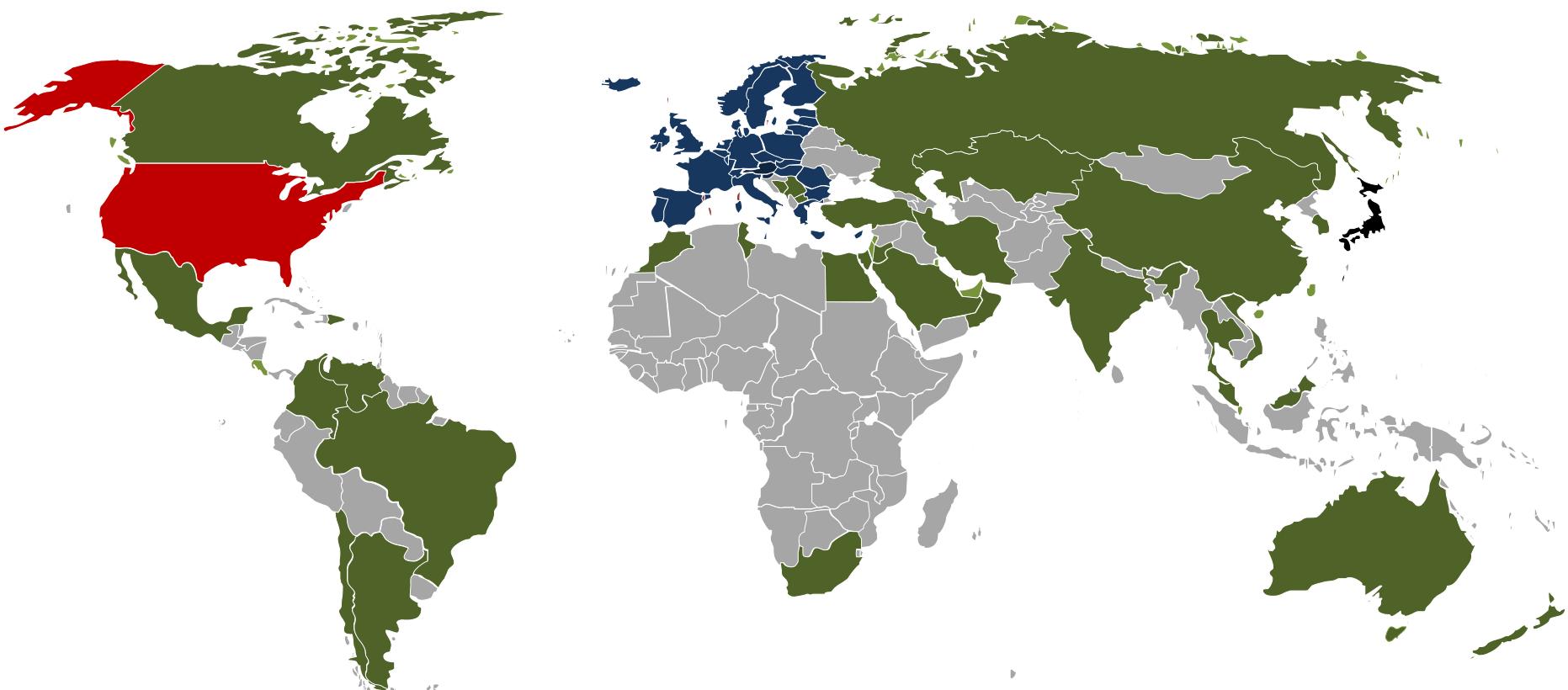
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%^d or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see Table 7), with TAVI being favoured in elderly patients suitable for transmamal access.^{91,94–102}

I

B

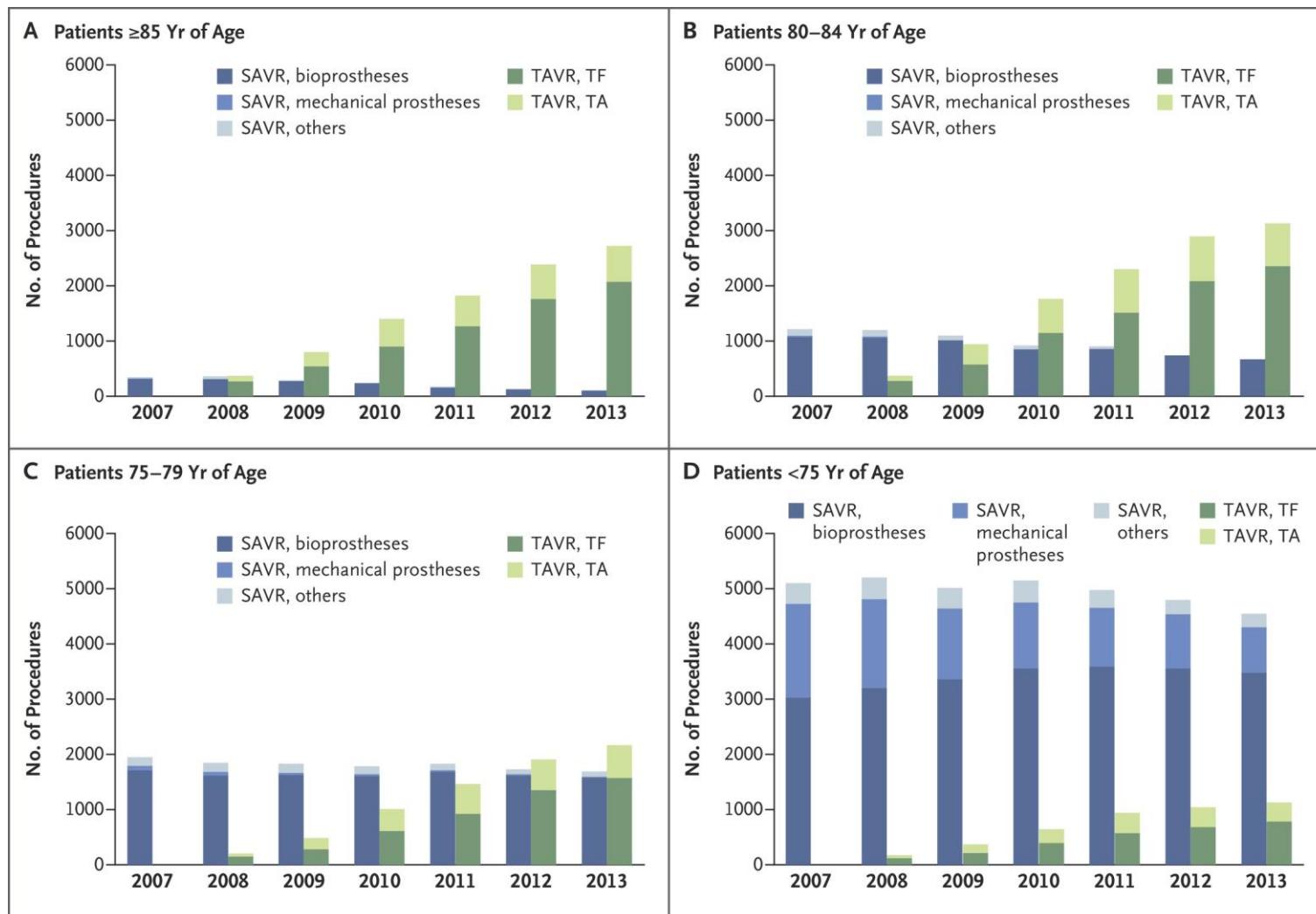


TAVI is Available in More Than 65 Countries Around the World



>250,000 total implants to date

Number of Transcatheter Aortic-Valve Replacement (TAVR) and Surgical Aortic-Valve Replacement (SAVR) Procedures Performed: 2007–2013.



Numbers of Surgical Aortic-Valve Replacement (SAVR) and Transcatheter Aortic-Valve Replacement (TAVR) Procedures, According to Year.

Table 1. Numbers of Surgical Aortic-Valve Replacement (SAVR) and Transcatheter Aortic-Valve Replacement (TAVR) Procedures, According to Year.*

Procedure	2007	2008	2009	2010	2011	2012	2013	Total
SAVR								
Total — no. (frequency)†								
Total — no. (frequency)†	8622 (10.5)	8603 (10.5)	8259 (10.1)	8109 (9.9)	7899 (9.7)	7452 (9.1)	7048 (8.7)	55,992 (9.8)
Bioprostheses — no. (%)	6128 (71.1)	6196 (72.0)	6284 (76.1)	6266 (77.3)	6296 (79.7)	6050 (81.2)	5838 (82.8)	43,058 (76.9)
Mechanical prostheses — no. (%)	1810 (21.0)	1703 (19.8)	1333 (16.1)	1228 (15.1)	1104 (14.0)	1013 (13.6)	847 (12.0)	9,038 (16.1)
Other prostheses — no. (%)‡	689 (8.0)	712 (8.3)	645 (7.8)	621 (7.7)	505 (6.4)	391 (5.2)	365 (5.2)	3,928 (7.0)
TAVR								
Total — no. (frequency)†								
Total — no. (frequency)†	144 (0.2)	1122 (1.4)	2599 (3.2)	4806 (5.9)	6523 (8.0)	8240 (10.1)	9147 (11.3)	32,581 (5.7)
Transfemoral — no. (%)	NA	825 (73.5)	1618 (62.3)	3051 (63.5)	4283 (65.7)	5881 (71.4)	6794 (74.3)	22,452 (68.9)
Transapical — no. (%)	NA	302 (26.9)	986 (37.9)	1772 (36.9)	2253 (34.5)	2363 (28.7)	2367 (25.9)	10,043 (30.8)
All procedures — no.	8766	9725	10,858	12,915	14,422	15,692	16,195	88,573

* Numbers represent procedures, not individual patients; some patients may have undergone more than one procedure. The number of procedures in the subgroups exceeds the total number of procedures for various reasons (e.g., double coding). Percentages may not sum to 100 because of rounding. NA denotes not available.

† Frequency (number of procedures per 100,000 population) is based on population data for Germany from the Organisation for Economic Co-operation and Development (<http://stats.oecd.org>).

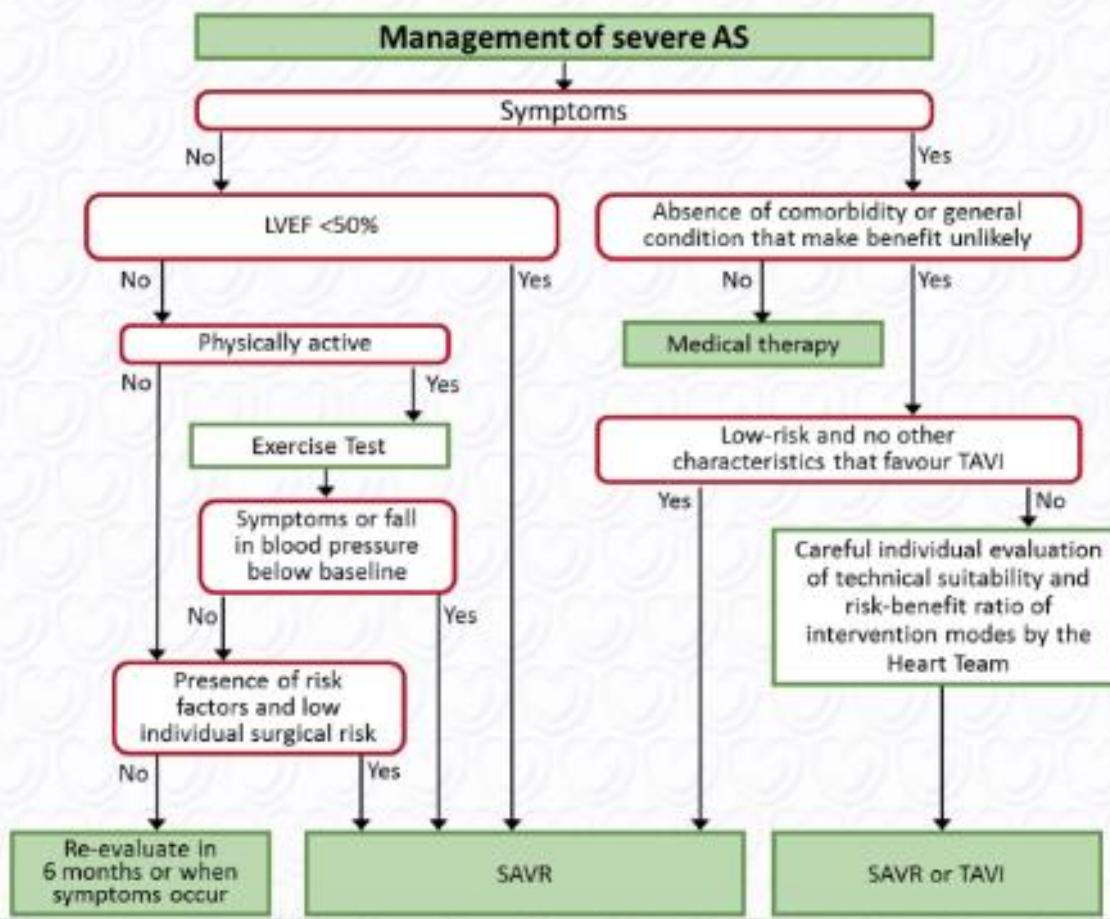
‡ As shown in Table S1 in the Supplementary Appendix, this category includes allotransplants (German Procedure Classification [OPS] code 5-351.01) and stentless bioprostheses (OPS code 5-351.03).

Klappenvitien bei Dialyse Patienten

TAVI

- 1) Entwicklung TAVI Global/Deutschland
- 2) TAVI vs. SAVR – Neue ESC/EACTS Guidelines
- 3) TAVI bei Dialyse Patienten

Management of Severe Aortic Valve Stenosis: New 2017 ESC/EACTS Guidelines



www.escardio.org/guidelines

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

Heart Team Decisions in Aortic Valve Disease: New 2017 ESC/EACTS Guidelines



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	+	

Heart Team Decisions in Aortic Valve Disease: New 2017 ESC/EACTS Guidelines



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

Heart Team Decisions in Aortic Valve Disease: New 2017 ESC/EACTS Guidelines



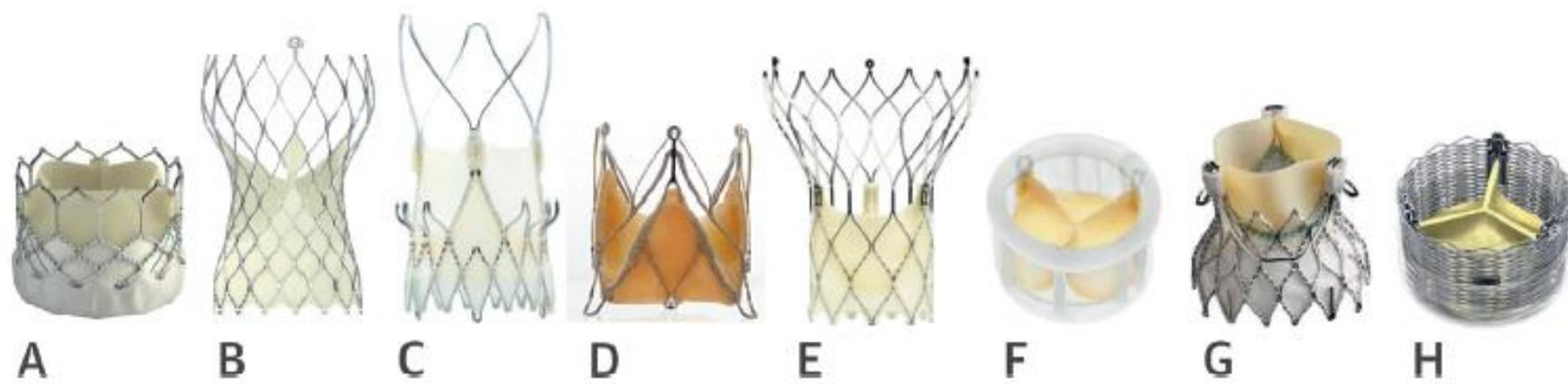
**Aspects to be considered by the Heart Team
for the decision between SAVR and TAVI
in patients at increased surgical risk (continued)**



	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		+

Development of TAVI Prothesis

FIGURE 3 Overview of TAVR Systems

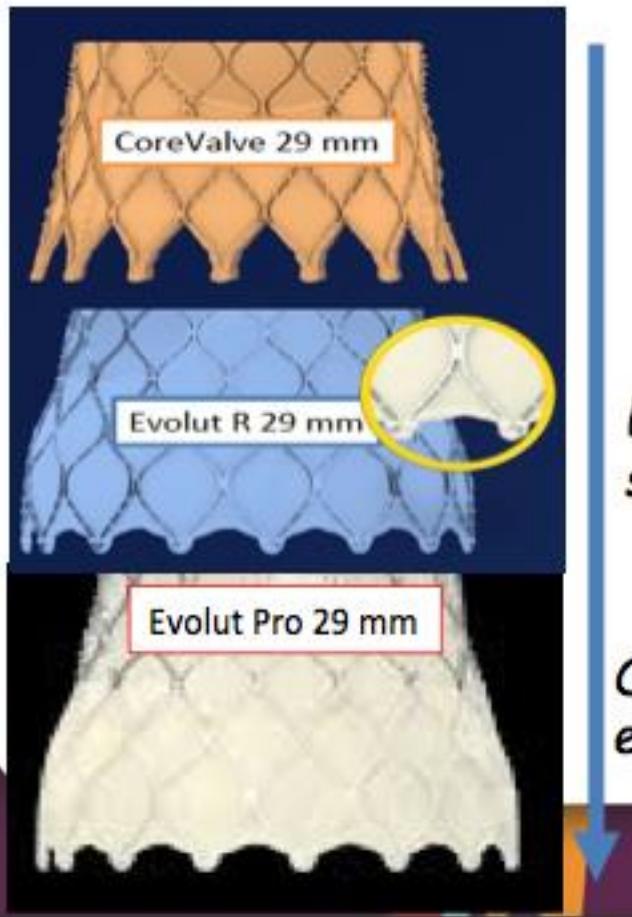


Currently, 8 transcatheter aortic valve replacement (TAVR) systems are commercially available in Europe (A-H), whereas 2 TAVR systems are approved by the U.S. Food and Drug Administration in the United States (A, B). (A) Edwards Lifesciences Sapien 3 Valve (Edwards Lifesciences, Irvine, California); (B) Medtronic CoreValve Evolut R (Medtronic, Minneapolis, Minnesota); (C) Synteris Acurate neo Valve (Synteris, 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).

Reducing Paravalvular Leaks (PVL)

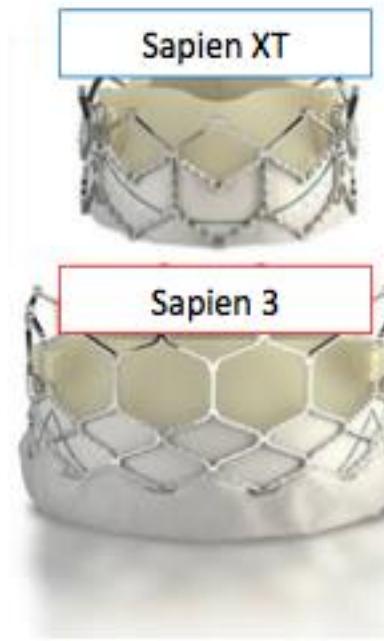
PVL

Incidence: role of newer devices



Extended sealing skirt

Outer wrap to enhance sealing



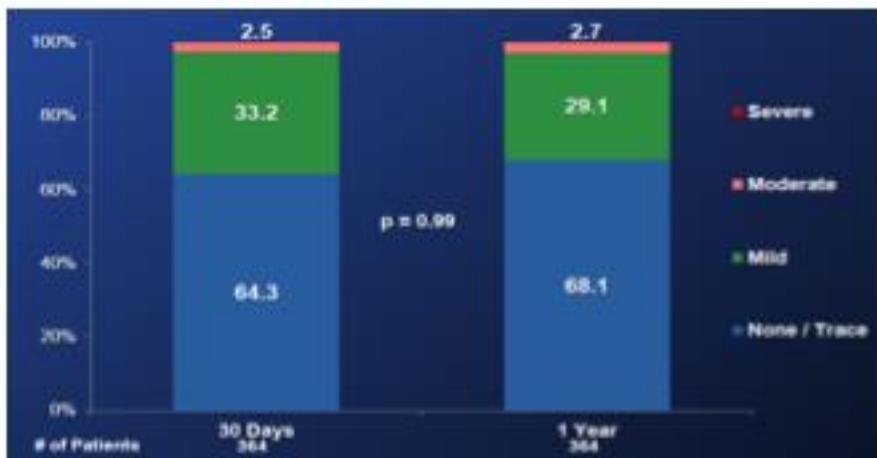
Outer skirt; slightly higher profile

Incidence of Paravalvular Leaks (PVL)

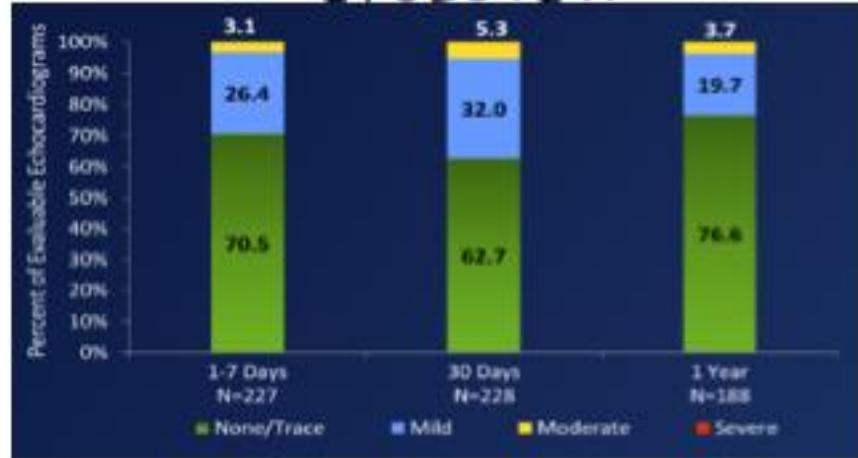
PVL

Incidence of PVL in Newer Devices

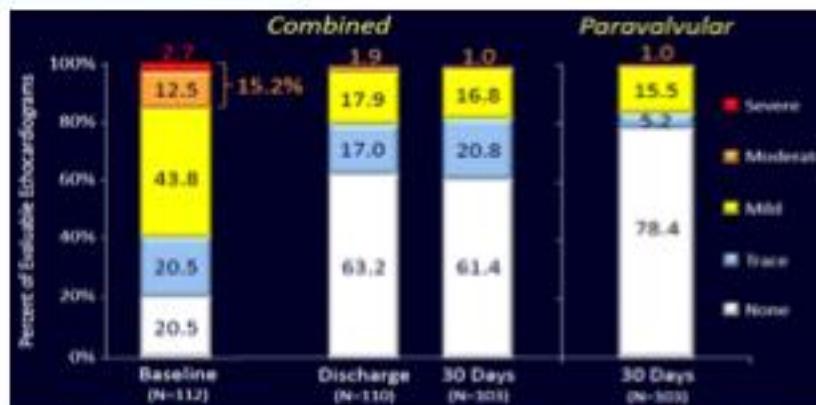
- PARTNER II



- EVOLUTE R



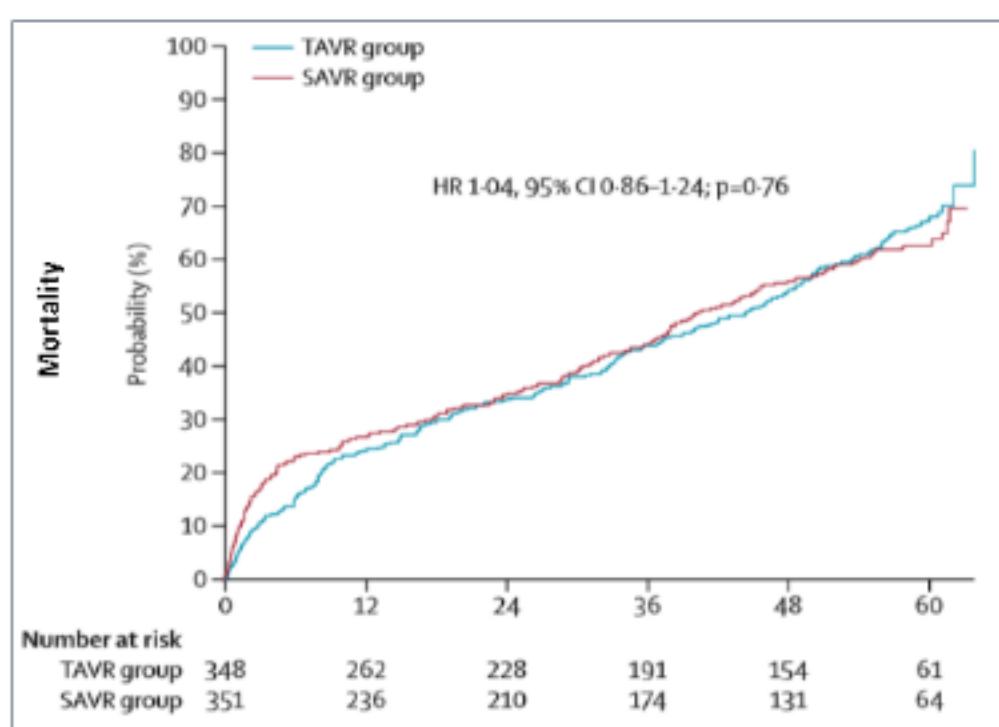
- REPRISE



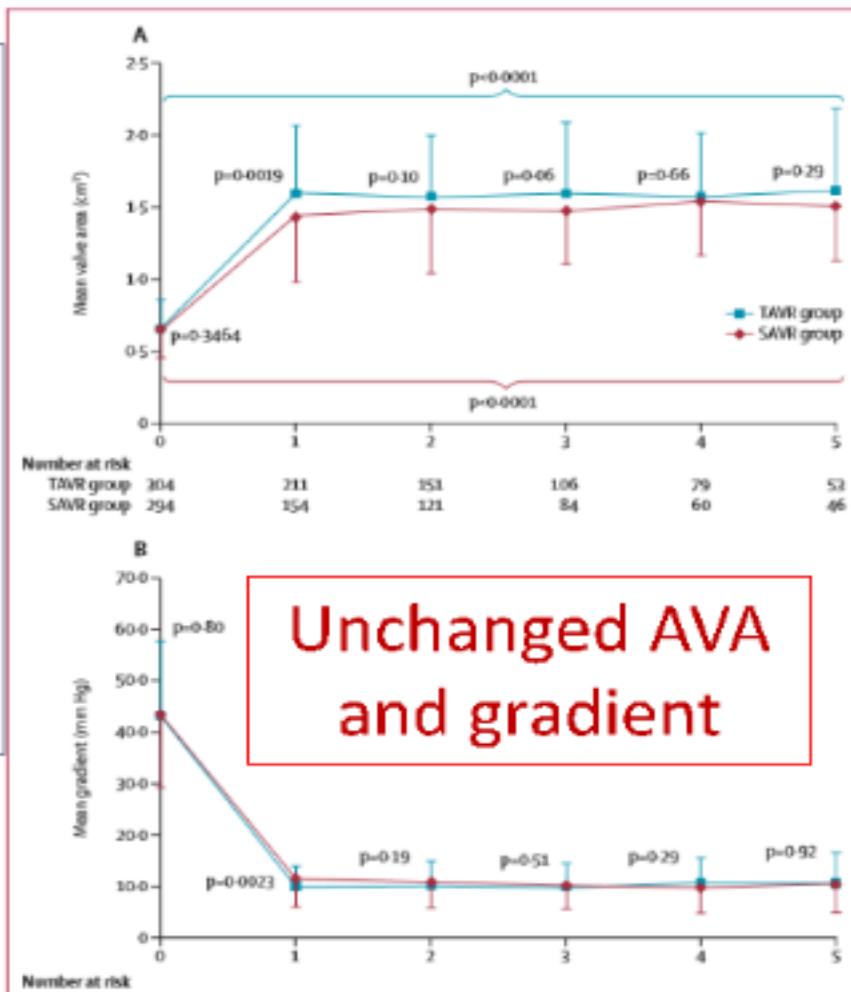
Durability of Hemodynamic Results after TAVI and SAVR ?

– Follow-up at 5 years – PARTNER-1

Excellent Hemodynamic Results of both TAVI and SAVR



No Pt with SVD



M Mack et al. The Lancet 2016

Klappenvitien bei Dialyse Patienten

TAVI

- 1) Entwicklung TAVI Global/Deutschland
- 2) TAVI vs. SAVR – Neue ESC/EACTS Guidelines
- 3) TAVI bei Dialyse Patienten



Transcatheter and Surgical Aortic Valve Replacement in Patients With End-Stage Renal Disease

TABLE 1 Pre- and Post-Propensity-Matched Baseline Demographics and Outcomes Comparing TAVR and SAVR in ESRD Patients

	Pre-Propensity Match			Post-Propensity Match		
	TAVR (n = 158)	SAVR (n = 546)	p Value	TAVR (n = 119)	SAVR (n = 244)	p Value
Mean age, yrs	76.27	67.08	<0.001	74.32	74.32	1.00
Female	41.1	33.5	<0.001	35.3	35.3	0.986
Charlson Comorbidity Index, mean	3.97	3.90	0.540	3.99	4.1	0.450
In-hospital mortality	9.5	14.3	0.118	9.2	10.9	0.784
In-hospital complications						
Blood transfusion	38.6	44.7	0.175	37.8	46.2	0.389
Pacemaker placement	12.6	8.1	0.077	11.7	10.1	0.750
Post-procedure length of stay, days, mean	8.87	17.08	<0.001	8.31	17.71	<0.001
Total hospital costs, mean	\$69,540	\$101,097	<0.001	\$66,672	\$99,676	<0.001
Discharge disposition to home	50.6	38.5	0.006	56.3	42.8	0.010

Values are % unless otherwise indicated.

ESRD = end-stage renal disease; SAVR = surgical aortic valve replacement; TAVR = transcatheter valve replacement.

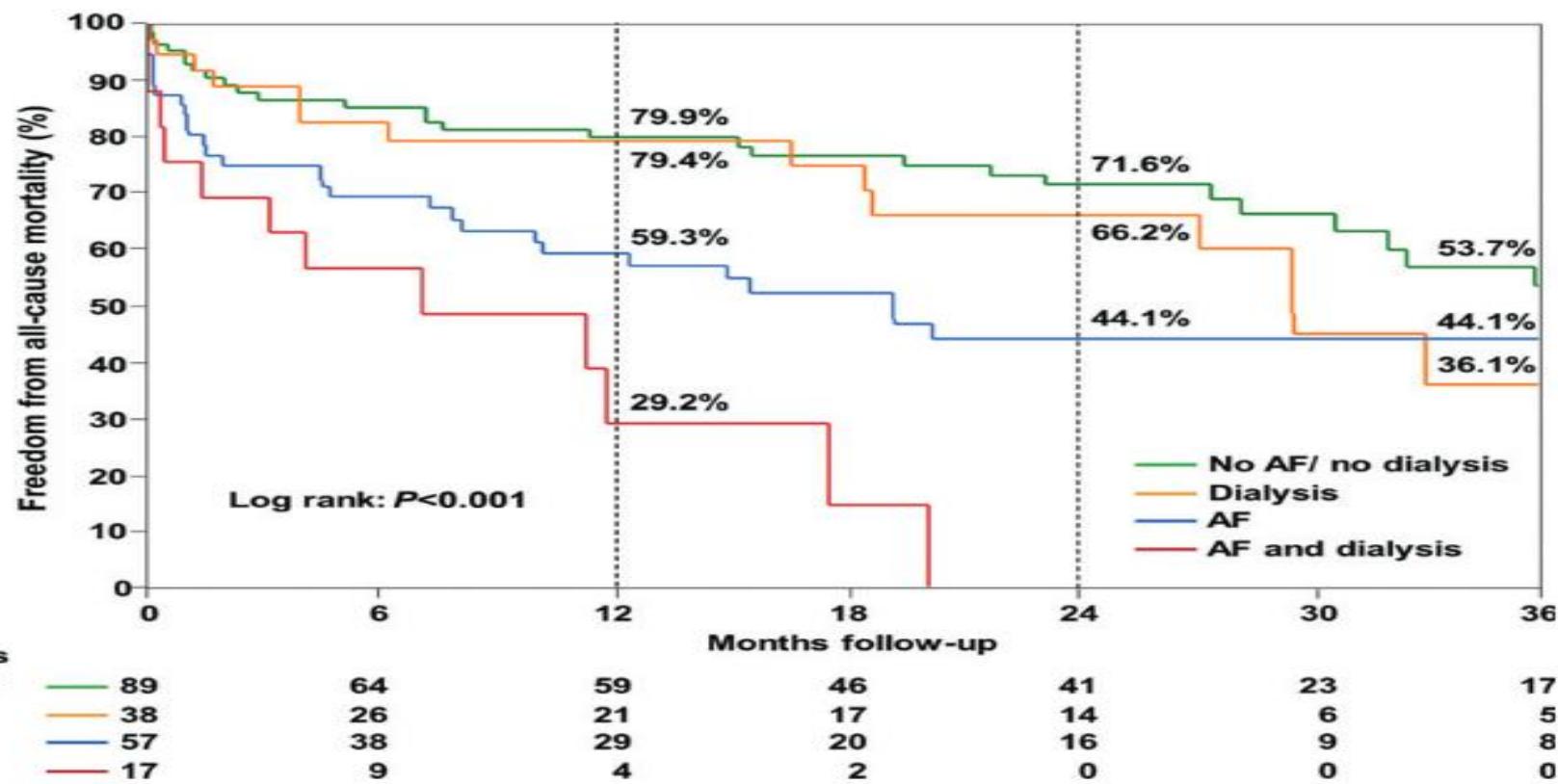
Transcatheter or surgical aortic valve replacement in patients with advanced kidney disease: A propensity score-matched analysis

Rajkumar Doshi¹  | Jay Shah² | Vaibhav Patel¹ | Varun Jauhar¹ | Perwaiz Meraj¹

Results: After propensity matching, 2485 patients were included in each group. The primary outcome of in-hospital mortality (12.9% vs 6.2%; $P < 0.01$) was higher with SAVR as compared with TAVR. Patients who underwent SAVR reported higher acute kidney injury (50.3% vs 33%; $P < 0.01$) and dialysis requirements (26.8% vs 20.1%; $P < 0.01$). Other secondary outcomes including blood transfusion, atrial fibrillation, iatrogenic cardiac complications, pericardial complications, perioperative stroke, perioperative infections, and postoperative shock were more common with SAVR. With SAVR, the length of hospitalization and hospitalization costs were significantly higher; however, permanent pacemaker placement was more common with TAVR compared with SAVR.

Conclusions: In patients with advanced kidney disease, SAVR was associated with higher mortality and higher periprocedural complications, as compared with TAVR. Thus, benefits of TAVR could be extended in patients with advanced kidney disease who cannot undergo surgery.

Advanced chronic kidney disease in patients undergoing transcatheter aortic valve implantation: insights on clinical outcomes and prognostic markers from a large cohort of patients



EDITORIAL COMMENT

TAVR and SAVR in ESRD: Just because we can doesn't necessarily mean that we should

Mark Hensey MB, BCh, BAO  |

John G. Webb MD 

Key Points

- In patients with end stage renal disease on hemodialysis, TAVR resulted in reduced length of stay, hospitalization cost, complication rate and higher rates of home discharge compared to SAVR.
- In-hospital mortality and complication rates were high in both groups.
- Careful patient selection and further research is required to identify patients with end-stage renal disease who might, or might not, benefit from intervention.