

TAVI

Welche Entwicklungen sind zu erwarten?

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Medizinische Klinik III

Abteilung für Kardiologie, Angiologie & Kreislauferkrankungen

Universitätsklinikum Tübingen



Interessenskonflikte

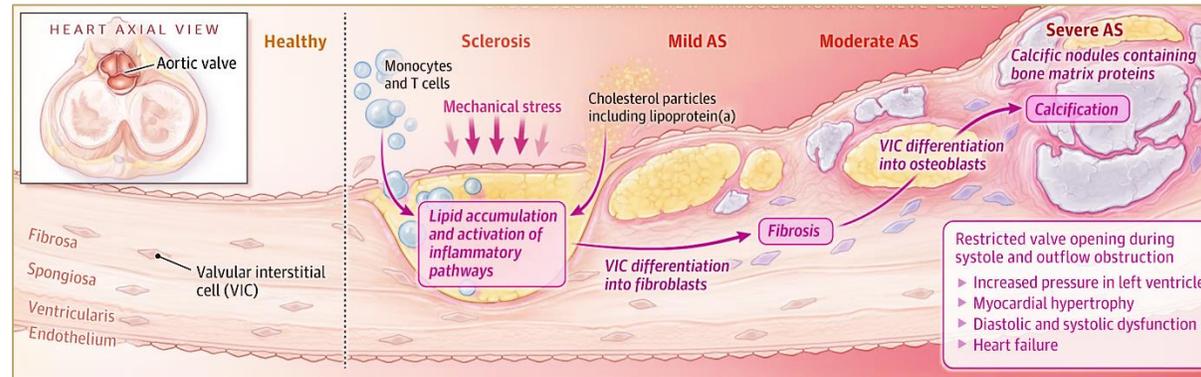
Vortragshonorare: Bayer Vital, Daiichi Sankyo, Pfizer, Amgen, Sanofi, Edwards Lifesciences, Boston Scientific

Beratertätigkeit: Amgen, Bayer Vital, Daiichi Sankyo, Maquet, Medtronic

Studienzuwendung/Forschungsförderung: Edwards Lifesciences, Bayer Vital, Medtronic



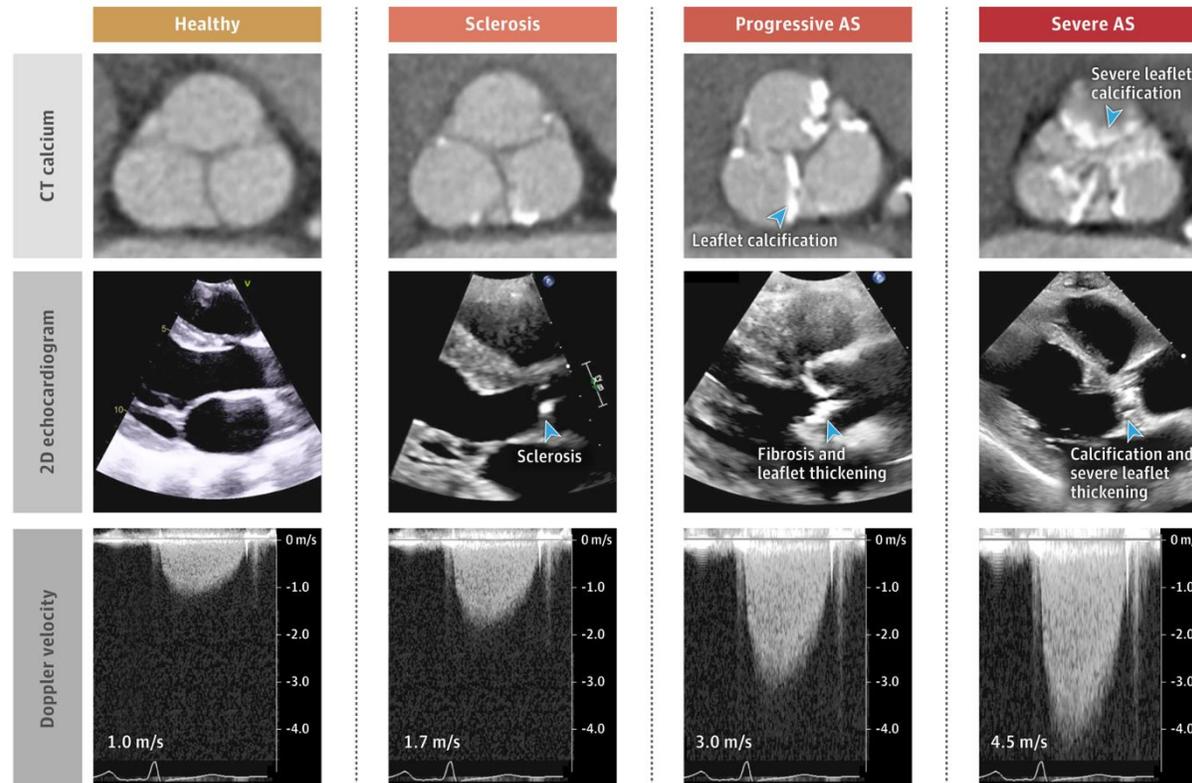
Aortenklappenstenose



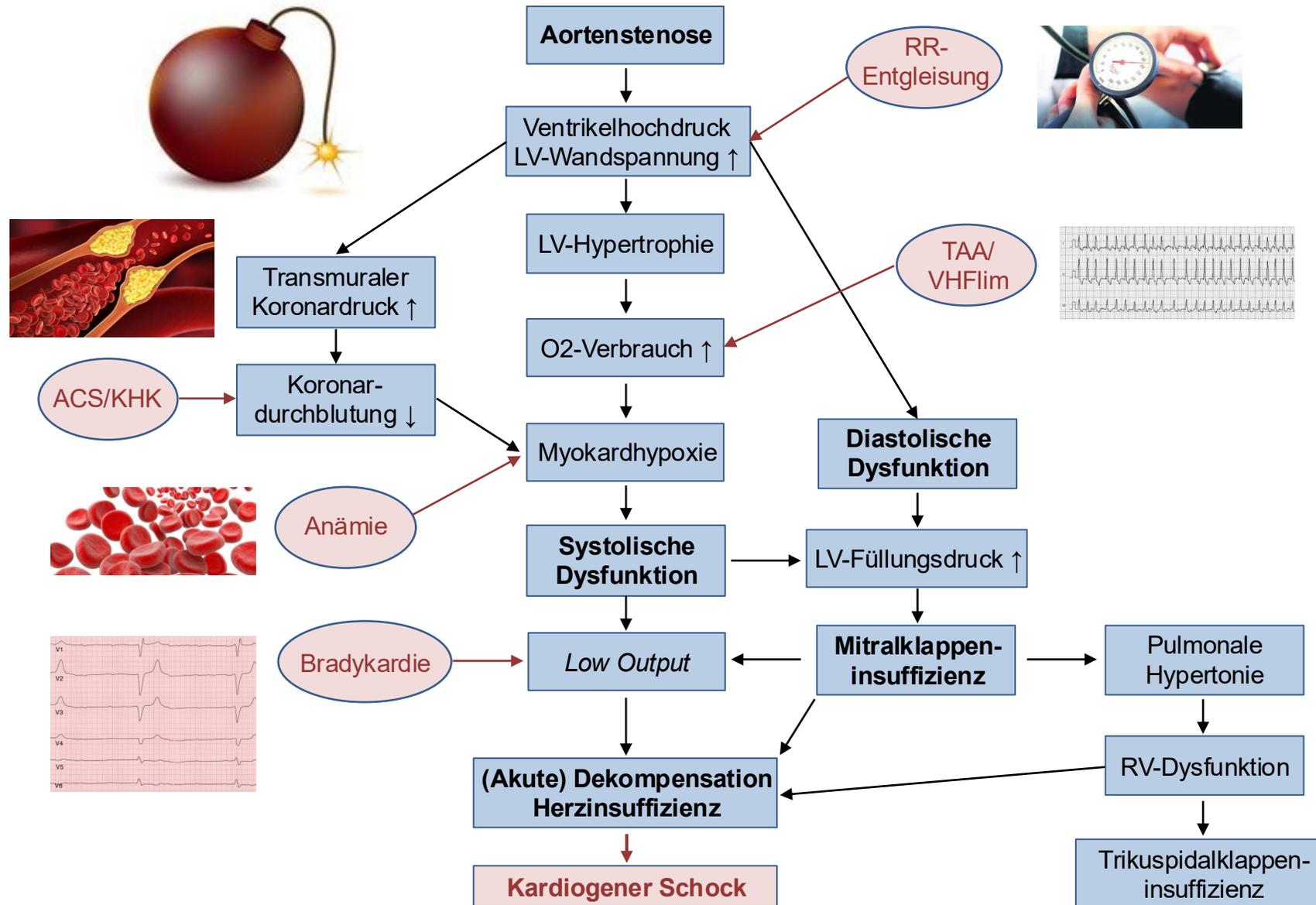
Inflammation/Lipide

Fibrose

Kalzifizierung



Aortenklappenstenose



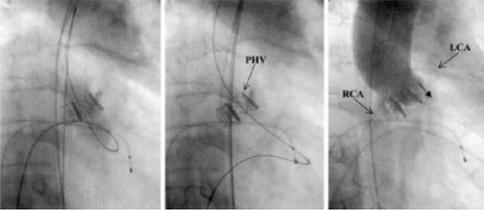
TAVI – Eine Erfolgsgeschichte...

First in man

Circulation Special Report

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

Alain Cribier, MD; Helene Elchaninoff, 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

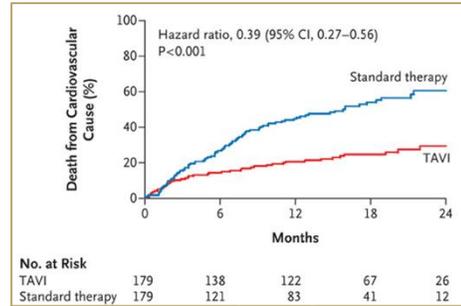


PARTNER

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

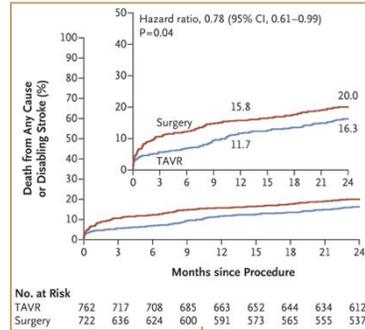


PARTNER-2

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 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 Babaliaros, M.D., Wilson Y. Szeto, M.D., Matthew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Grason, 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*

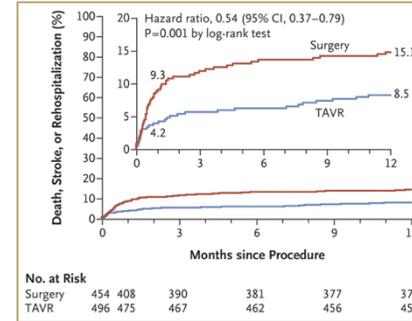


PARTNER-3

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 MAY 2, 2019 VOL. 380 NO. 18

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldmann, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*



Goldstandard



Patients ≥70 years with a tricuspid aortic valve if anatomy is suitable

TAVI (Class I)

2002

2010

2016

2019

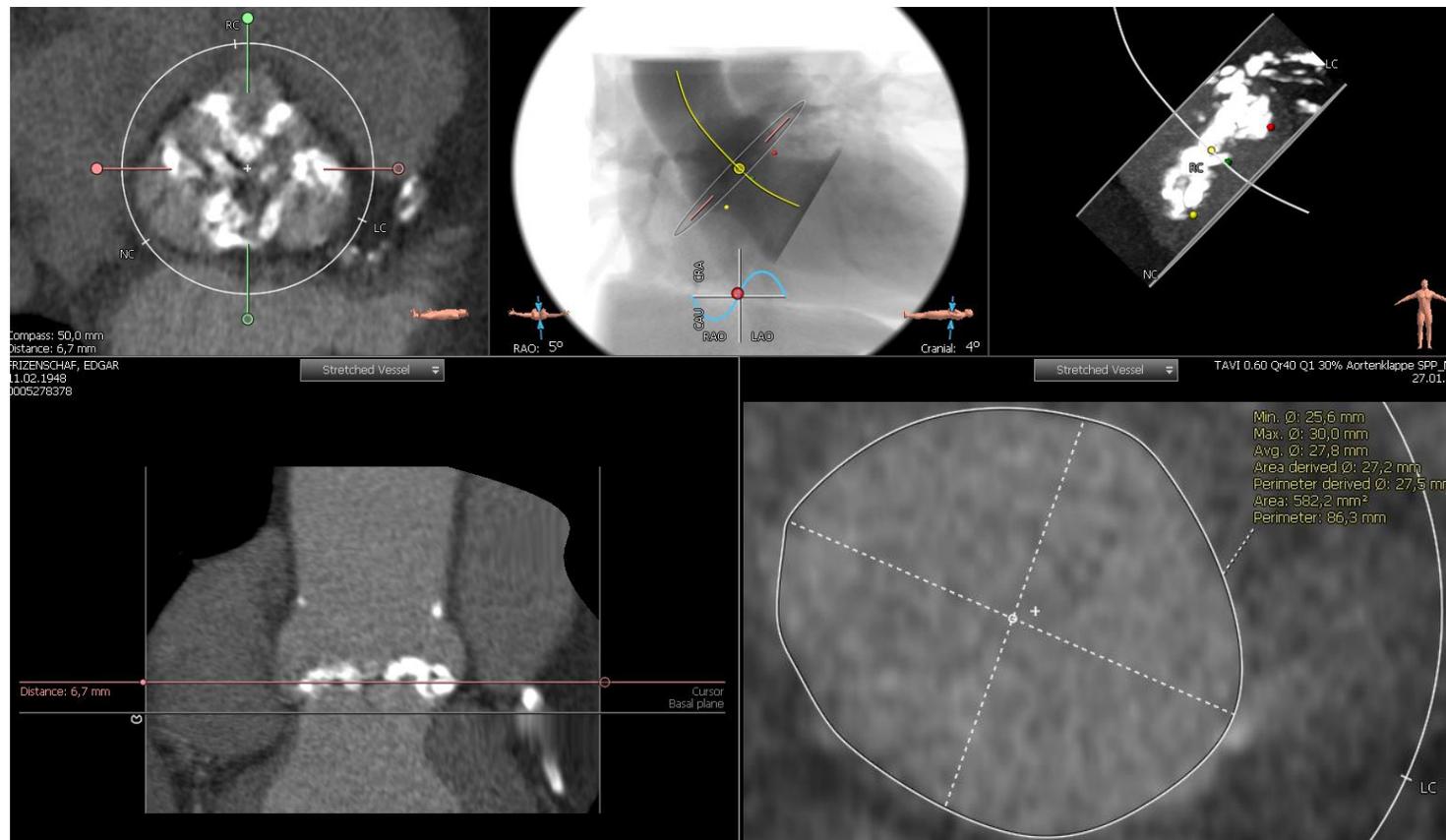
2025



Goldstandard: Kathetergestützter Aortenklappenersatz (TAVI)

75-jähriger Patient mit symptomatischer hochgradiger Aortenklappenstenose (Dyspnoe NYHA III)

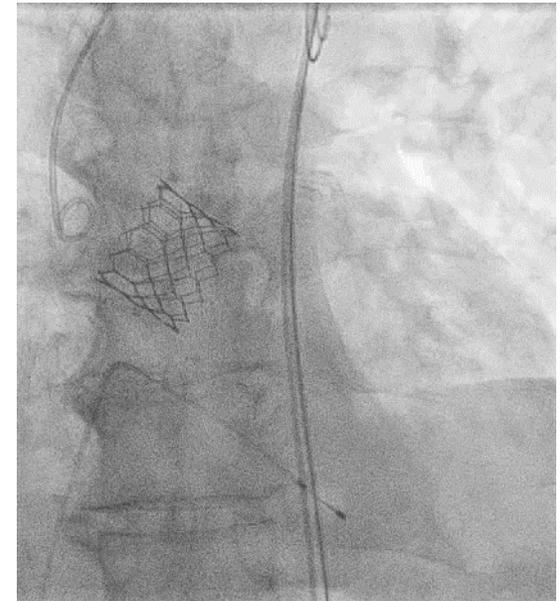
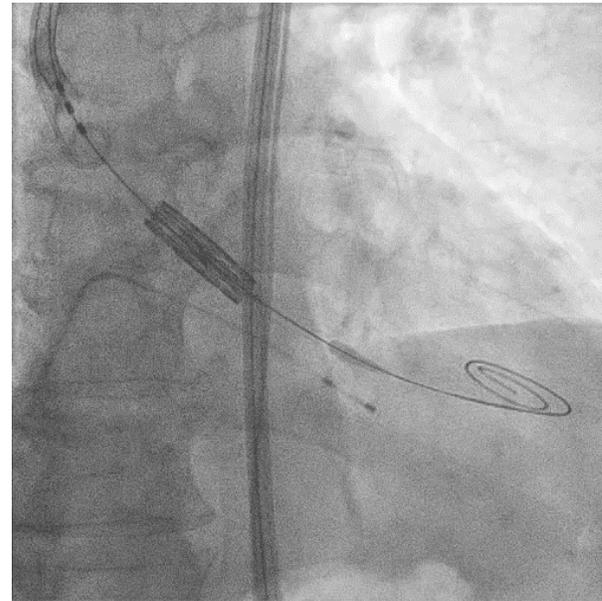
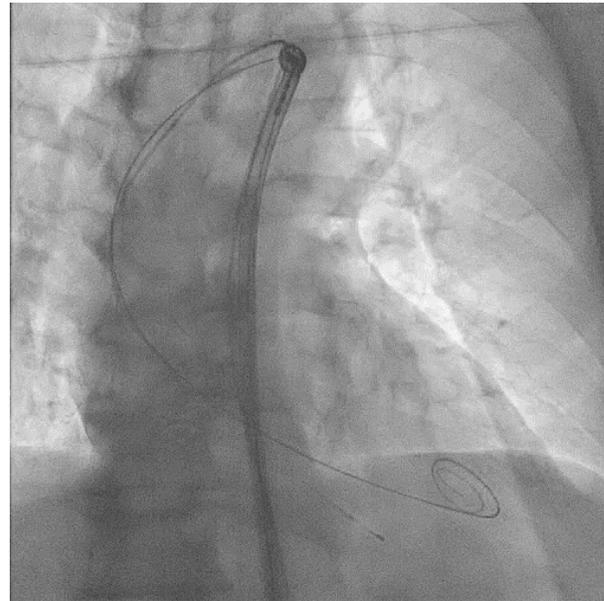
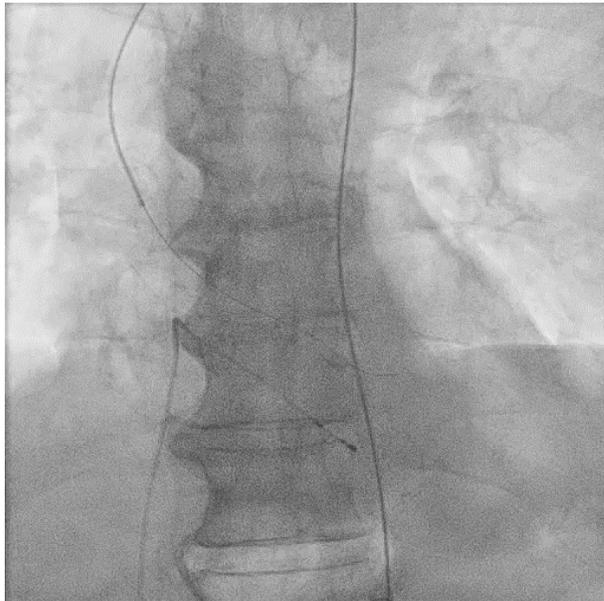
KÖF 0.6 cm^2 (Pmax/Pmean 96/64 mmHg)



Goldstandard: Kathetergestützter Aortenklappenersatz (TAVI)

75-jähriger Patient mit symptomatischer hochgradiger Aortenklappenstenose (Dyspnoe NYHA III)

KÖF 0.6 cm^2 (Pmax/Pmean 96/64 mmHg)



Prozedurzeit 25-35 Minuten
Lokalanästhesie
Klinikaufenthalt 4-6 Tage



1. Jüngere Patienten/**Lifetime management** – und wen nicht mehr behandeln?
2. Strategien **Valve-in-Valve**
3. **Bikuspide** Aortenklappe
4. Großer Annulus und/oder reine **Aortenklappeninsuffizienz**



Jüngere Patienten („low risk Kollektiv“)

Prozedurerfolg der TAVI ist nachhaltig (5 Jahres Follow up)!

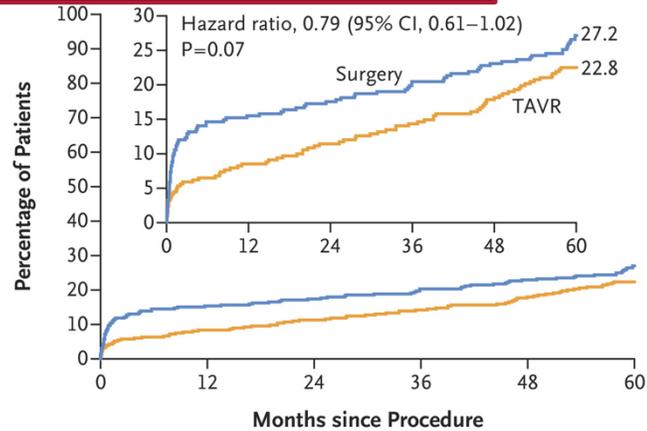
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

M.J. Mack, M.B. Leon, V.H. Thourani, P. Pibarot, R.T. Hahn, P. Genereux, S.K. Kodali, S.R. Kapadia, D.J. Cohen, S.J. Pocock, M. Lu, R. White, M. Szerlip, J. Ternacle, S.C. Malaisrie, H.C. Herrmann, W.Y. Szeto, M.J. Russo, V. Babaliaros, C.R. Smith, P. Blanke, J.G. Webb, and R. Makkar, for the PARTNER 3 Investigators*

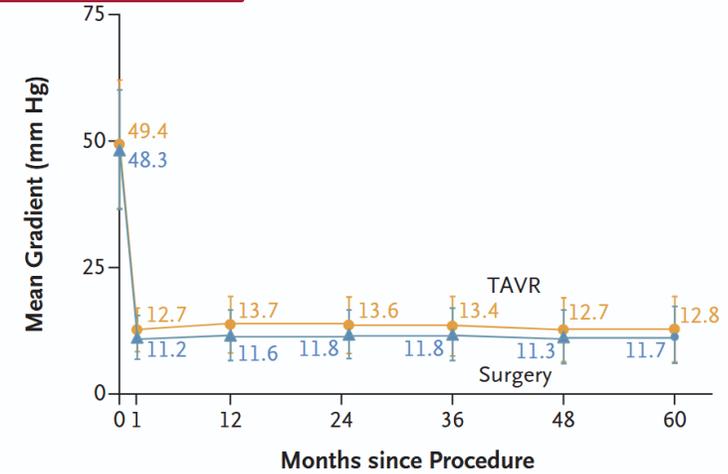
Death from Any Cause, Stroke, or Rehospitalization



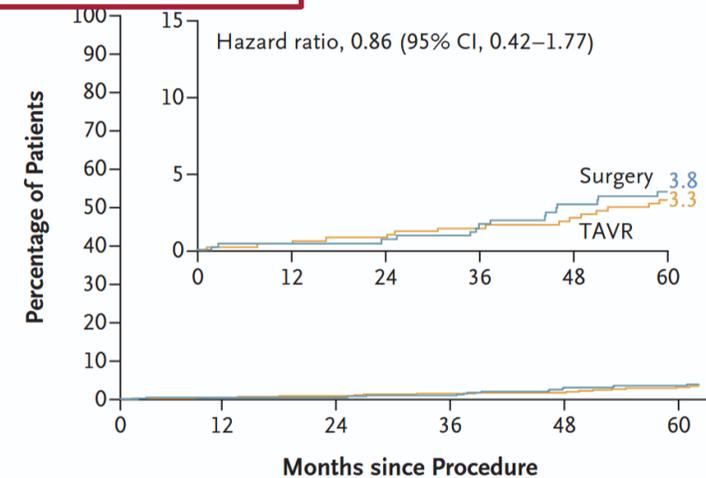
No. at Risk

Surgery	454	372	349	328	309	276
TAVR	496	453	434	415	391	353

Aortic-Valve Gradient



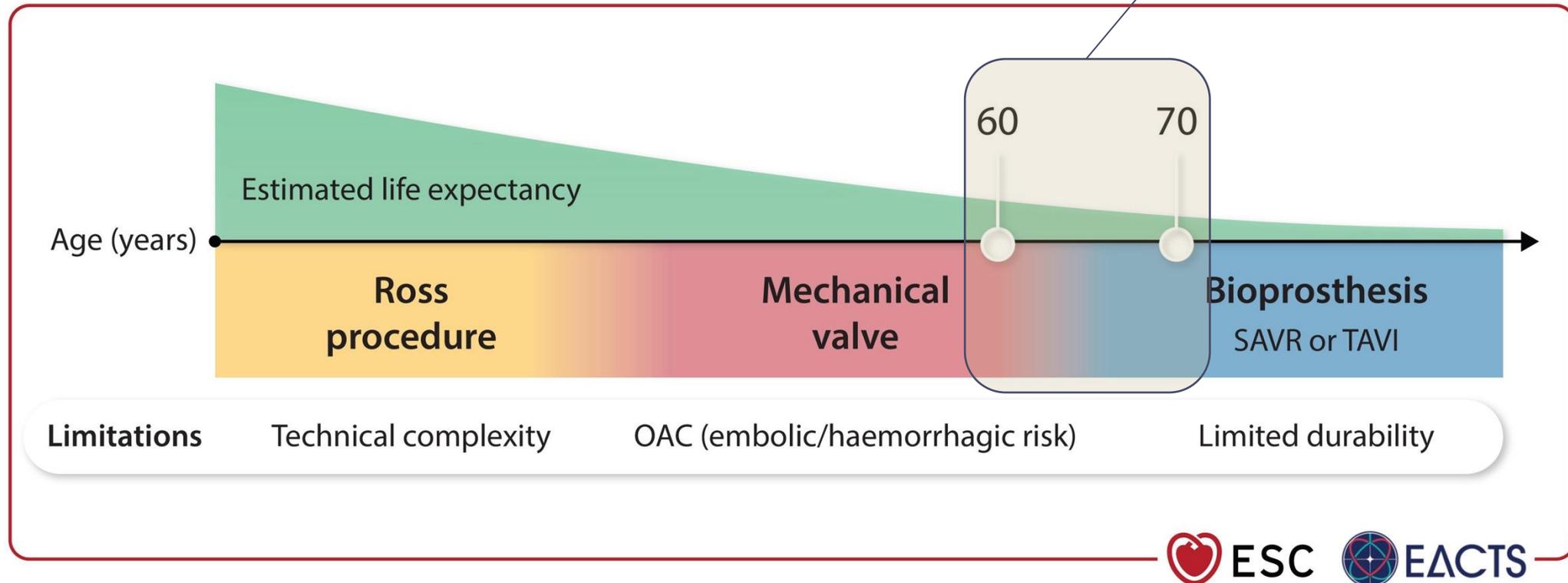
Bioprosthetic-Valve Failure



Jüngere Patienten („low risk Kollektiv“)

2025 ESC/EACTS Guidelines for the management of valvular heart disease

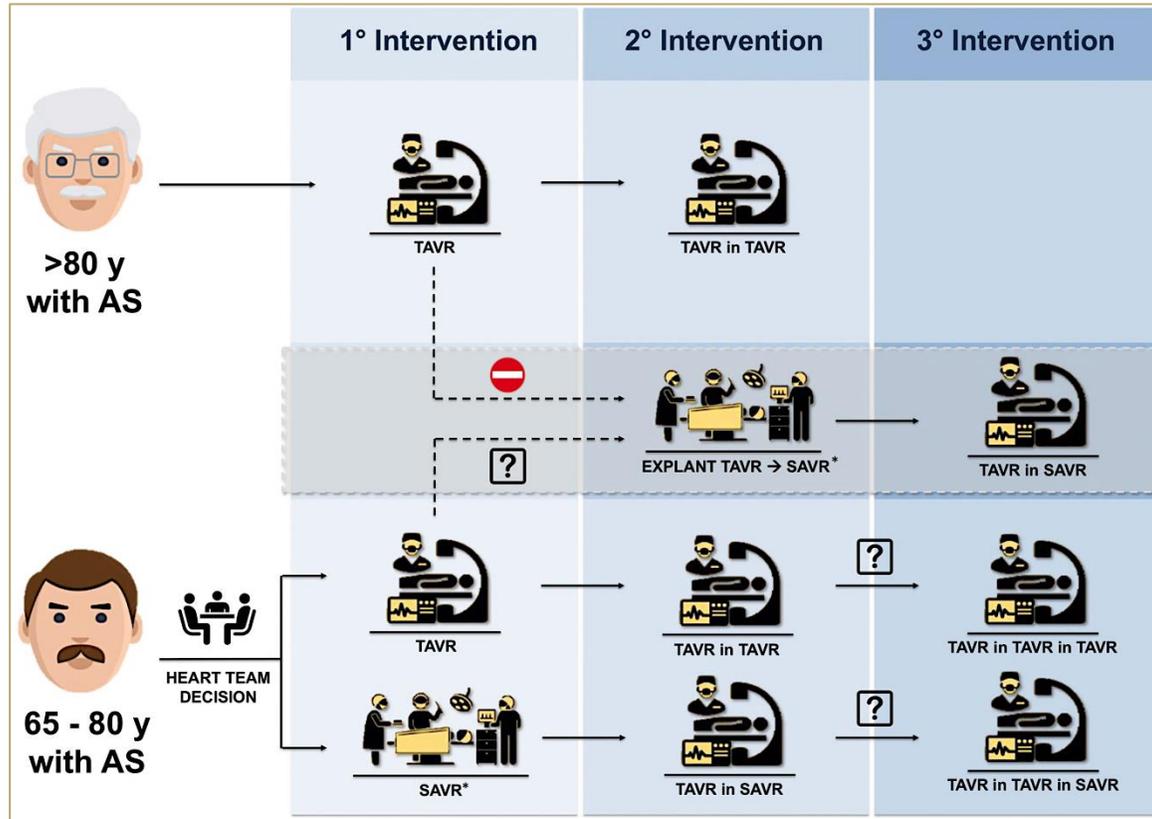
Lifetime Management: Welche Strategie?



60-75 Jahre: Lebenserwartung? Prothese für Ersteingriff immer unter Berücksichtigung für Zweiteingriff?!



Jüngere Patienten („low risk Kollektiv“)



Selbstexpandier-/Repositionierbar

Ballonexpandierbar



CV Evolut FX+



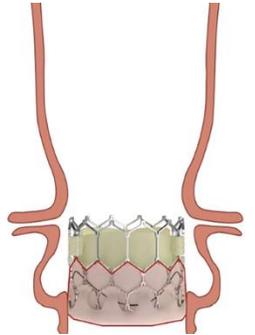
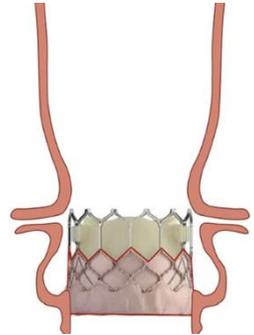
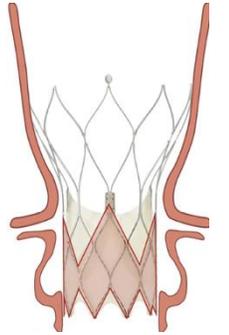
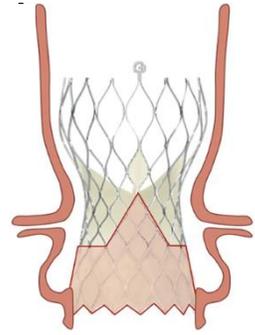
Navitor



ESIII Ultra (Resilia)



Octapro



Valve in Valve



- Anatomie (Annulusgröße, LVOT, A. ascendens)
- Paravalvuläres Leck/AI
- Prothesenhaltbarkeit
- Koronarzugänglichkeit
- Risiko für Schrittmacherpflichtigkeit



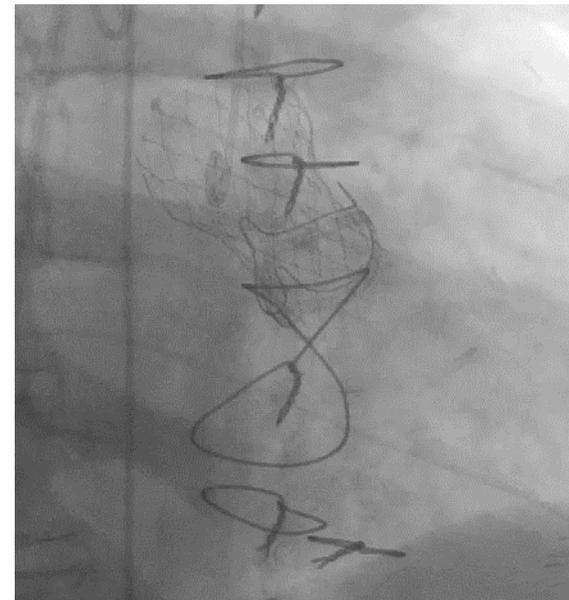
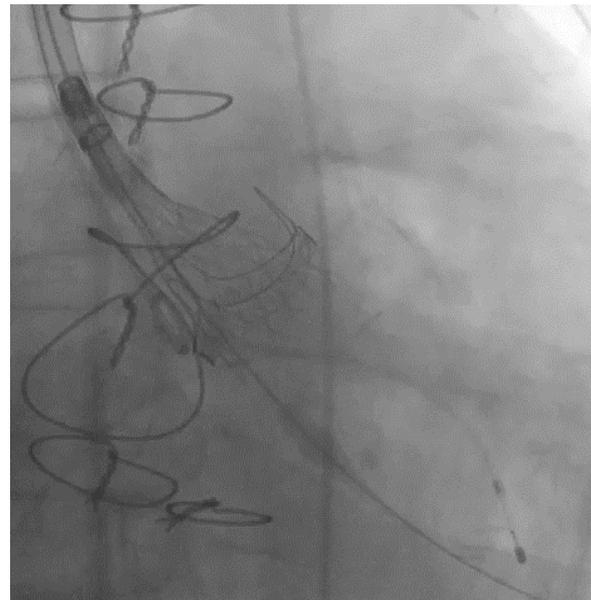
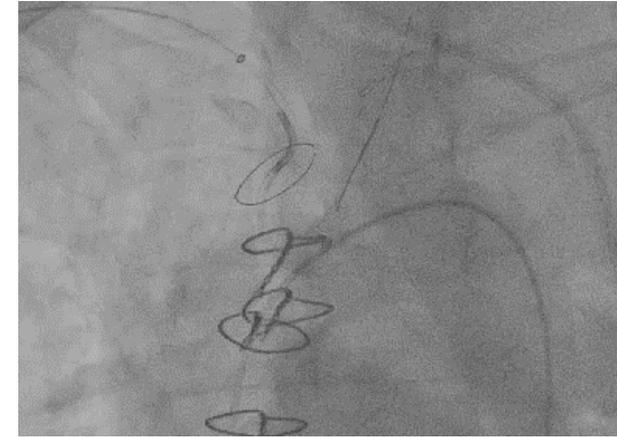
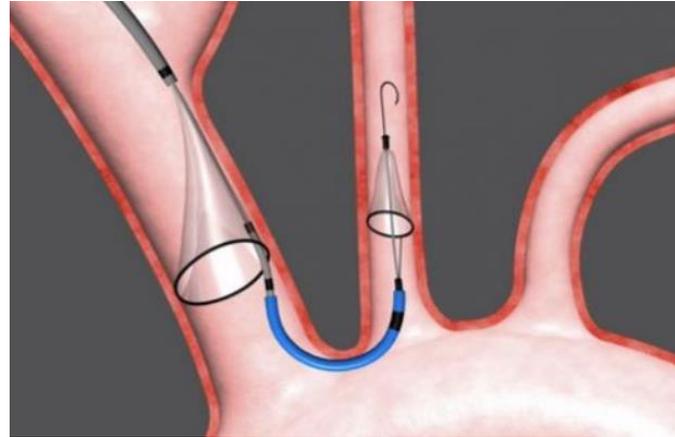
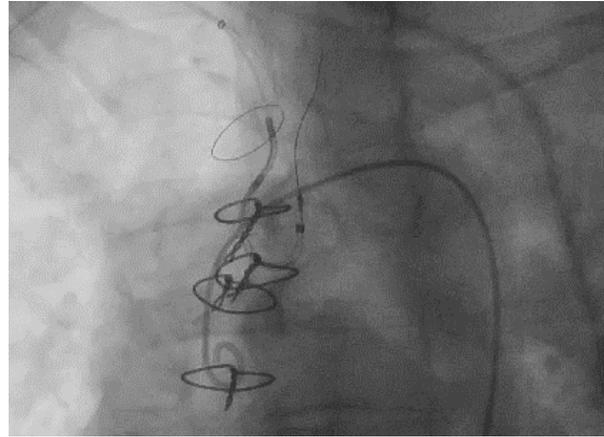
- **Ursache Degeneration?** Prothesenmismatch? Thrombose? Degeneration?
TEE und CT-Gefäße, ggf. OAK oder Cracking der Prothese
- **Supraannuläre oder intraannuläre Prothese?**
Rigidiät und true ID des biologischen AKE?
- **Koronarzugänglichkeit?**
Prothesentyp mit hohem Koronarobstruktionsrisiko?
Bspw. BASILICA Device oder Protektion des Koronargefäßes? Re-OP?
- **Embolierisiko?**
Cerebrale Protektionssysteme (Sentinel oder Triguard)



Valve-in-Valve: TAVI in AKE

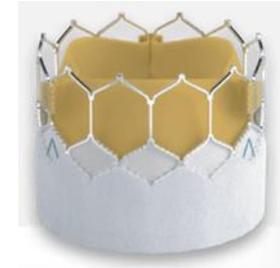
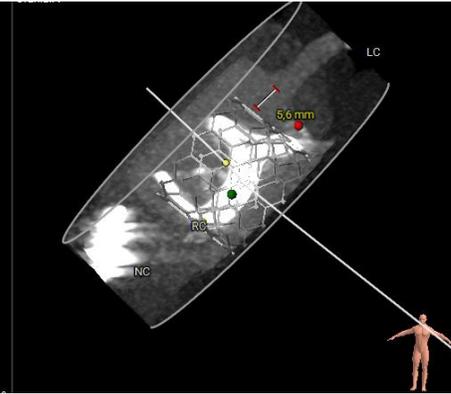
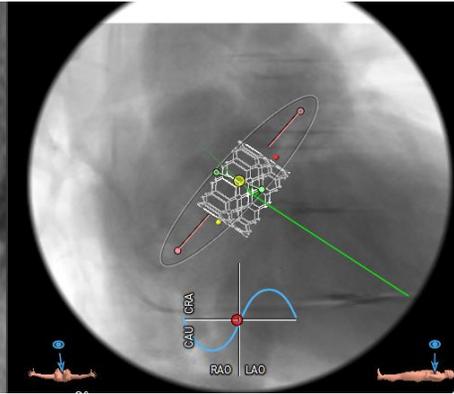
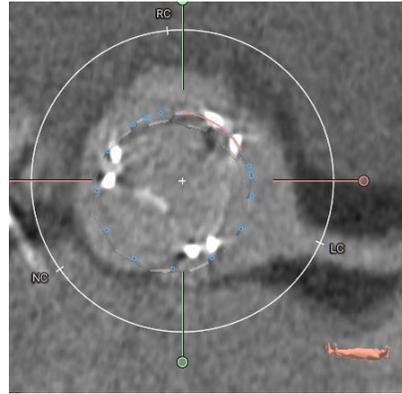
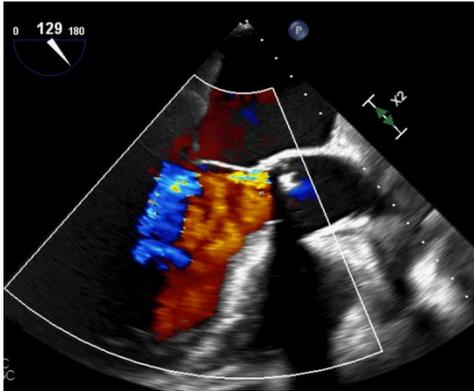
Valve-in-Valve TAVI (Supravalvuläre CoreValve Prothese 29 mm in Perimount 25 mm Bioprothese)

+ Cerebrale Protektion (Sentinel)

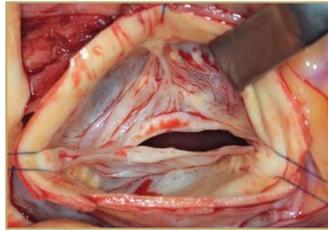


Jüngere Patienten: Redo after SAVR

65 jähriger Patient, Z.n. zweimaligem AKE (AS 2017, dann Endokarditis 2019), aktuell schwere **transvalvuläre AI** der 25 mm Magna Ease Prothese mit LV-Dilatation (EF 45%) und Dyspnoe NYHA III

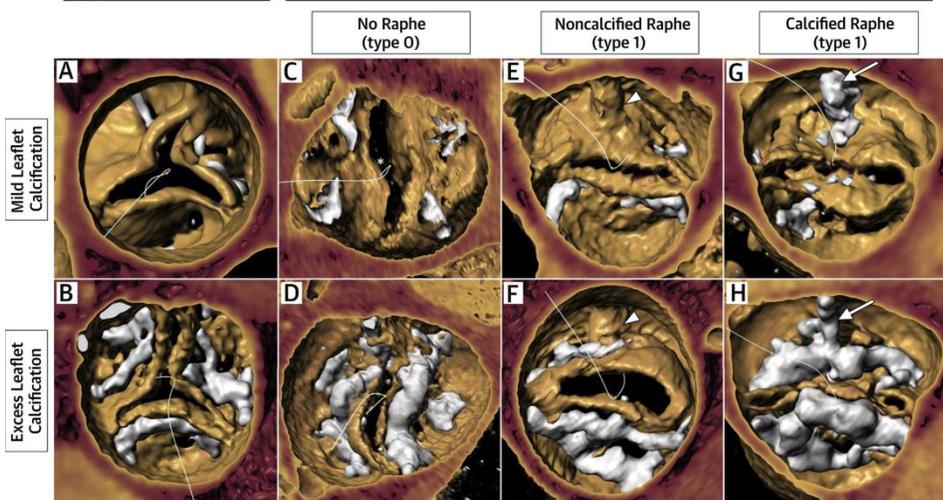
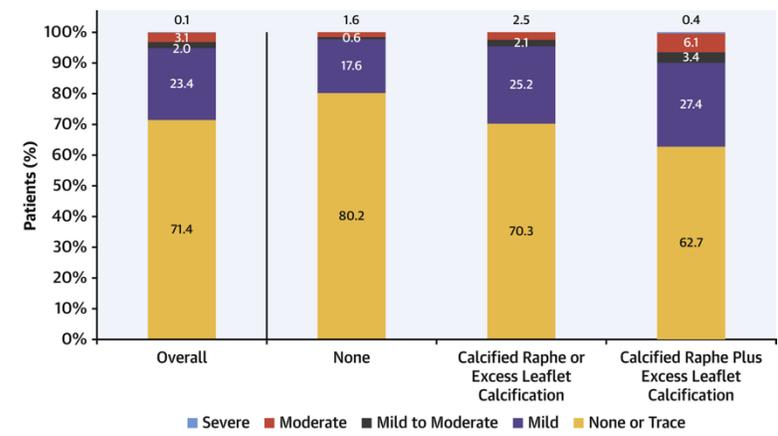
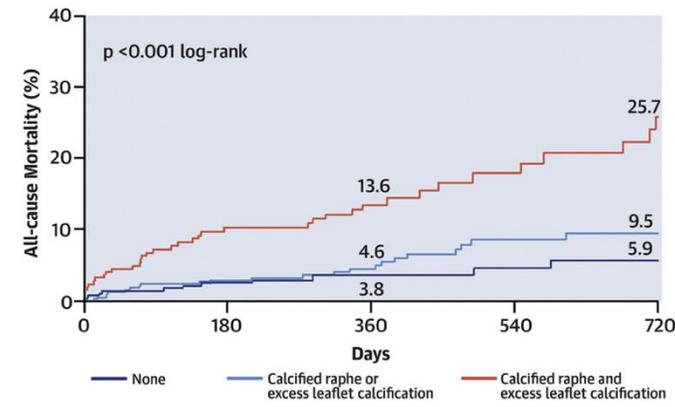
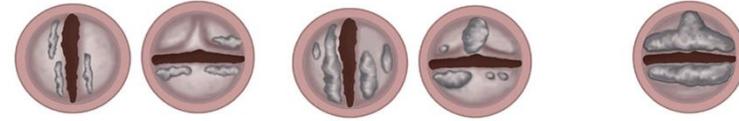


Bicuspide Aortenklappe



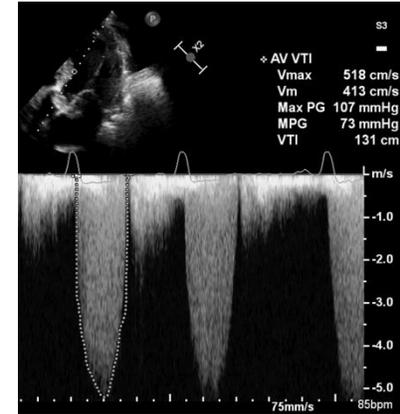
	Type 0	Type 1	Type 2			
Main Category Number of raphe	0 raphe 21(7)	1 raphe 269(88)	2 raphe 14(5)			
Subcategory 1 Spatial position of: • Cusps in type 0 • Rapses in types 1 and 2	Lat. 13(4)	AP 7(2)	L-R 216(71)	R-N 45(15)	N-L 8(3)	L-R / R-N 14(5)
	Tricuspid Aortic Valve		Bicuspid Aortic Valve			

Death From Any Cause, According to Morphological Features



Bikuspide Aortenklappe

70 jähriger Patient, Dyspnoe NYHA III, bikuspid Aortenklappe (Sievers Typ 0) mit high gradient Aortenklappenstenose

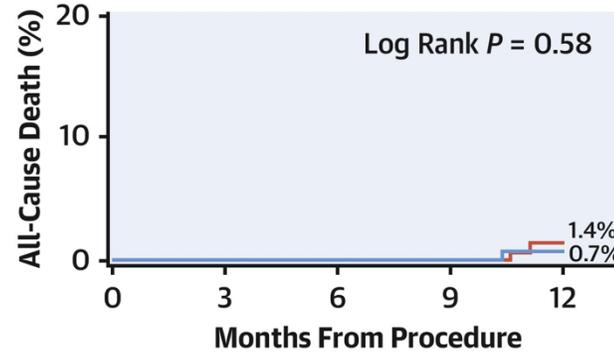


JACC: CARDIOVASCULAR INTERVENTIONS
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VOL. 15, NO. 5, 2022

The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients

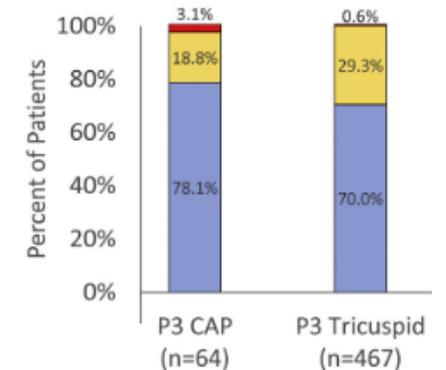
Mathew R. Williams, MD,^{a,*} Hasan Jilaihawi, MD,^{a,*} Raj Makkar, MD,^b William W. O'Neill, MD,^c Robert Guyton, MD,^d S. Chris Malaisrie, MD,^e David L. Brown, MD,^f Philipp Blanke, MD,^g Jonathon A. Leipsic, MD,^g Philippe Pibarot, DVM, PhD,^h Rebecca T. Hahn, MD,^{i,j} Martin B. Leon, MD,^{i,j} David J. Cohen, MD,^{j,k} Jeroen J. Bax, MD, PhD,^l Susheel K. Kodali, MD,^l Michael J. Mack, MD,^f Michael Lu, PhD,^m John G. Webb, MD^g



No. at risk:
 — Tricuspid 148 140
 — Bicuspid 135 135

Paravalvular Regurgitation (Unmatched Patients)

■ None / Trace ■ Mild ■ ≥Moderate

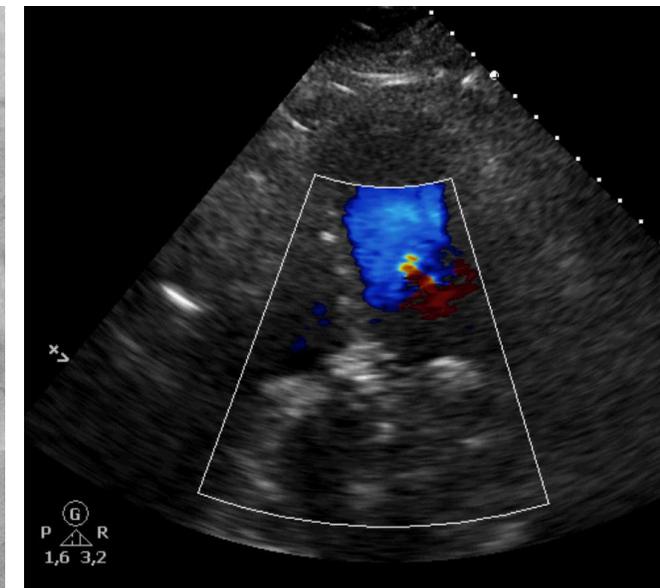
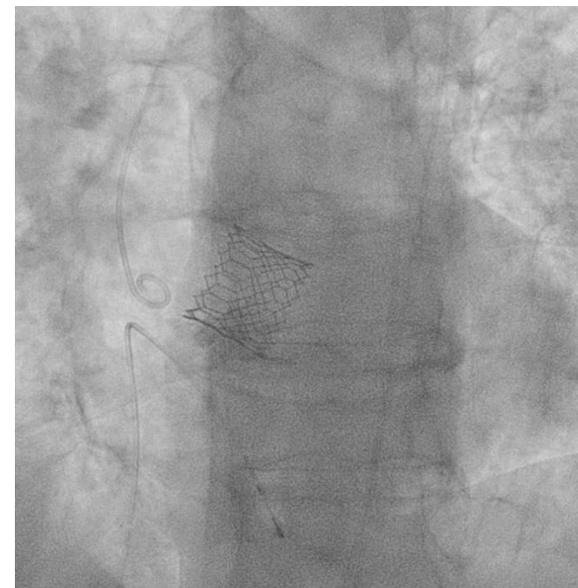
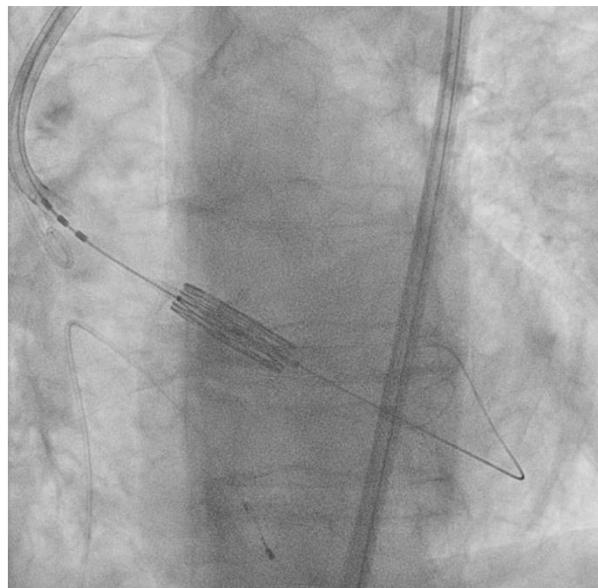
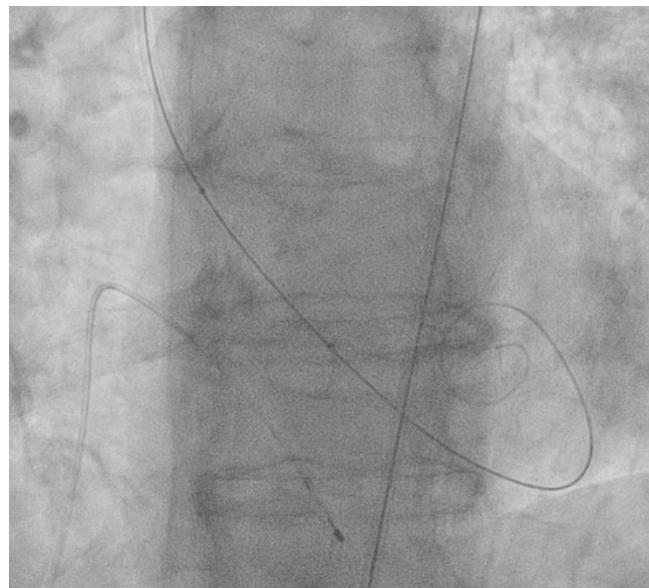


Bikuspide Aortenklappe



Ist die TAVI sicher in dieser bikuspiden Anatomie?

- Annulus diameter passend (für 29 mm Prothese)
- A. ascendens nicht signifikant erweitert (43 mm)
- Keine verkalkte Raphe
- Keine extreme Verkalkung der Segel



Lifetime Management: AKE/TAVI aus prognostischer Indikation

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 9, 2020 VOL. 382 NO. 2

Early Surgery or Conservative Care for Asymptomatic Aortic Stenosis

Duk-Hyun Kang, M.D., Ph.D., Sung-Ji Park, M.D., Ph.D., Seung-Ah Lee, M.D., Sahmin Lee, M.D., Ph.D., Dae-Hee Kim, M.D., Ph.D., Hyung-Kwan Kim, M.D., Ph.D., Sung-Cheol Yun, Ph.D., Geu-Ru Hong, M.D., Ph.D., Jong-Min Song, M.D., Ph.D., Cheol-Hyun Chung, M.D., Ph.D., Jae-Kwan Song, M.D., Ph.D., Jae-Won Lee, M.D., Ph.D., and Seung-Woo Park, M.D., Ph.D.

Mittleres Alter 65 Jahre
>50% bikuspidale AK
Pmean AK >60 mmHg
 Normale LVEF

The NEW ENGLAND JOURNAL of MEDICINE

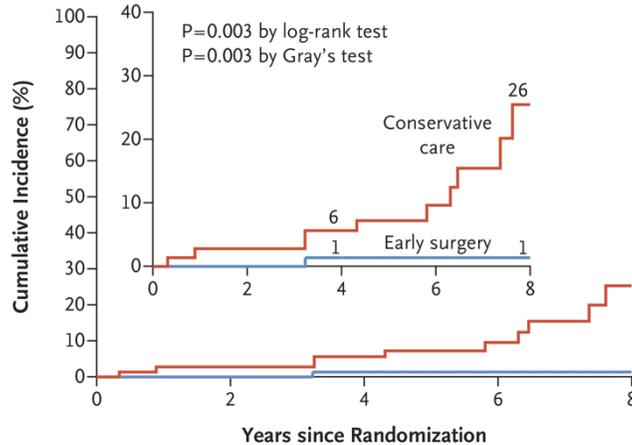
ESTABLISHED IN 1812 JANUARY 16, 2025 VOL. 392 NO. 3

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

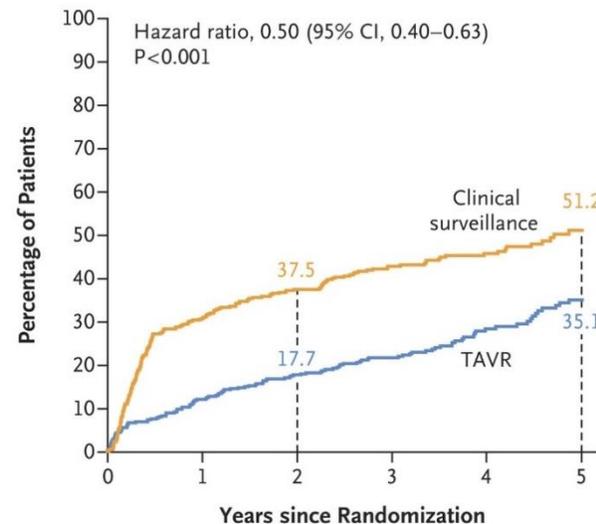
P. Généreux, A. Schwartz, J.B. Oldemeyer, P. Pibarot, D.J. Cohen, P. Blanke, B.R. Lindman, V. Babaliaros, W.F. Fearon, D.V. Daniels, A.K. Chhatriwalla, C. Kavinsky, H. Gada, P. Shah, M. Szerlip, T. Dahle, K. Goel, W. O'Neill, T. Sheth, C.J. Davidson, R.R. Makkar, H. Prince, Y. Zhao, R.T. Hahn, J. Leipsic, B. Redfors, S.J. Pocock, M. Mack, and M.B. Leon, for the EARLY TAVR Trial Investigators*

Mittleres Alter 76 Jahre
 8% bikuspidale AK
Pmean AK 47 mmHg
 Normale LVEF
 NT-proBNP <300 pg/ml

Operative Mortality or Death from Cardiovascular Causes



Death, Stroke, or Unplanned Hospitalization for Cardiovascular Causes (%)



	Early AVR n/N (%)	Clinical Surveillance n/N (%)	Pooled HR* (95% CI)	P Value
All-Cause Mortality	70/719 (9.7%)	97/708 (13.7%)	0.68 (0.40-1.17)	0.17
Cardiovascular Mortality	37/719 (5.1%)	59/708 (8.3%)	0.67 (0.35-1.29)	0.23
Heart Failure Hospitalization	18/606 (3.0%)	65/597 (10.9%)	0.28 (0.17-0.47)	<0.01
Unplanned CV or HF Hospitalization	105/719 (14.6%)	226/708 (31.9%)	0.40 (0.30-0.53)	<0.01
Stroke	32/719 (4.5%)	51/708 (7.2%)	0.62 (0.40-0.97)	0.03

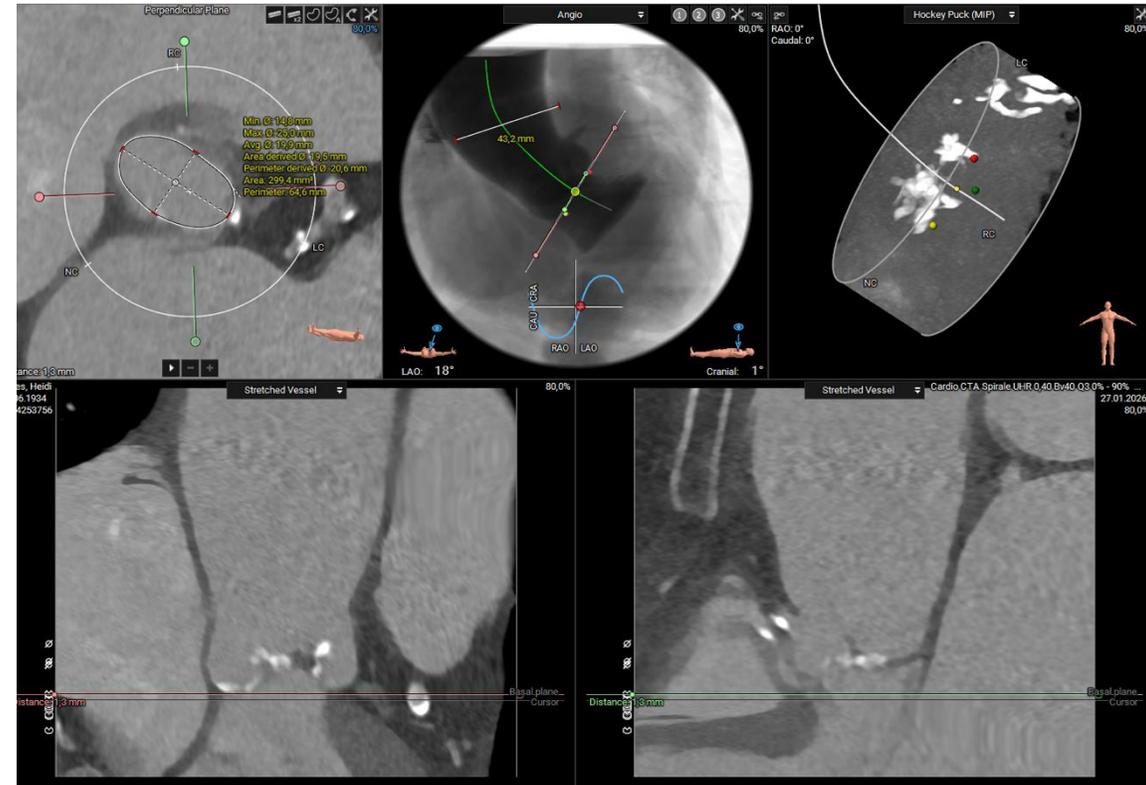
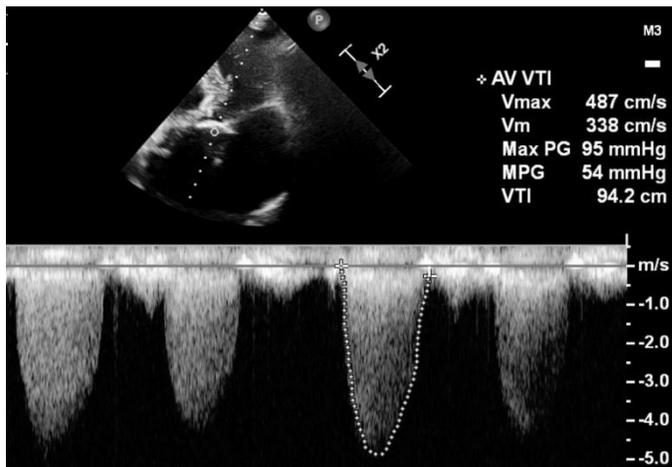
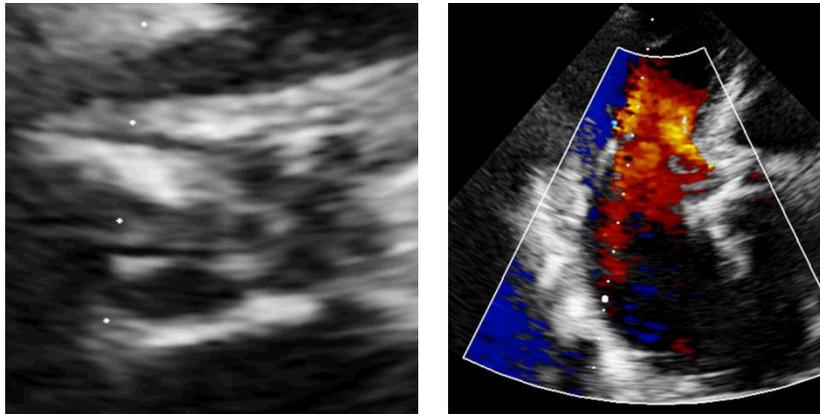
*Pooled HR (95% CI) Log Scale



Lifetime Management/Therapie der AS: Wann ist es noch sinnvoll?

91 jährige sehr rüstige selbstversorgende Patientin, Dyspnoe NYHA IV bei high gradient Aortenklappenstenose und sekundären AV-Vitien bei normaler LVEF

Vor 5 Jahren kein Therapiewunsch aufgrund des nach eigener Auffassung hohen Alters, jetzt dringender Therapiewunsch bei Erstickungsangst

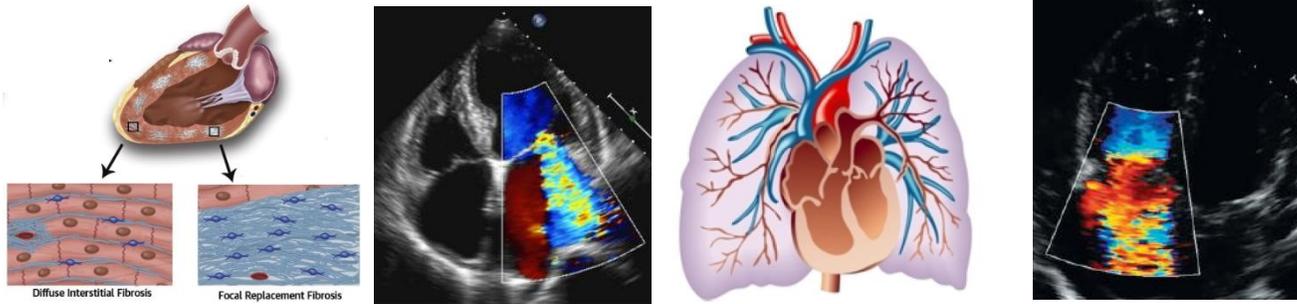


Komplexe Anatomie mit kleinem schwer kalifiziertem Annulus und Ascendensaneurysma

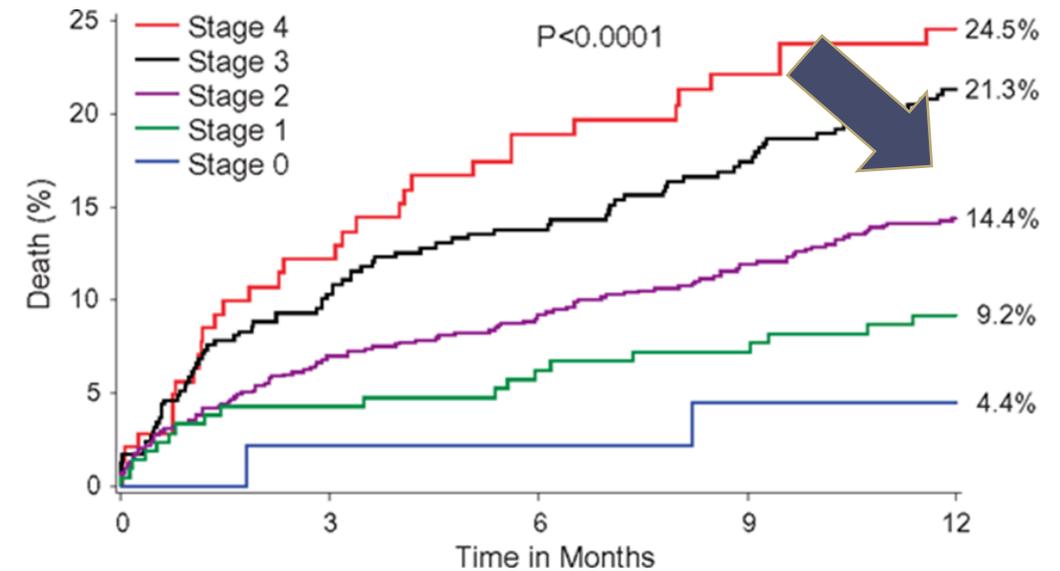


Lifetime Management/Therapie der AS: Wann ist es noch sinnvoll?

Rechtzeitige Versorgung der AS (vor struktureller Schädigung) entscheidend für Prognose!



Stage 1	Stage 2	Stage 3	Stage 4
LV Damage	LA or Mitral Damage	Pulmonary Vasculature or Tricuspid Damage	RV Damage
Increased LV Mass Index >115 g/m ² (Male) >95 g/m ² (Female)	Indexed left atrial volume >34mL/m ²	Systolic Pulmonary hypertension ≥60 mmhg	Moderate-Severe right ventricular dysfunction
E/e' >14	Moderate-Severe mitral regurgitation	Moderate-Severe tricuspid regurgitation	
LV Ejection Fraction <50%	Atrial Fibrillation		



Lifetime Management/Therapie der AS: Wann ist es noch sinnvoll?



Octapro

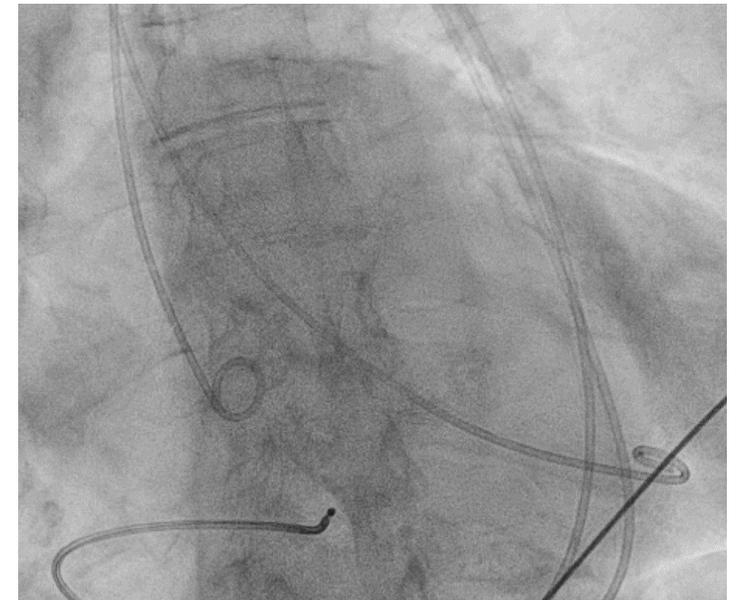
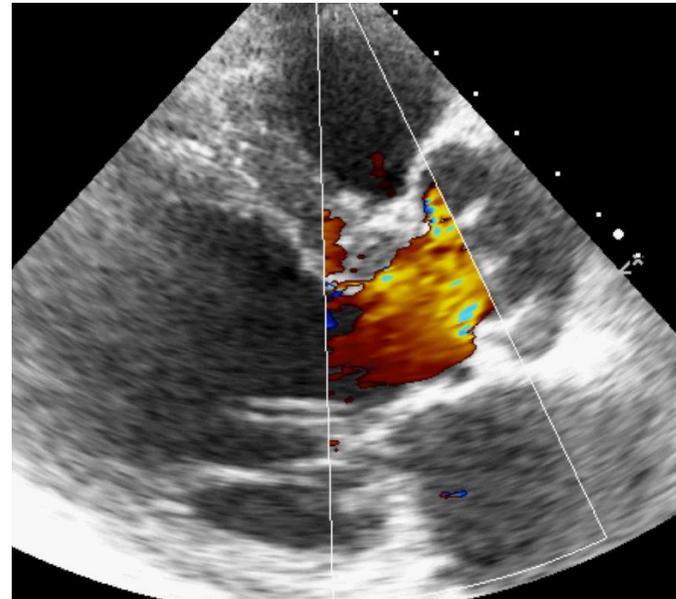
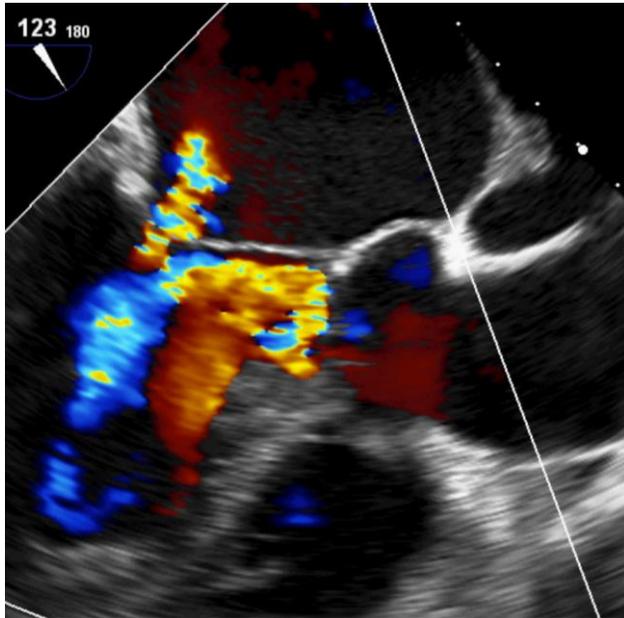
Myval Octapro Size Matrix & Technical Specs.	Area 303 mm ² 19.50 mm 20 mm	Area 363 mm ² 20.50 mm 21.5 mm	Area 415 mm ² 19.50 mm 23 mm	Area 471 mm ² 20.70 mm 24.5 mm	Area 531 mm ² 20.80 mm 26 mm	Area 594 mm ² 21.40 mm 27.5 mm	Area 661 mm ² 22.50 mm 29 mm	Area 731 mm ² 23.10 mm 30.5 mm	Area 804 mm ² 23.50 mm 32 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm	81.68 mm	86.39 mm	91.11 mm	95.82 mm	100.53 mm
Python Expandable Introducer Sheath	14 Fr	14 Fr	14 Fr						
Native Annulus Area (CT Derived)	270 – 330 mm ²	314 – 380 mm ²	360 – 440 mm ²	410 – 500 mm ²	460 – 560 mm ²	510 – 630 mm ²	570 – 700 mm ²	630 – 770 mm ²	700 – 840 mm ²



Aortenklappeninsuffizienz

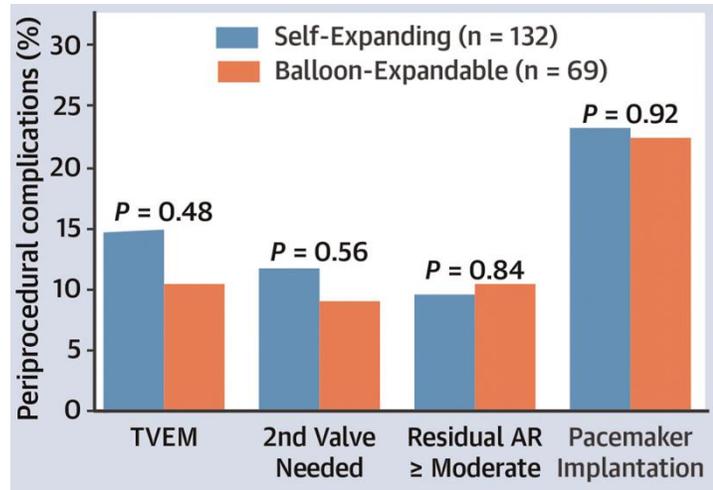
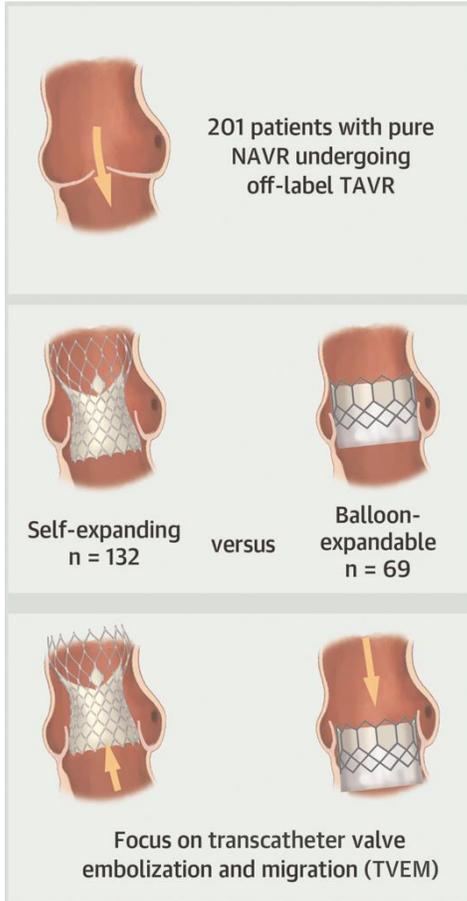
84 jährige Patientin, Dyspnoe NYHA III bei schwerer Aortenklappeninsuffizienz (pure AR) und LV-Dilatation, Ascendensaneurysma

„Lasse mich auf keinen Fall aufschneiden – gibt’s denn da nichts anderes?“



Aortenklappeninsuffizienz

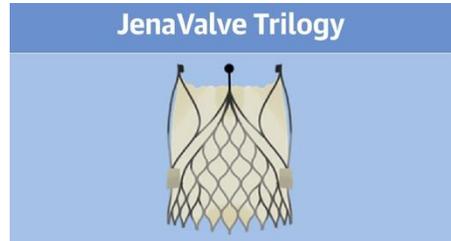
Welche Optionen gibt es bislang?



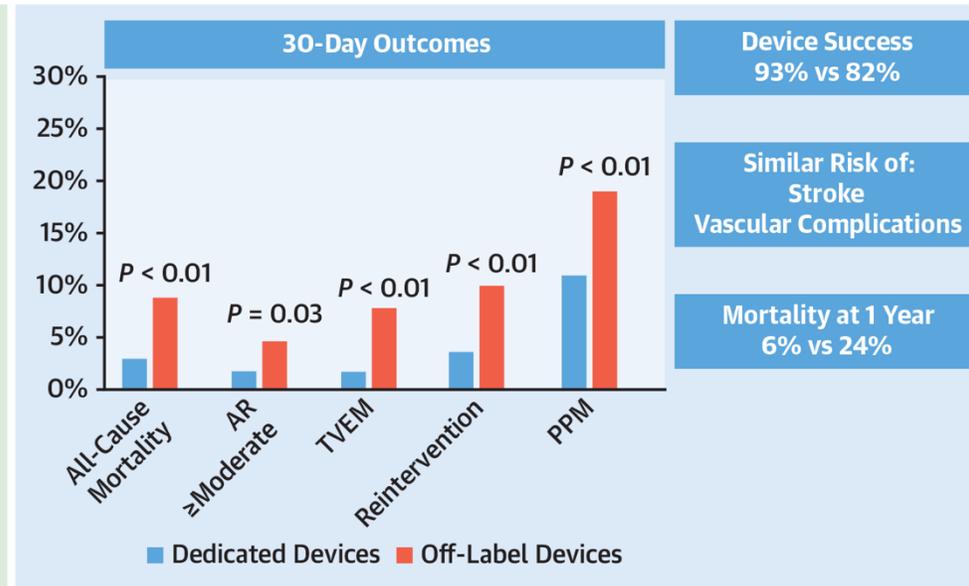
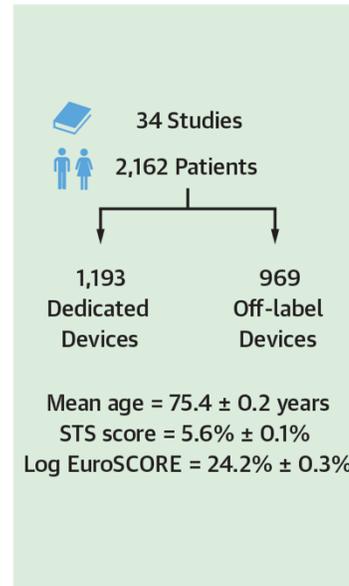
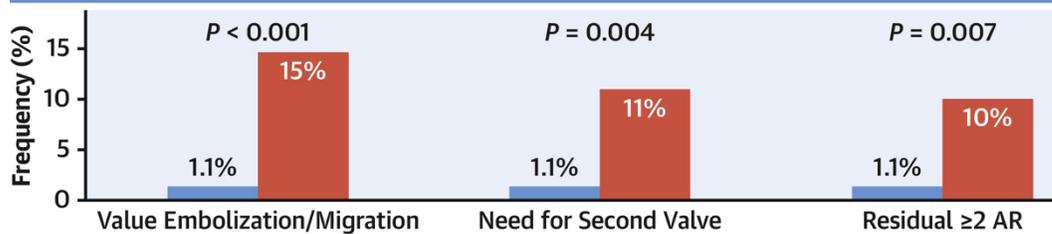
Aortenklappeninsuffizienz

JenaValve Trilogy ein Gamechanger für die versorgung der pure AR?

Procedural and Clinical Outcomes With Dedicated THV Versus Off-Label Devices for Aortic Regurgitation, N = 256



Periprocedural Complications



Zusammenfassung

- ✓ TAVI bei AS ab 70 Jahren ist der Goldstandard (ESC Leitlinie 2025)
- ✓ Versorgung AS frühzeitig (auch aus prognostischer Indikation)
- ✓ Lifetime Strategie bei jüngeren Patienten interdisziplinär antizipieren
- ✓ Breites Portfolio an hochwertigen TAVI Prothesen – Adaption and Anatomie!
- ✓ Valve in Valve Prozeduren sicher durchführbar
- ✓ Bikuspidale Aortenklappen subtil CT-morphologisch charakterisieren und
hiervon Indikationsstellung für TAVI abwägen, häufig sicher möglich
- ✓ Reine Aorteninsuffizienz noch Domäne der Herzchirurgie, jedoch neue Generation
Prothesen am Horizont (bspw. Jena Valve Trilogy)



Vielen Dank für Ihre Aufmerksamkeit



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