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Robert-Bosch-Krankenhaus


21.11.2024

Die richtigen Patienten für die interventionelle Herzklappentherapie

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Abteilung für Kardiologie und Angiologie
Bosch Health Campus Stuttgart

Präsentation Robert-Bosch-Krankenhaus 1

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Disclosures

Financial disclosures (speakers honoraria, proctoring, traveling expenses)

- Abbott Medical
- Bristol-Myers-Sqibb
- Philips
- Bayer
- Pfizer
- Daiichi Sankyo
- Edwards Lifesciences
- Products & Features
- Cardiovalve

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Aortenstenose

Mitralsuffizienz

Trikuspidal-Insuffizienz

Evidenz

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Leitlinien Aortenklappenstenose

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

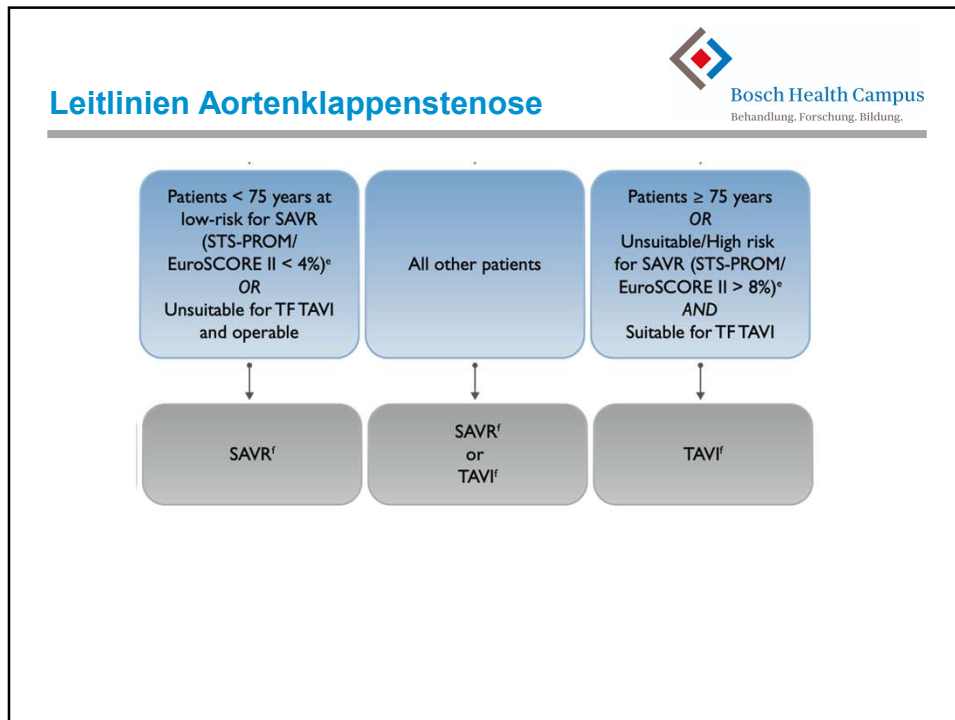
Management of patients with severe aortic stenosis*

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graph TD
    Start[Management of patients with severe aortic stenosis*] --> LVEF{LVEF < 50%}
    Start --> Symptoms{Symptoms}
    
    LVEF -- N --> Educate[Educate patient and reassess in 6 months  
(or as soon as possible if symptoms occur)]
    LVEF -- Y --> Symptoms
    
    Symptoms -- N --> Medical[Medical therapy]
    Symptoms -- Y --> Benefit[Intervention likely to be of benefit*  
(after assessment of comorbidity and frailty)]
    
    Benefit --> Active{Physically active}
    Active -- Y --> Exercise[Exercise test]
    Active -- N --> Educate
    
    Exercise --> BP{Symptoms or sustained fall in BP  
below baseline}
    BP -- Y --> Benefit
    BP -- N --> Indicators{Indicators of adverse prognosis*  
and low procedural risk}
    
    Indicators -- N --> Educate
    Indicators -- Y --> Heart[Heart Team evaluation*]
    
    Heart --> LowRisk{Patients < 75 years at low-risk for SAVR  
(STS-PROM) OR EuroSCORE II < 4%*  
AND Unsuitable for TF TAVI and operable}
    Heart --> AllOther{All other patients}
    Heart --> HighRisk{Patients ≥ 75 years OR Unsuitable/high risk for SAVR  
(STS-PROM/ EuroSCORE II > 8%)* AND Suitable for TF TAVI}
    
    LowRisk --> SAVR1[SAVR*]
    AllOther --> SAVRTAVI[SAVR* or TAVI*]
    HighRisk --> TAVI[TAVI*]
    
    Educate --> ESC[EESC]
    SAVR1 --> ESC
    SAVRTAVI --> ESC
    TAVI --> ESC
    
```


* ESC EACTS

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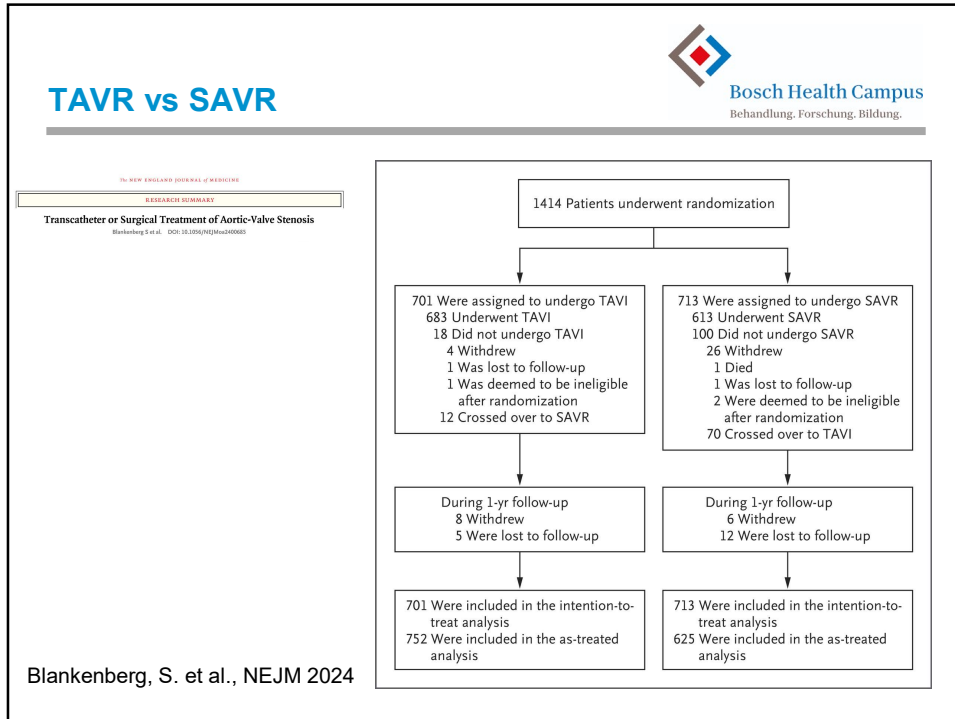
Leitlinien Aortenklappenstenose



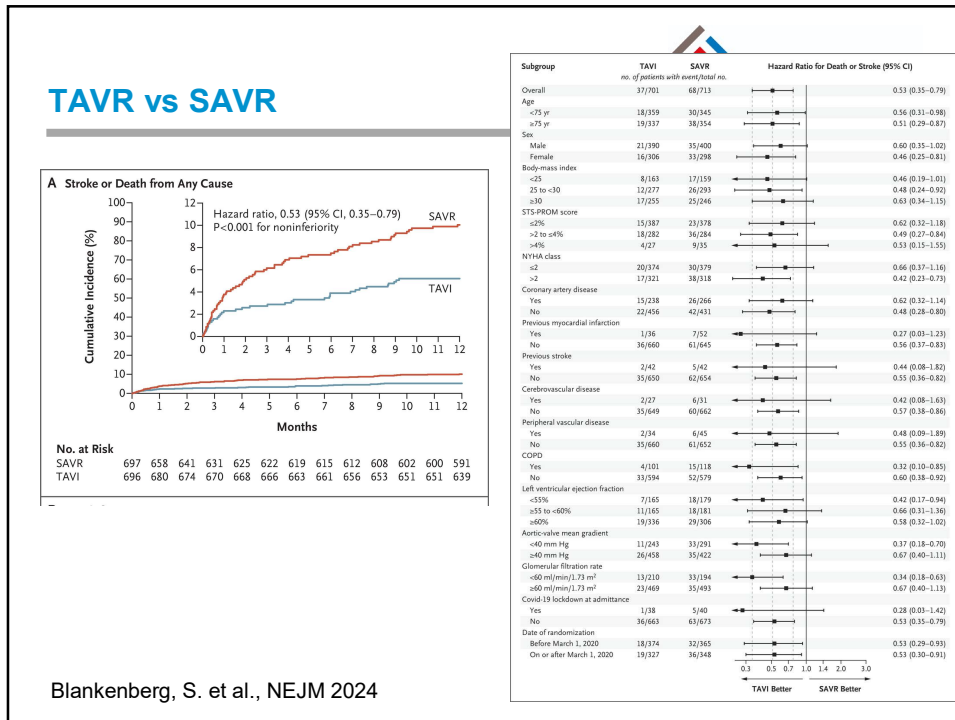
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	Favours TAVI	Favours SAVR
Anatomical and procedural factors		
TAVI feasible via transfemoral approach	+	-
Transfemoral access challenging or impossible and SAVR feasible	-	+
Transfemoral access challenging or impossible and SAVR inadvisable	+ ^c	-
Sequelae of chest radiation	+	-
Porcelain aorta	+	-
High likelihood of severe patient–prosthesis mismatch (AVA < 0.65 cm ² /m ² BSA)	+	-
Severe chest deformation or scoliosis	+	-
Aortic annular dimensions unsuitable for available TAVI devices	-	+
Bicuspid aortic valve	-	+
Valve morphology unfavourable for TAVI (e.g. high risk of coronary obstruction due to low coronary ostia or heavy leaflet/LVOT calcification)	-	+
Thrombus in aorta or LV	-	+


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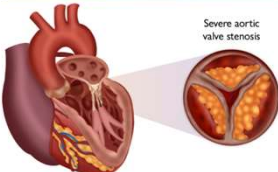
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NOTION-Trial - 10 years outcome


Severe aortic valve stenosis:
mean age 79 years; 80% with low mortality risk




Severe aortic valve stenosis

280 patients in nordic region
Randomized 1:1 in 2009-2013

145 TAVI
self-expanding bioprosthesis



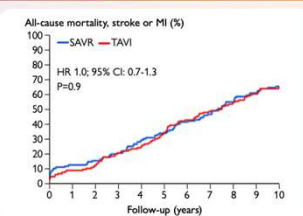
135 SAVR
any type of bioprosthesis



10-year follow-up

Primary composite outcome

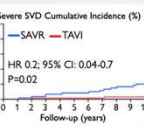
All-cause mortality, stroke or MI (%)



HR 1.0; 95% CI: 0.7-1.3
P=0.9

Severe structural valve deterioration (modified VARC-3 criteria)

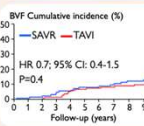
Severe SVD Cumulative Incidence (%)



HR 0.2; 95% CI: 0.04-0.7
P=0.02

Bioprosthetic valve failure (modified VARC-3 criteria)


BVF Cumulative incidence (%)



HR 0.7; 95% CI: 0.4-1.5
P=0.4


Thyregod, HGH et al. EuropHeartJ 2024;00,1-9

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TAVI bei asymptomatischen Patienten?



Study Design

Prospective, multicenter RCT evaluating patients with asymptomatic, severe AS aged ≥ 65 years w/ an STS score ≤ 10% and LVEF ≥ 50%

Asymptomatic Assessment
Confirmed by negative stress test*

Randomization 1:1

Transfemoral-TAVR
(SAPIEN 3 or SAPIEN 3 Ultra THV)

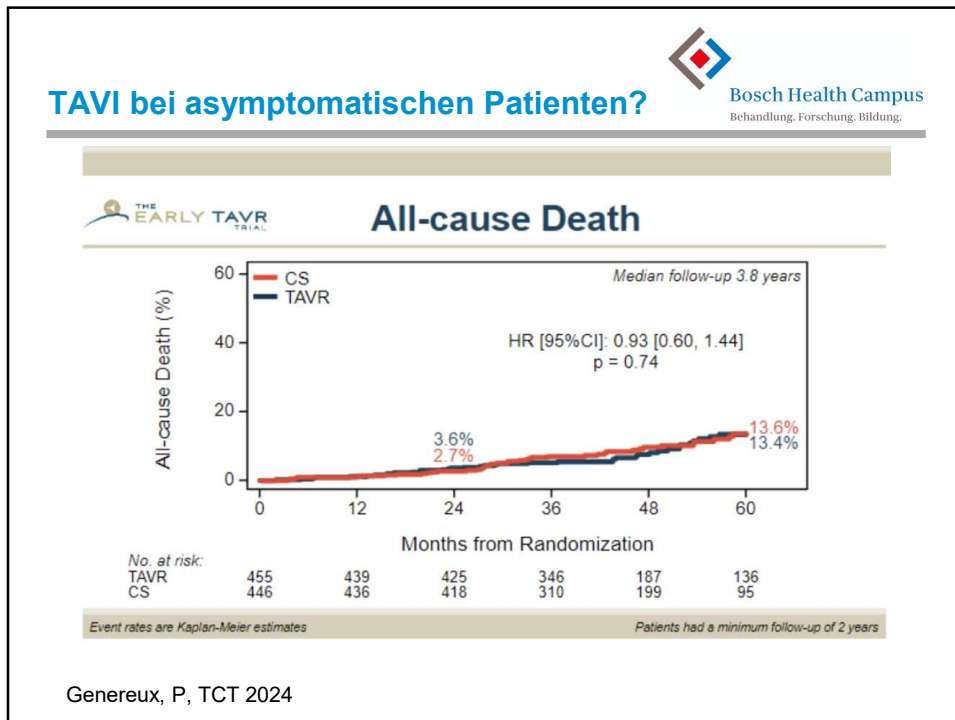
Clinical Surveillance

PRIMARY ENDPOINT (Superiority)
Non-hierarchical composite of all-cause death, any stroke, or unplanned CV hospitalization at a minimum follow-up of 2 years

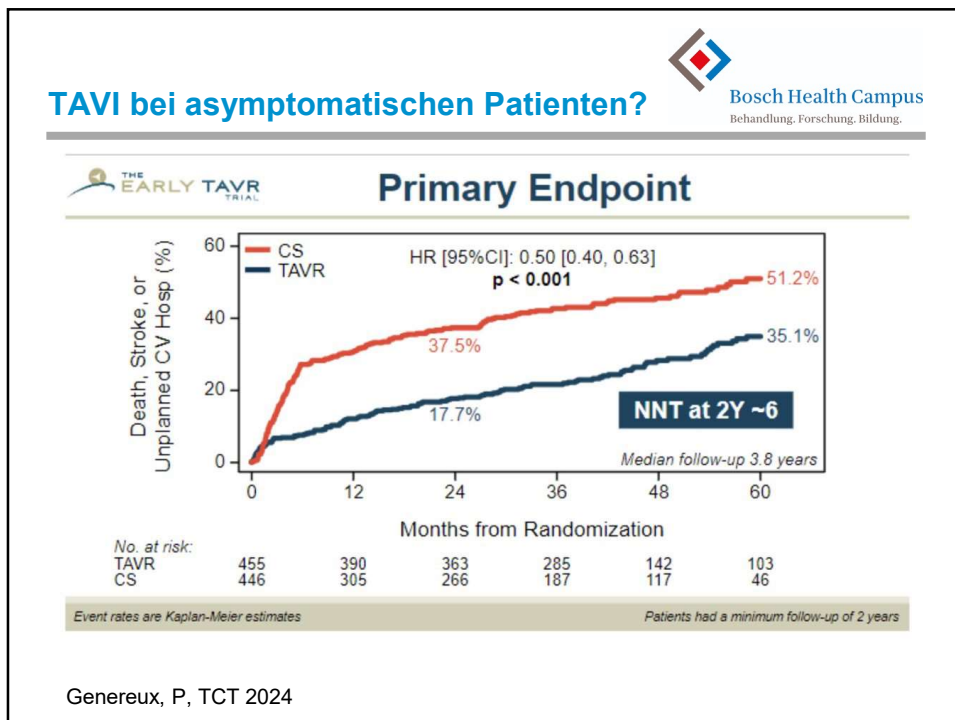
*Confirmed by detailed clinical history alone if patient was unable to perform stress test

Geneux, P, TCT 2024


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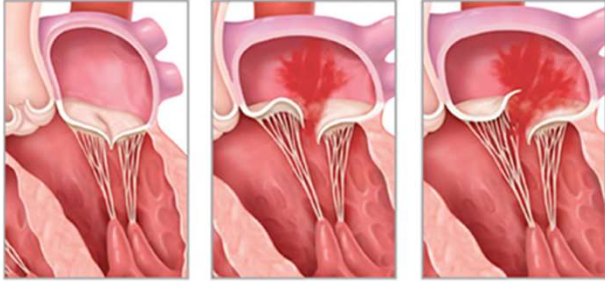


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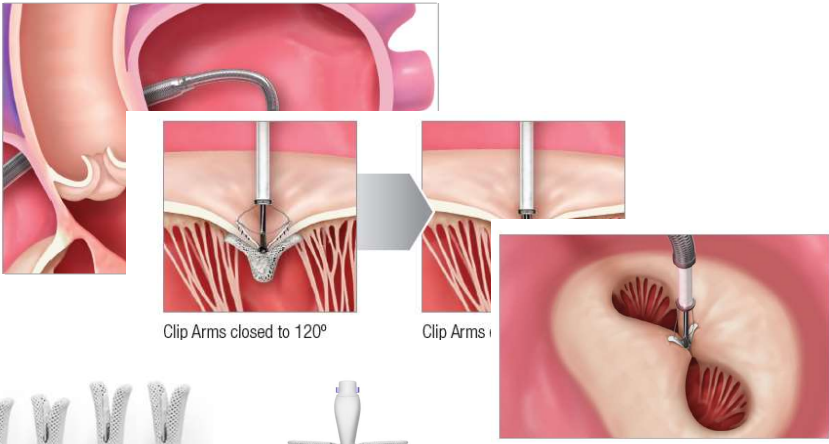
Normal mitral valve **Degenerative MR caused by mitral valve prolapse** **Degenerative MR caused by flail leaflet**

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Transkatheter edge-to-edge-repair



Clip Arms closed to 120° Clip Arms



NT NTW XT XTW

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wie alles begann...

2001
"Final" Clip Design

Abbott Medical

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wie alles begann....

The **NEW ENGLAND**
JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2011 VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald D. Clower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fai, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engoron, M.D., Catalin Iughin, M.D., Alfredo Trento, M.D., Eric R. Sieger, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

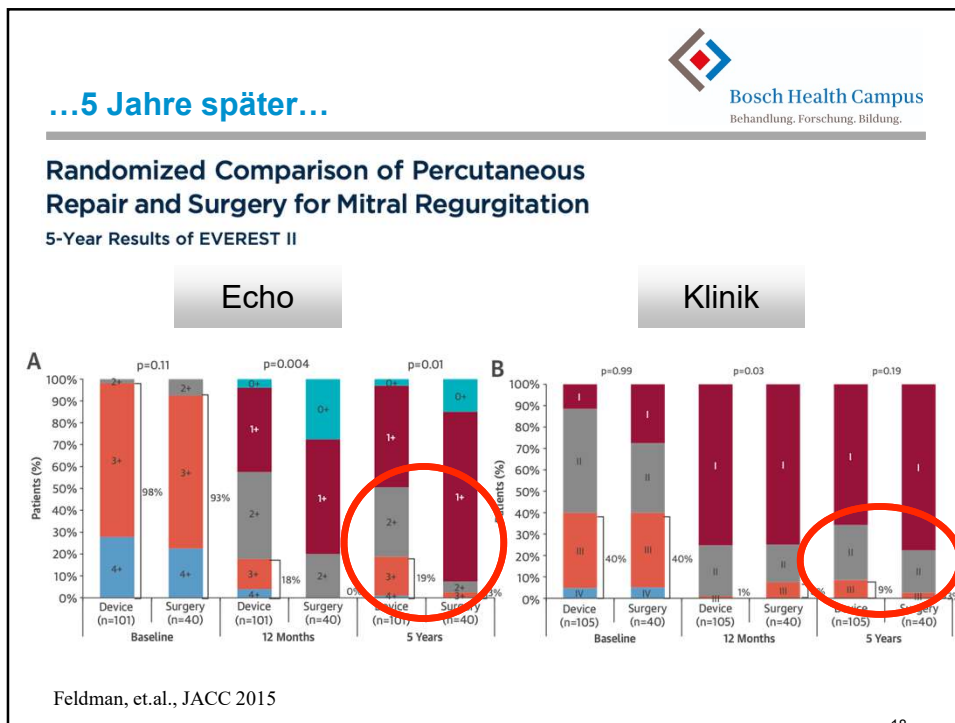
Table 1. Baseline Characteristics of the Patients.*

Characteristic	Percutaneous Repair (N=184)	Surgery (N=95)	P Value
Cause of mitral regurgitation — no. (%)			0.81
Functional	49 (27)	26 (27)	
Degenerative			
With anterior or bileaflet flail or prolapse	58 (32)	25 (26)	
With posterior flail or prolapse	72 (39)	42 (44)	
With no flail and no prolapse	5 (3)	2 (2)	

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primär vs sekundäre Mi



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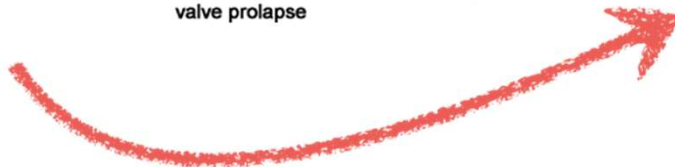
Normal mitral valve



Degenerative MR
caused by mitral
valve prolapse



Degenerative MR
caused by flail leaflet



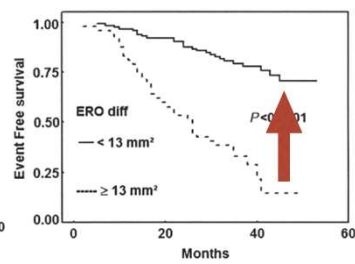
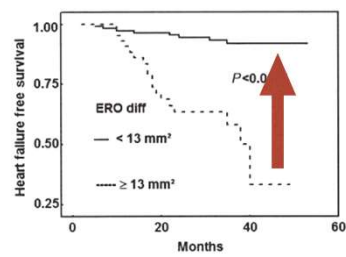
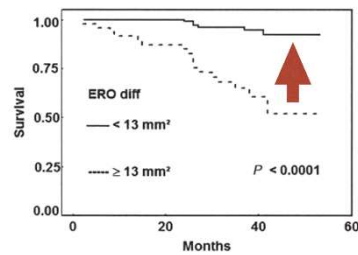
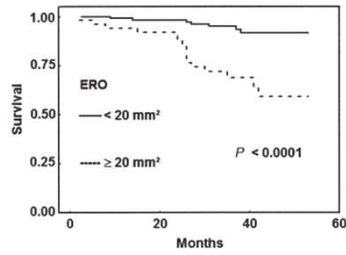
20

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Die Welt bis zum 25.08.2018



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Lancilotto P et. al. Eur. Heart Journal 2005 (26) 1528-1532

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Mitra-FR

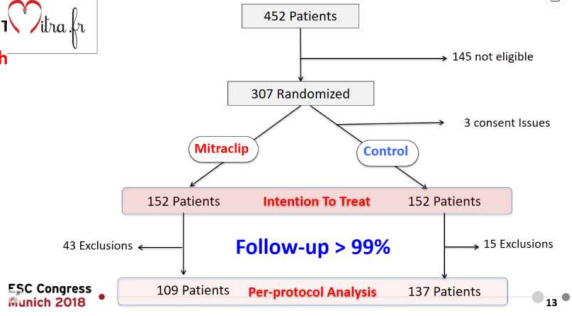


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Inclusion Criteria

- **Symptomatic** despite Optimal Treatment (NYHA ≥II).
- At least **one hospitalization** for HF within 12 months preceding randomization
- Severe Secondary MR → **ERO > 20 mm²** or R.vol>30 mL/beat
- **15% < EF < 40%**
- Not eligible for surgery "Heart 1" 
- **Centralized echocardiograph**




ESC Congress Munich 2018

Obadia, ESC 2018

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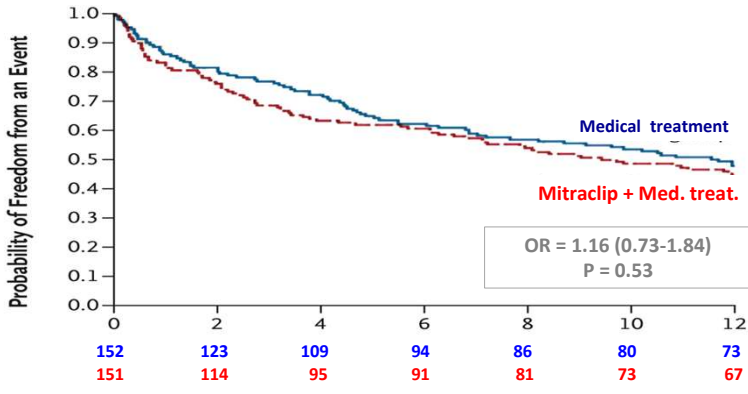
Mitra-FR



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Primary composite endpoint (99% follow-up)

- All-Cause Death
- Unplanned rehospitalization for HF



0	2	4	6	8	10	12
152	123	109	94	86	80	73
151	114	95	91	81	73	67

Obadia, ESC 2018

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Mitra-FR



Frankfurter Allgemeine
ZEITUNG FÜR DEUTSCHLAND



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UMSTRITTENER EINGRIFF

Wem nützt der Clip im Herzen?


VON NICOLA VON LUTTEROTTI · AKTUALISIERT AM 19.09.2018 · 19:43



Eine schwächelnde Herzklappe mit einem „Mitra-Clip“ abzudichten, zählt zu den beliebtesten und einträglichen Eingriffen von Kardiologen. Leider bringt das nicht viel, zeigt nun eine große Studie.

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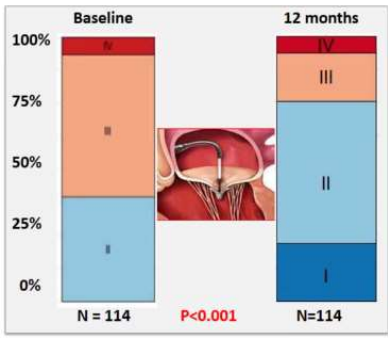
Mitra-FR



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Prespecified Secondary Endpoints


NYHA evolution (paired data)



NYHA Class	Baseline (N=114)	12 months (N=114)
I	~15%	~18%
II	~35%	~45%
III	~45%	~25%
IV	~5%	~12%

Obadia, ESC 2018

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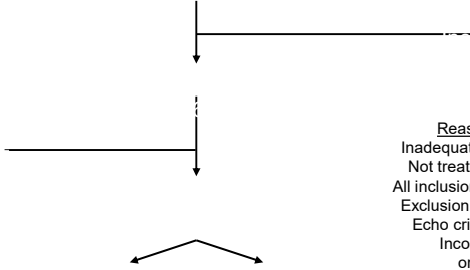
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....einen Monat später....

COAPT

A Randomized Trial of Transcatheter Mitral Valve Leaflet Approximation in Patients with Heart Failure and Secondary Mitral Regurgitation




Reasons for exclusion

- Inadequate MR or DMR (n=244)
- Not treated with GDMT (n=79)
- All inclusion criteria not met (n=85)
- Exclusion criteria present (n=34)
- Echo criteria not met (n=255)
- Incomplete screening or other (n=419)

Stone, -G; ESC 2018

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COAPT

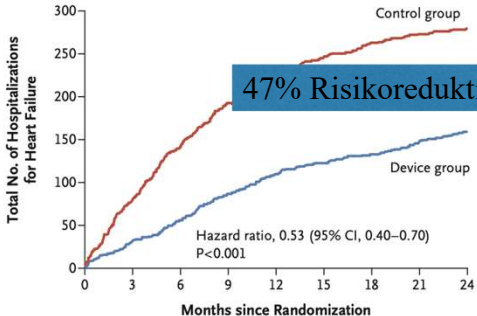
THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brilke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

Hospitalization for Heart Failure

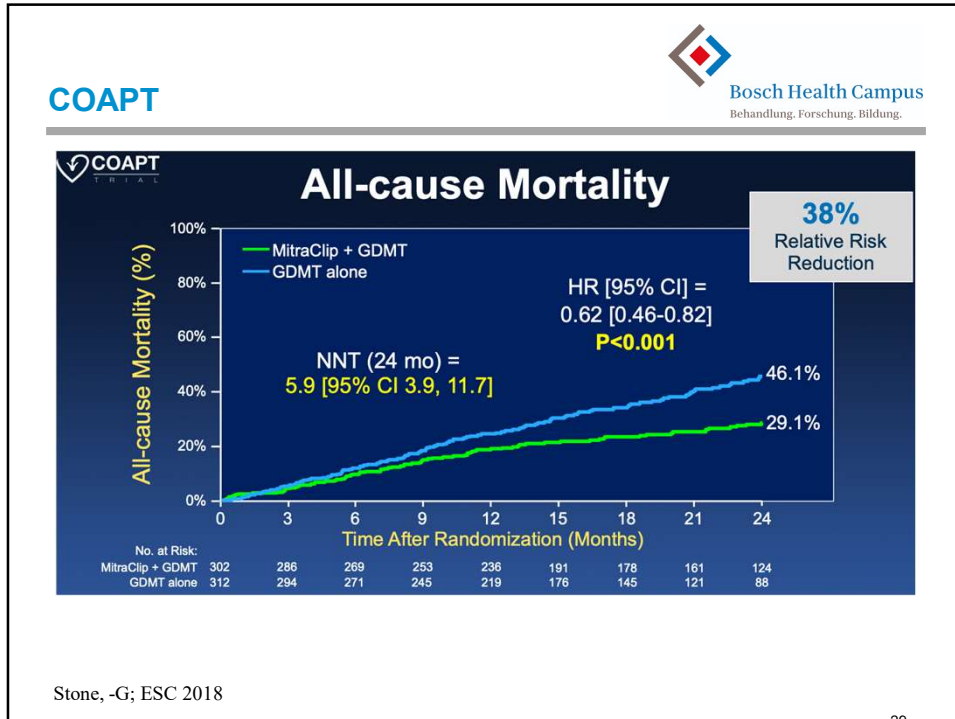


47% Risikoreduktion
 Hazard ratio, 0.53 (95% CI, 0.40–0.70)
 P<0.001

No. at Risk

	0	3	6	9	12	15	18	21	24
Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

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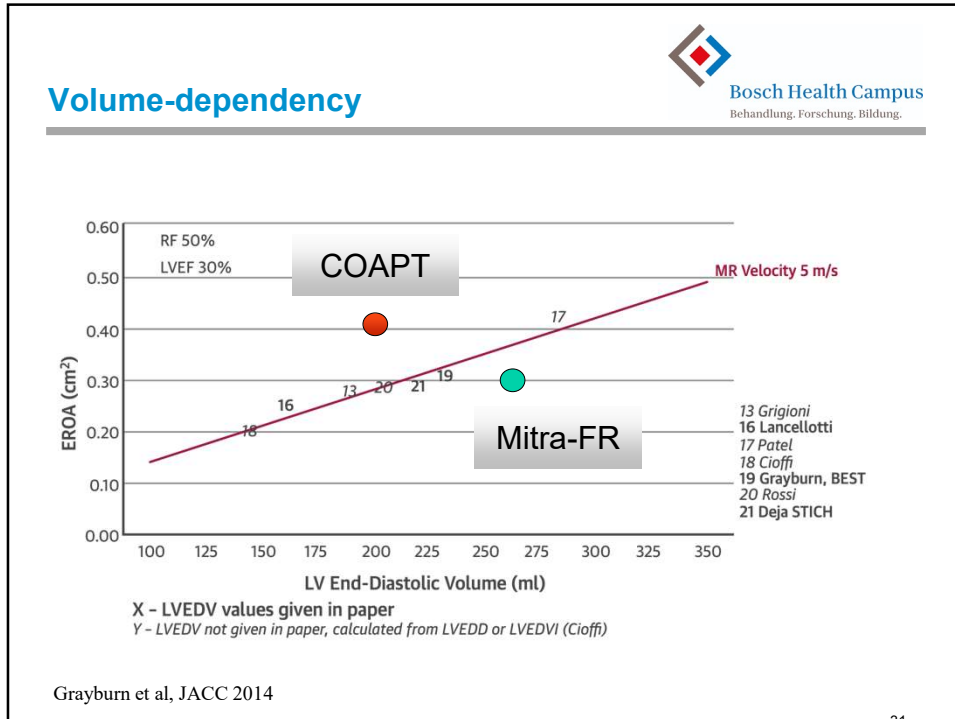
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COAPT vs Mitra-FR

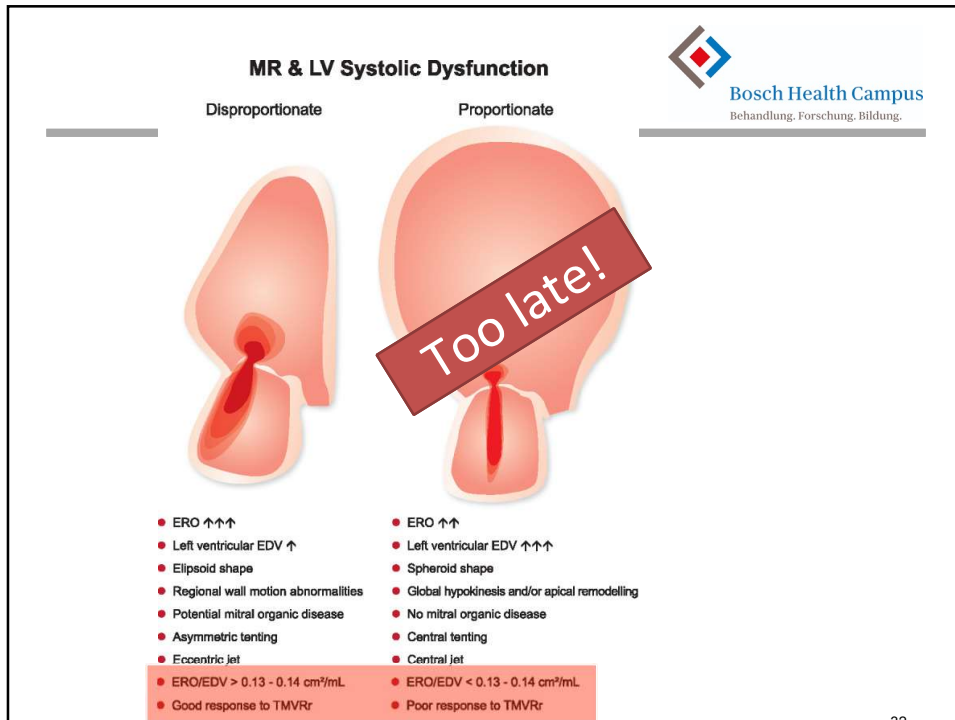
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	MITRA-FR (n=304)	COAPT (n=614)
Vordefinierte Zugangskriterien		
• Schwere MI	Schwere FMI nach EU-Richtlinien: ERO > 20 mm ² oder RV > 30 ml/Herzschlag	Schwere FMI nach US-Richtlinien: EROA > 30 mm ² oder RV > 45 ml/Herzschlag
• LVESD	Keine Einschränkungen	≤ 70 mm innerhalb der letzten 90 Tage
An der Baseline		
• EROA (Mittelwert ± SD)	31 ± 10 mm ²	41 ± 15 mm ²
• < 0,30	52 % (157/301)	14 % (80/591)
• 0,30-0,40	32 % (95/301)	46 % (270/591)
• > 0,40	16 % (49/301)	41 % (241/591)
• LVEDVI (Mittelwert ± SD)	135 ± 35 ml/m ²	101 ± 34 ml/m ²
Medikation	Erhalt von HI-Medikamenten zu Beginn der Studie - zulässige variable Anpassung in jeder Gruppe während der Nachbeobachtung in der realen Praxis.	CEC bestätigte, dass die Patienten zu Studienbeginn nicht die maximal tolerierte Dosis an GDMT erhielten - wenige wesentliche Änderungen während der Nachbeobachtung.
	größere Ventrikel kleinere MI	kleinere Ventrikel größere MI

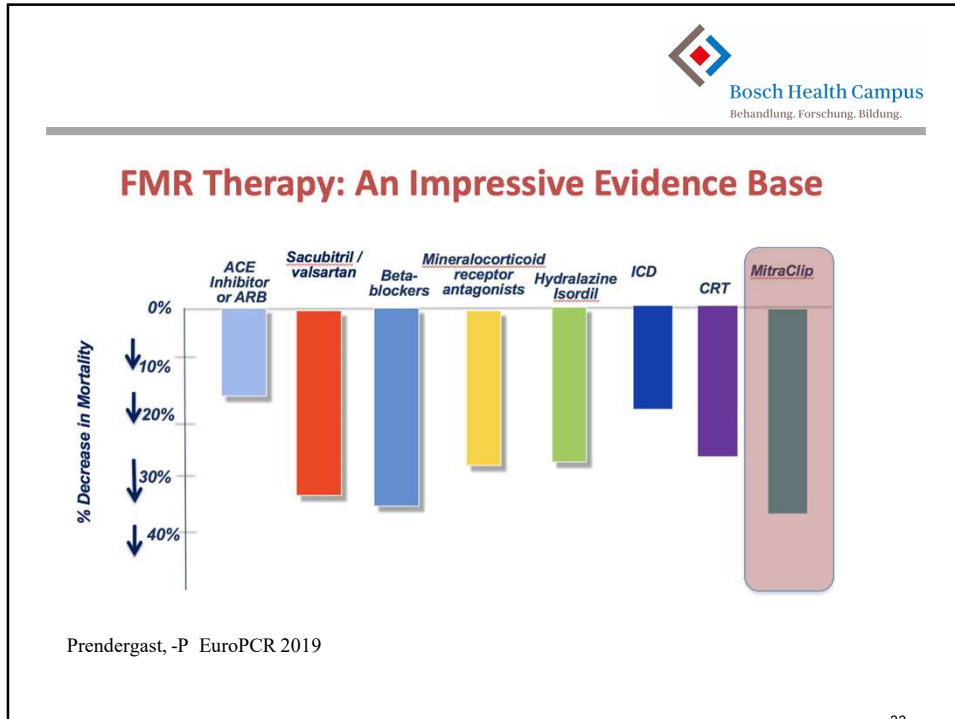
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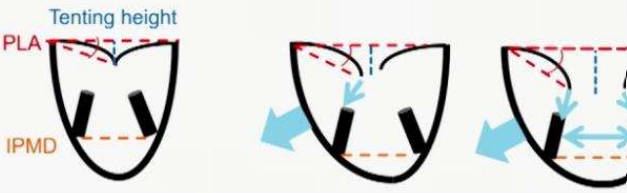
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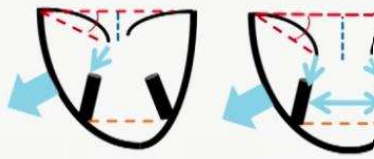
...und was macht der Herzchirurg?

High likelihood of durable repair ?


Tethering	asymetric	symetric
Posterior leaflet angle (°)	<45	>45
Systolic sphericity index	<0,7	>0,7
LVEED (mm)	<65	>65
Tenting height (mm)	<1cm	>1cm
Interpapillary muscle distance (mm)	< 2cm	>2cm
Likelihood of durable repair	high	low



PLA
IPMD



Tenting height



Coaptation depth < 1mm

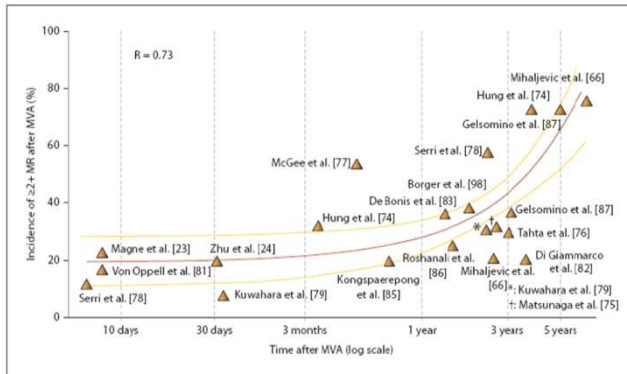
V. Falk, EACTS 2017

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surgical approach



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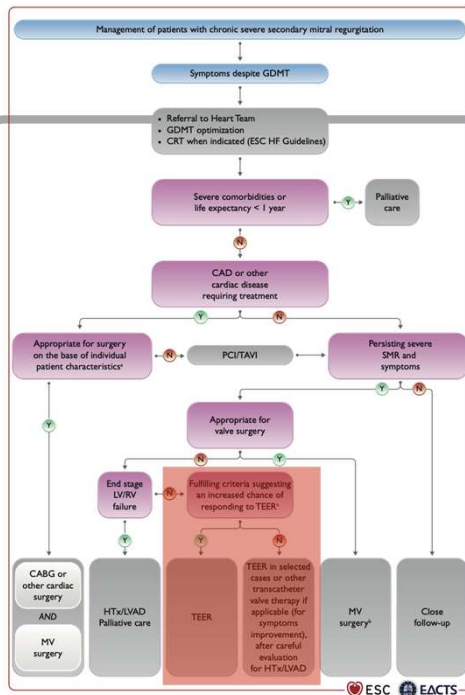


Magne et al. Cardiology 2009;112:21 112:244

...up to 80% residual high-grade MR


Consider TEER also in patients with low surgical risk and low likelihood for durable repair (tenting height > 1cm)

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functional MR

TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.^{337,338,356,357 e}

IIa

B

COAPT-Patients

In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant.^e

IIb


C

non-COAPT-Patients

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2021 ESC/EACTS Guidelines for the management of valvular heart disease
European Heart Journal (2021) 00, 1–72

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Mitra-FR

Delayed hospitalisation for heart failure after transcatheter repair or medical treatment for secondary mitral regurgitation: a landmark analysis of the MITRA-FR trial

Guillaume Leurent^{1,2*}, MD; Vincent Auffret^{1,2}, MD, PhD; Erwan Donal^{1,2}, MD, PhD; Hervé Corbineau¹, MD, PhD; Daniel Grinberg¹, MD; Guillaume Bonnet¹, MD; Pierre-Yves Leroux⁴, MD; Patrice Guérin¹, MD, PhD; Fabrice Wautot⁴, MD; Thierry Lefèvre⁴, MD; David Messika-Zeitoun¹⁰, MD, PhD; Bernard Jung¹¹, MD; Xavier Armoiry^{12,13}, PhD, PharmD; Jean-Noël Trochu⁷, MD, PhD; Florent Boutitie¹⁴, PhD; Jean-François Obadia¹, MD, PhD

307 patients included in the MitraFR trial

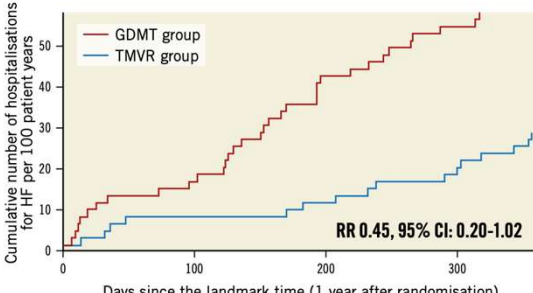
↓ 12 months

140 surviving patients free from heart failure hospitalisation

↙ ↘

TMVR: 67 GDMT: 73
(similar characteristics at inclusion)

EuroIntervention 2022;18:514-523



	73	62	55	50
GDMT	73	62	55	50
TMVR	67	63	61	55

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Zu spätes Krankheitsstadium...



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Risiko für M-TEER in erfahrenen Zentren <1%

Konservative Therapieoption nur, dann wenn **absolut sicher** dass keine Symptomverbesserung / Lebensqualität / Lebenserwartung erreicht werden kann!

Schlimmstes Szenario: Einen Patienten nicht zu behandeln, der mit niedrigem prozeduralem Risiko verbessert werden kann!



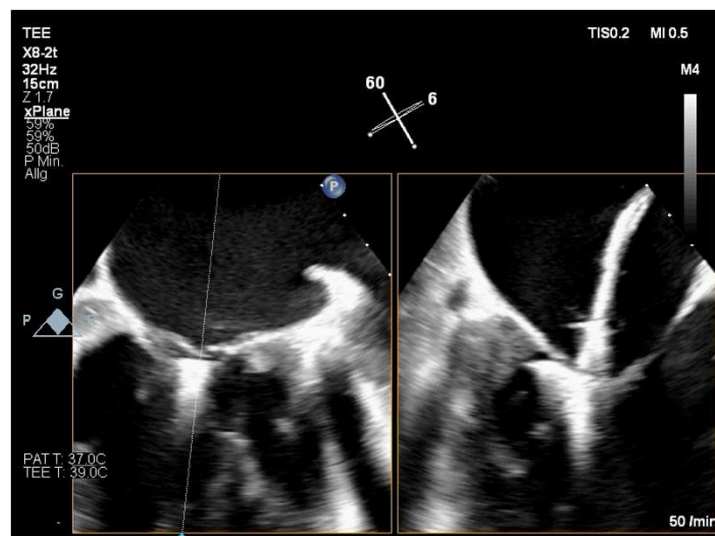
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Controlled gripper actuation

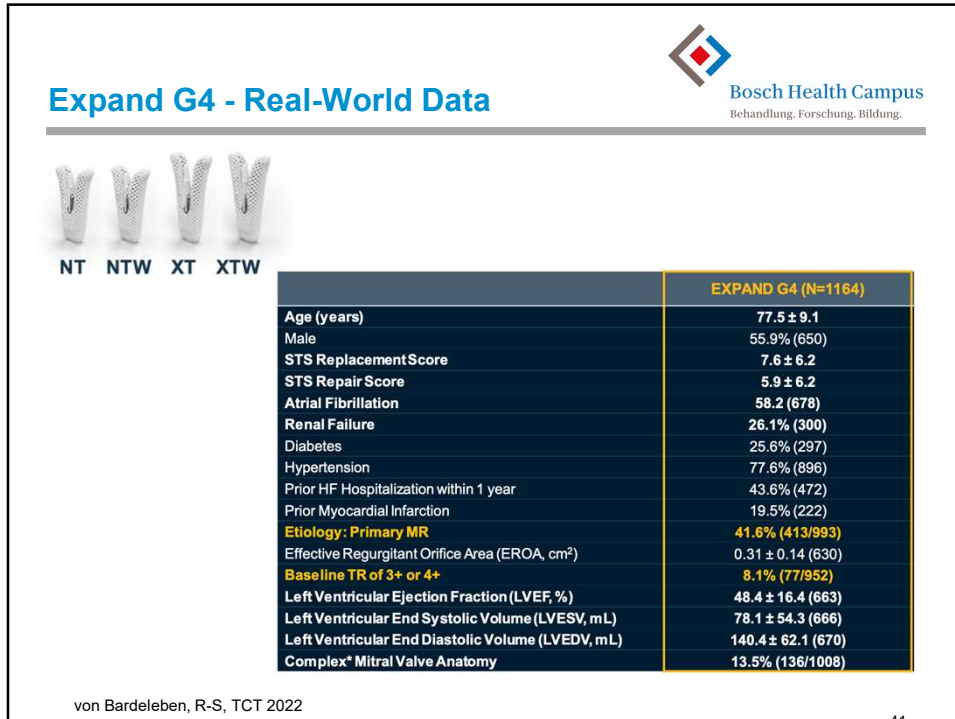


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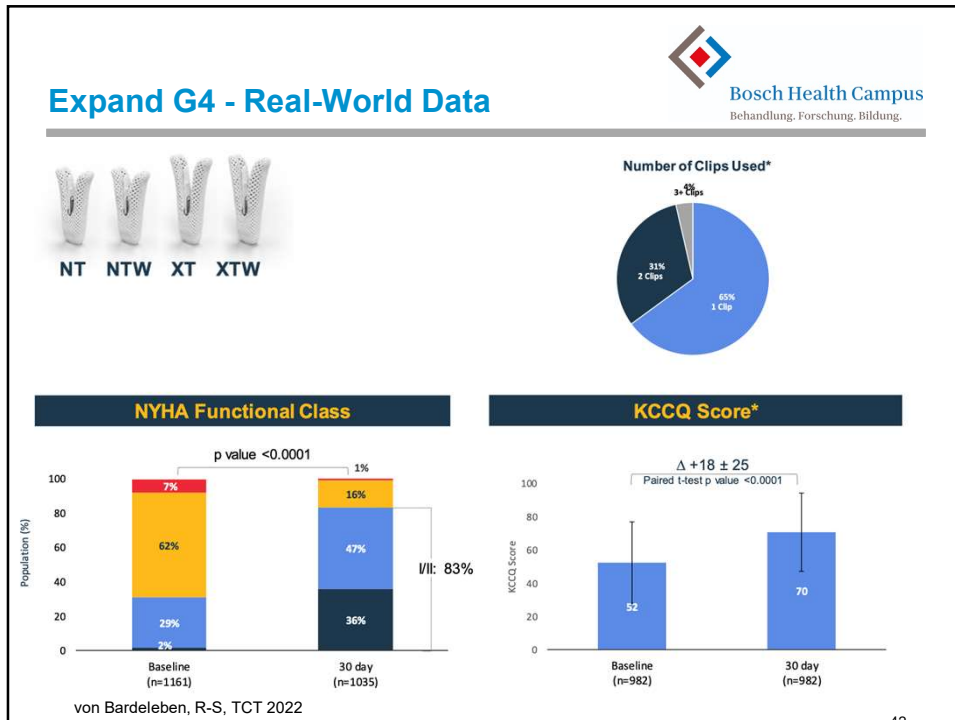


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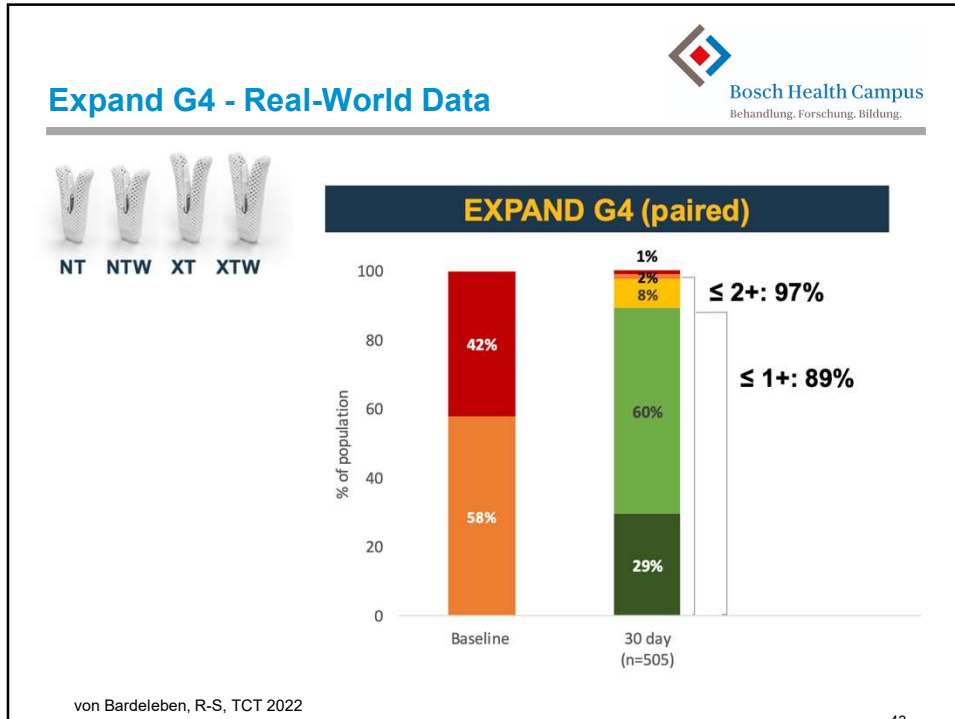
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Expand G4 - Real-World Data

30-Day Adverse Event


	EXPAND G4 (N=1158)
All-cause Death	0.3% (15)
Myocardial Infarction	0.2% (2)
Stroke	0.0% (0)
Non-elective CV Device-related Complications	0.9% (10)
Leaflet Adverse Events SLDA*	1.0% (12)

real World?!
No!

*Single leaflet device attachment (SLDA) events in the EXPAND G4 study were assessed by the ECL based on procedural and follow-up images.

von Bardeleben, R-S, TCT 2022

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Complex Anatomy

	EXPAND G4 (N=1164)
Age (years)	77.5 ± 9.1
Male	55.9% (650)
STS Replacement Score	7.6 ± 6.2
STS Repair Score	5.9 ± 6.2
Atrial Fibrillation	58.2 (678)
Renal Failure	26.1% (300)
Diabetes	25.6% (297)
Hypertension	77.6% (896)
Prior HF Hospitalization within 1 year	43.6% (472)
Prior Myocardial Infarction	19.5% (222)
Etiology: Primary MR	41.6% (413/993)
Effective Regurgitant Orifice Area (EROA, cm ²)	0.31 ± 0.14 (630)
Baseline TR of 3+ or 4+	8.1% (77/952)
Left Ventricular Ejection Fraction (LVEF, %)	48.4 ± 16.4 (663)
Left Ventricular End Systolic Volume (LVESV, mL)	78.1 ± 54.3 (666)
Left Ventricular End Diastolic Volume (LVEDV, mL)	146.4 ± 62.4 (670)
Complex* Mitral Valve Anatomy	13.5% (136/1008)

Complex mitral valve anatomy includes

- presence of a wide jet
- multiple jets
- primary jet outside of A2P2
- severely degenerative leaflets with large flail/prolapse gaps
- minimal leaflet tissue
- calcified landing zone or small valve




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Behandlung, Forschung, Bildung.

Leitlinie Anatomie

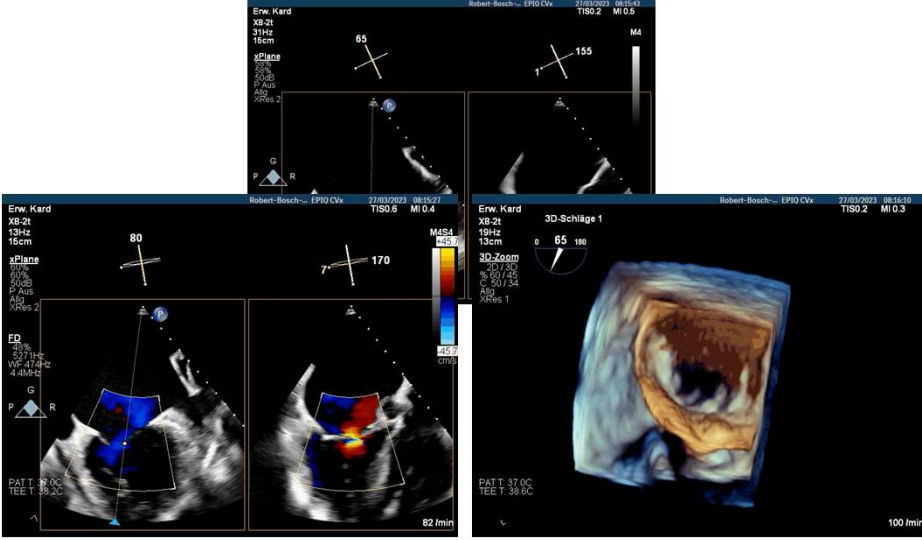
Optimal	Limited suitable	Inappropriate
Pathology in segment 2	Pathology in segment 1 or 3	Leaflet perforation or cleft
No calcification	- Slight calcification outside the grasping area - Ring calcification - Annuloplasty with ring	Severe calcification
Valve area >4cm ²	Valve area >3 cm ² and good leaflet mobility	Mitral stenosis (< 3cm ² , gradient >5mmHg)
Length of the posterior leaflet > 10mm	Length of the posterior leaflet 7-10mm	Length of the posterior leaflet < 7mm
Coaptation depth < 11mm	Coaptation depth >11mm	
Normal thickness and mobility of the leaflets	Restriction (Carpentier IIIB)	Rheumatic thickening and restriction (Carpentier IIIA)
MR with prolapse Flail size < 15mm Flail gap < 10mm	Flail size > 15mm only with large mitral annulus and option for more than 1 clip	Barlows disease

Boekstegers, P.; Hausleiter, J. et al. „Interventionelle Behandlung der Mitralklappeninsuffizienz mit dem MitraClip-Verfahren.“
 Empfehlungen des Arbeitskreises Interventionelle Mitralklappenherapie der Arbeitsgemeinschaft Interventionelle
 Kardiologie (AIK) der Deutschen Gesellschaft für Kardiologie und der Arbeitsgemeinschaft Interventionelle
 Krankenhauserkrankende Kardiologie (AIKK) Kardiologie 2013, 7:91-104

Inappropriate anatomical conditions




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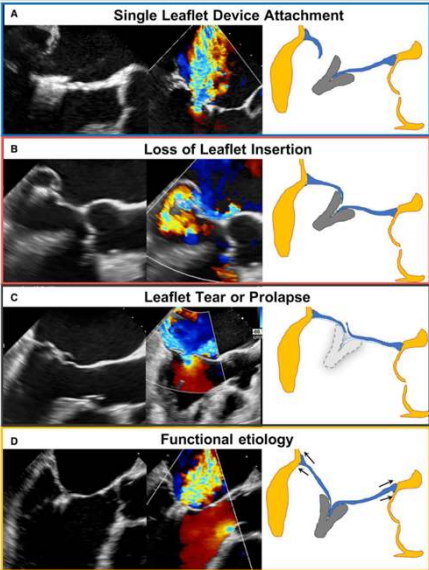
47

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recurrent MR after TEER



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Sugiura, A. et al. Circ Cardiovasc Interv. 2022

48

48

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Feinde der interventionellen AV-Klappentherapie:

- Stenosekomponente
- schlechtes / kurzes Segelmaterial
- „Kalk“
- Clefts / Segelperforationen

neoCHORD
transforming mitral valve repair

Carillon
Percutaneous Mitral Annuloplasty

49

Transcatheter MV Repair: Device Landscape 2016

Edge-to-edge	Coronary sinus annuloplasty	Other approaches
<ul style="list-style-type: none"> • MitraClip* • MitraFlex 	<ul style="list-style-type: none"> • Cardiac Dimensions Carillon* 	<ul style="list-style-type: none"> • MitraSpacer*
Direct annuloplasty and basal ventriculoplasty	Cerclage annuloplasty MV replacement	<ul style="list-style-type: none"> • St. Jude leaflet plication* • NeoChord* • Cardiac Implants • Babic chords • Valtech Vchordal • Middle Peak Medical • Mardil BACE • Mitralis
<ul style="list-style-type: none"> • Mitralign Bident* • GDS Accucinch* • Valtech Cardioband* • Quantum Cor (RF) • Micardia enCor • Millipede • Valcare 	<ul style="list-style-type: none"> • CardiAQ* • Neovasc Tiara* • Edwards Fortis* • Tendyne* • Twelve* • Cephea • Sinomed • Micro Interventional • Valtech Cardiovalve • ValveXchange • Lutter Valve • Medtronic • MitrAssist • MVValve 	<p style="color: red; font-weight: bold;">*In patients</p>


Courtesy of MB Leon

50

euro
PCR

R3K
Robert-Bosch-Krankenhaus

Tendyne™



VALVE DESIGN

- Dual-frame, tri-leaflet, bioprosthetic valve
- Outer frame contoured to mitral annulus
- Multiple valve sizes to address broad range of patient anatomies
- Low profile frames available that retain annular dimension with less LVOT protrusion

TETHER

- Enables full retrievability throughout procedure
- Enables repositionability for optimal placement


APICAL PAD


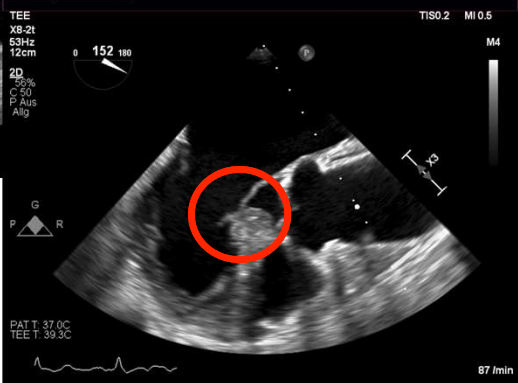
- Placed over ventricular access site

51

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anatomische Voraussetzungen



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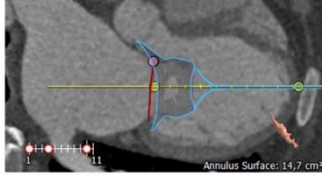
52

52


anatomische Voraussetzungen




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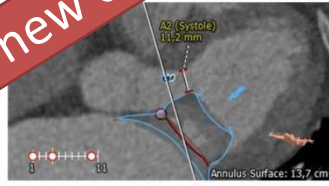
Annulus Surface: 14,7 cm²



Annulus Surface: 6,2 cm²



neo-LVOT (Systole)
Min. Ø: 15,3 mm
Area: 5,2 cm²
Distance: 20,8 mm




A2 (Systole)
13,2 mm
Annulus Surface: 13,7 cm²

LVOT is the new enemy!

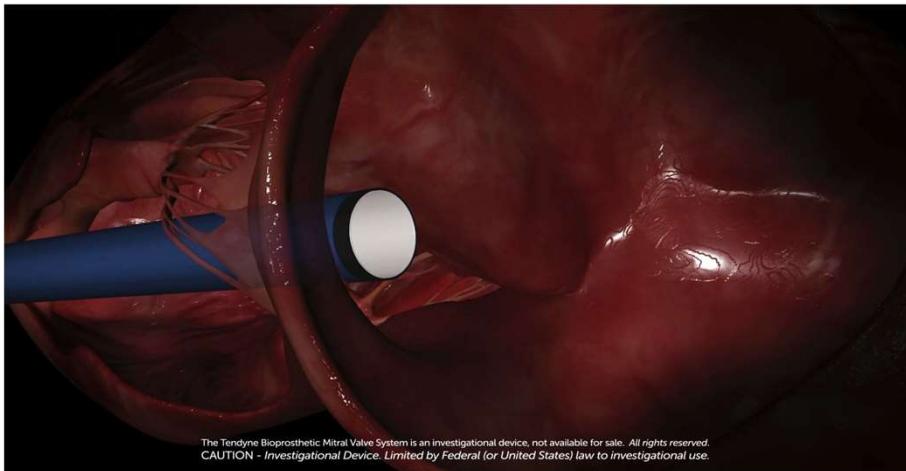
53

53

TMVR Procedure



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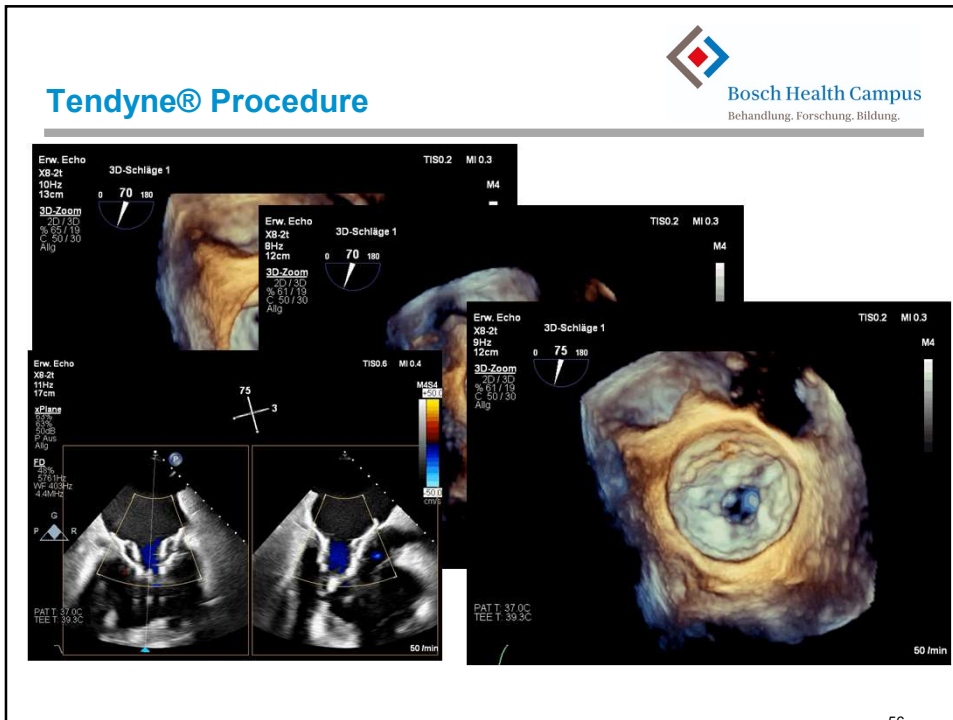
The Tendyne Bioprosthetic Mitral Valve System is an investigational device, not available for sale. All rights reserved.
CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.

54

54




55

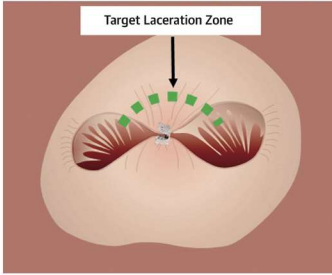


56

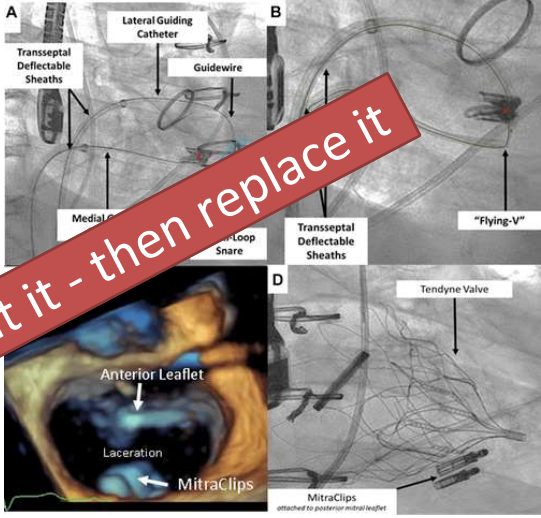
ELASTA-Clip-Procedure



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Target Laceration Zone




A: Lateral Guiding Catheter, Transseptal Deflectable Sheaths, Medial Loop Snare
B: Guidewire, Transseptal Deflectable Sheaths, "Flying-V"
C: Anterior Leaflet, Laceration, MitraClips
D: Tendyne Valve, MitraClips attached to posterior mitral leaflet


clip it - cut it - then replace it

Lisko, J. et. al. [J Am Coll Cardiol Intv](#). 2020 Oct, 13 (20) 2361–2370

57

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Tricuspid Regurgitation is Frequent but Rarely Treated

1.6M

Moderate to severe TR prevalence



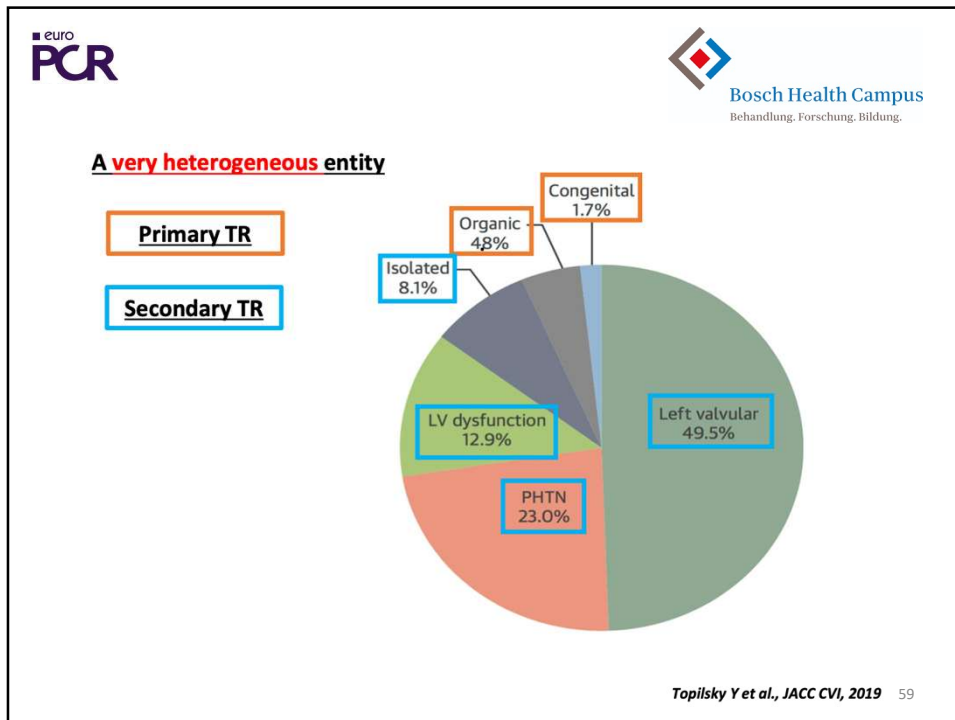
<8k

Surgical procedures annually

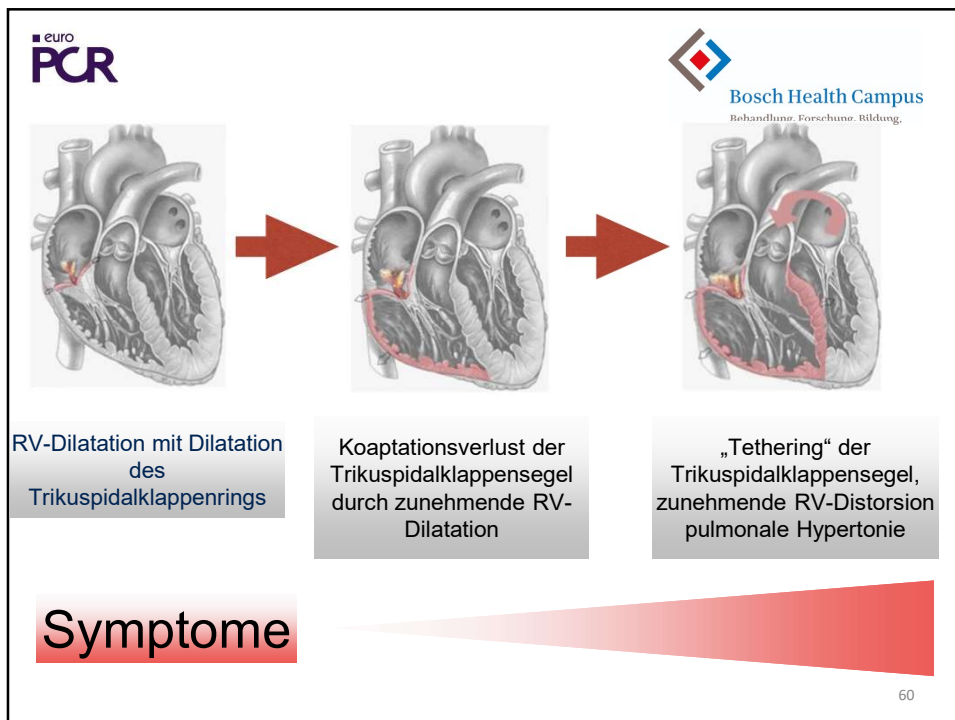
Numbers reflective of US data
 Stage O, Liodicost J. Journal of Thoracic and Cardiovascular Surgery. 2006;132:1258-61.
 McCarthy PM, Sales VL. Current Treatment Options in Cardiovascular Medicine. 2010;12:587-597.

58

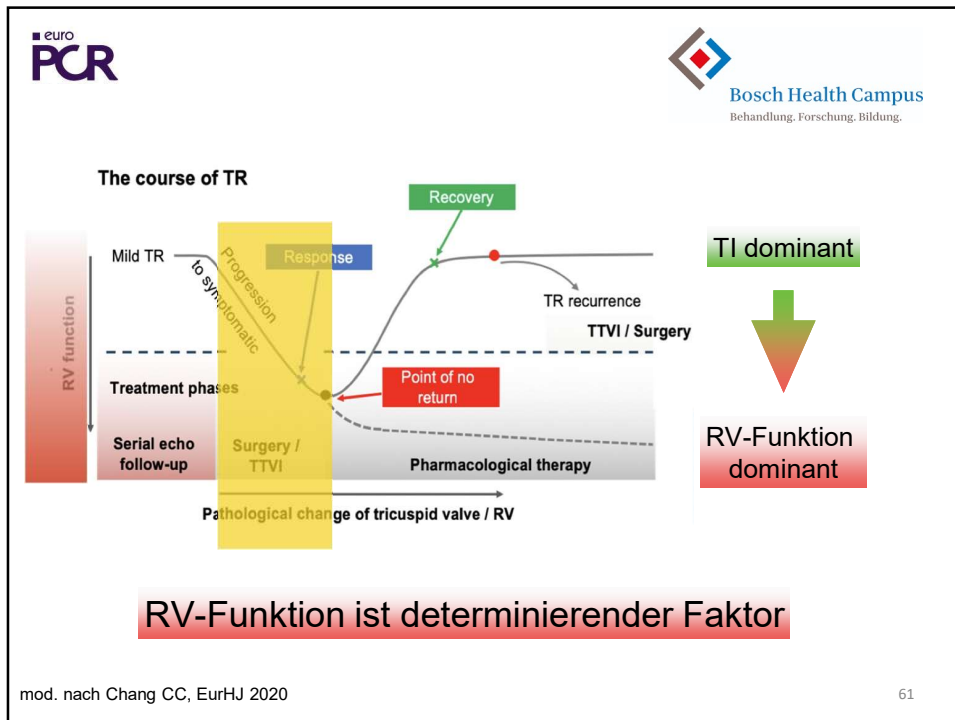
58



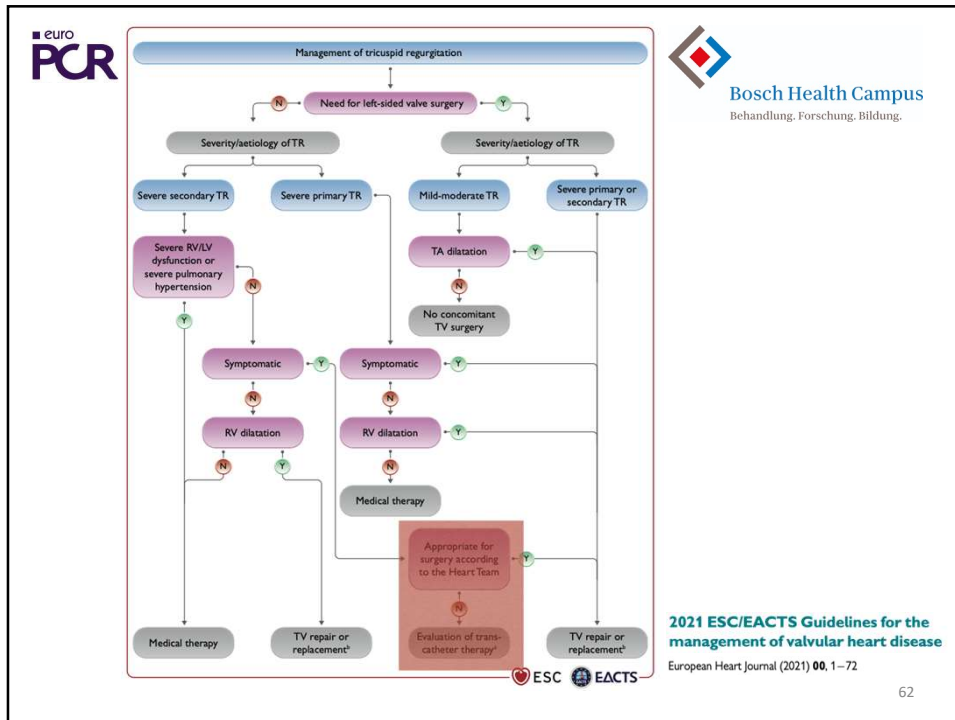
59



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61



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Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation may be considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease.^f

IIb **C**

^fTranscatheter treatment can be performed according to Heart Team at experienced valve centres in anatomically eligible patients in whom improvement of quality of life or survival can be expected.

Importantly, in the absence of advanced RV dysfunction or severe pulmonary hypertension, none of the above-mentioned therapies should delay referral for surgery or transcatheter therapy.


2021 ESC/EACTS Guidelines for the management of valvular heart disease
European Heart Journal (2021) 00, 1–72

63

63

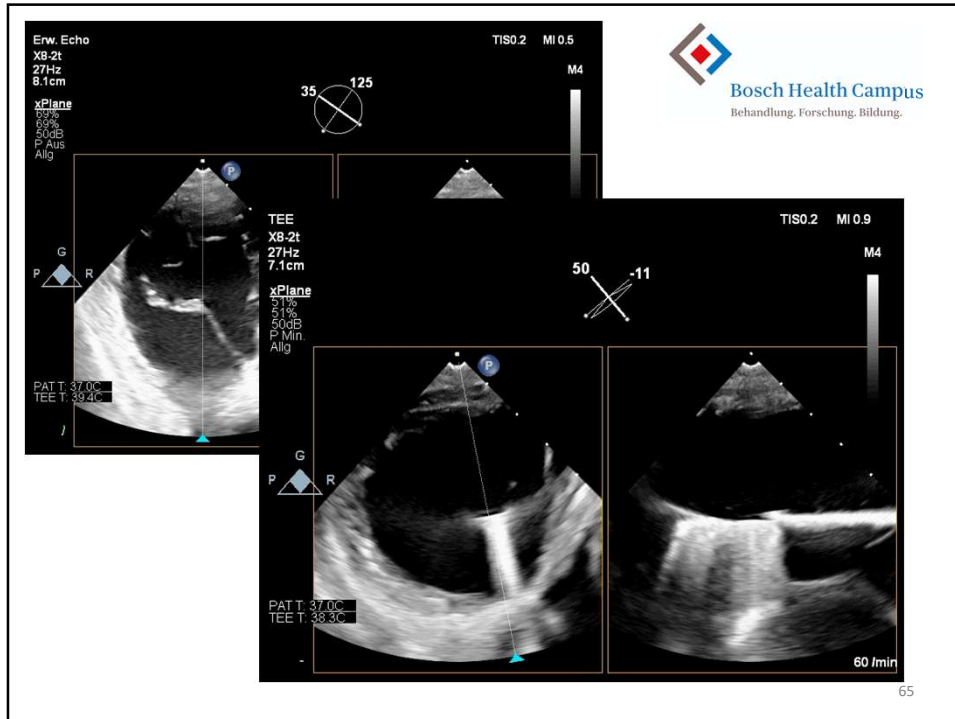
euro PCR

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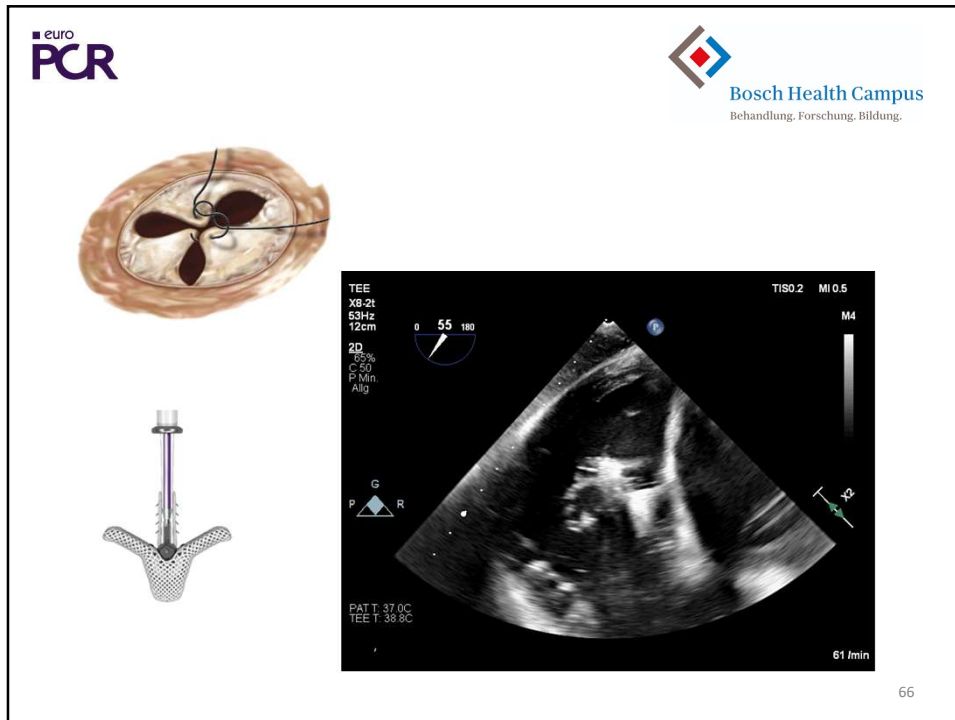


64


64



65



66




Risk Stratification for Isolated TV Surgery Assisted Using the MELD Score

Study population	Outcome
<ul style="list-style-type: none"> Isolated tricuspid valve surgery: <ul style="list-style-type: none"> n = 157 70% valve repair 98% beating heart Stratification according to MELD score: <ul style="list-style-type: none"> MELD < 10 (n = 53) MELD 10 to < 20 (n = 78) MELD ≥ 20 (n = 26) 	<p>Observed and expected 30-day mortality based on EuroSCORE II and STS-score depending on MELD category.</p> <p>Kaplan-Meier survival curves for patients subjected to isolated TV surgery depending on MELD category (colored areas - 95% confidence interval).</p> <p>EuroSCORE II and STS underestimate perioperative mortality in patients with high MELD scores. Using MELD score in addition to classic surgical risk stratification tools might allow identification of patients for whom STS and EuroSCORE II fail to properly assess mortality risk.</p> <p><small>MELD, Model for End-stage Liver Disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons Score; TV, Tricuspid Valve</small></p>

Färber, G. et al., JThorCardiovascSurg 2022 67

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Parameters

- Age ≥ 70 years
- NYHA functional class III or IV
- Right-sided heart failure signs ⁽¹⁾
- Daily dose of furosemide ≥ 125 mg
- eGFR < 30 mL/min ⁽²⁾
- Elevated total bilirubin ⁽³⁾
- Left ventricular ejection fraction < 60 % ⁽⁴⁾
- Moderate/severe right ventricular dysfunction ⁽⁵⁾

Prediction

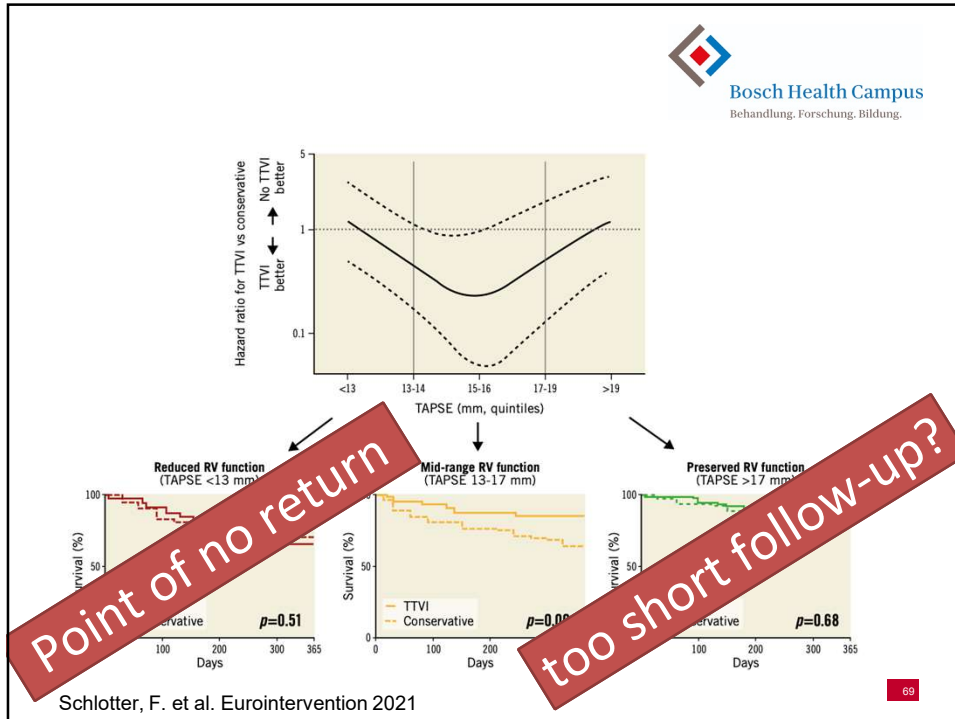
TRI-SCORE
7/12

Predicted in-hospital mortality
34 %

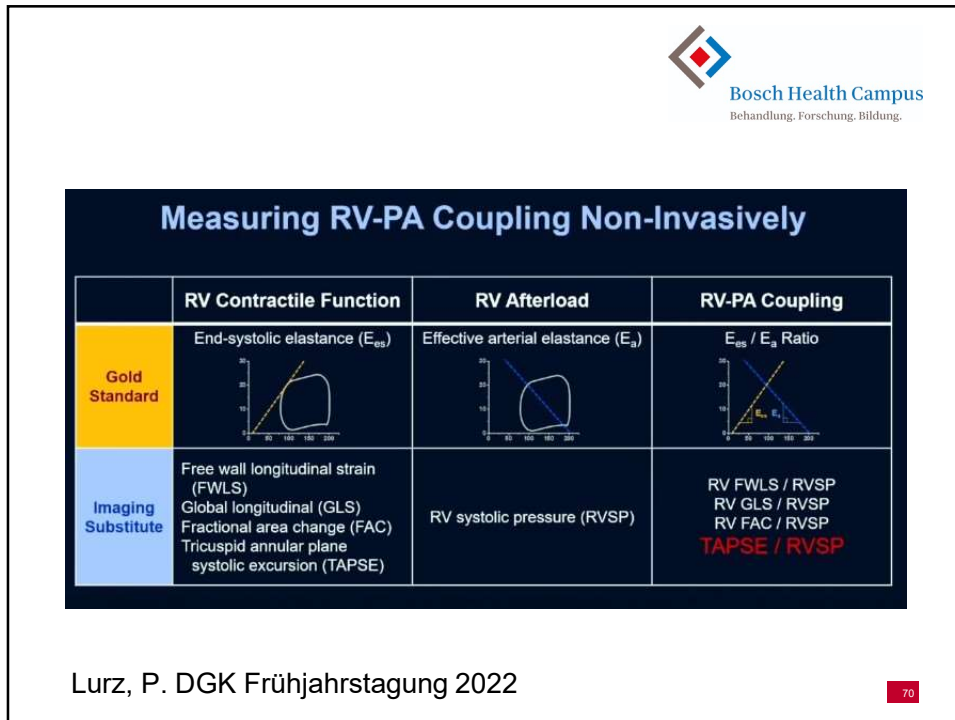
www.tri-score.com

Präsentation Robert-Bosch-Krankenhaus 68

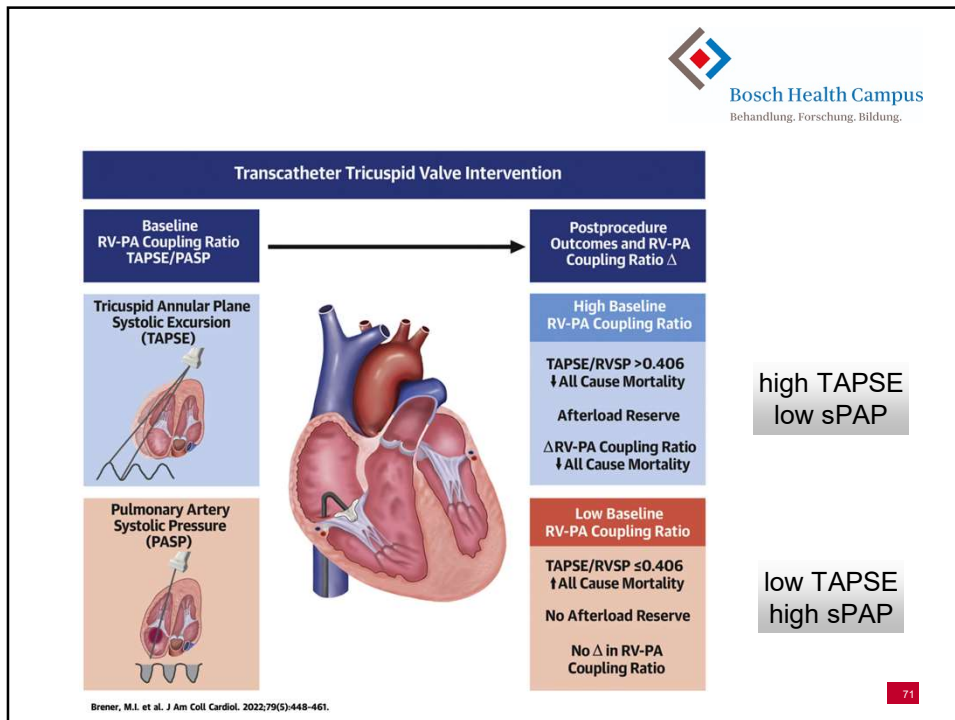
68



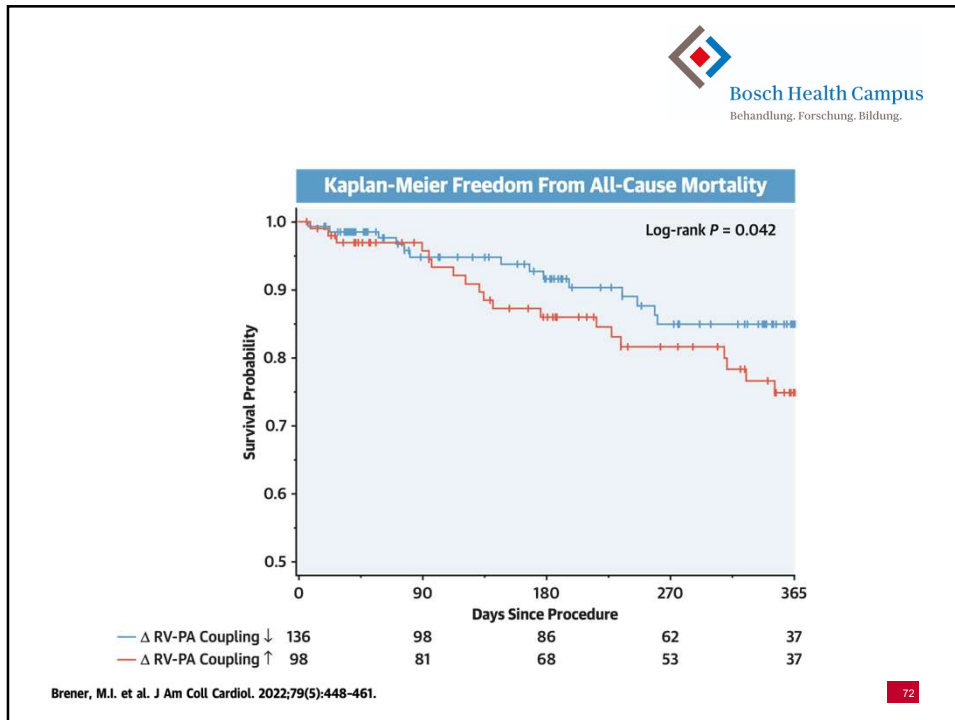
69



70



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...wenn die T-TEER nicht mehr geht...

- Koaptationsdefekte
- Dünne Segel
- Kurze Segel
- Verkalkung der Segel
- Verkalkung des Anulus
- Massive Ringdilatation
- Segel oft getethered
- Ursprung der TI zwischen Posterior und Anterior
- Chordaejungle
- Aszites
- Blutungen im Magenbereich/ gastrointestinaler Stau und vulnerabel Magenschleimhaut
- Schrittmacherinduzierte TI
- Valvula eustachii / Cor triatriatum
- Sehr abhängig von guter Visualisierung mittels TEE

COAPTATION GAP SIZE (mm)

7.0

8.0

9.0

10.0

11.0

TEER
commissural jet

Annuloplasty
central jet

Annuloplasty (± TEER)
moderate tethering

Transcatheter valve implantation

Caval devices
advanced disease
excessive annular dilatation

Praz, F., Bern 73

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...wenn die T-TEER nicht mehr geht...

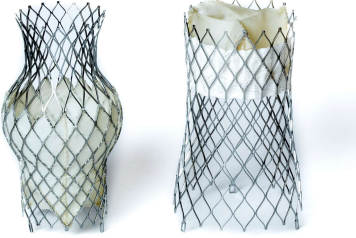
TricValve®, Fa. Products & Features®

74

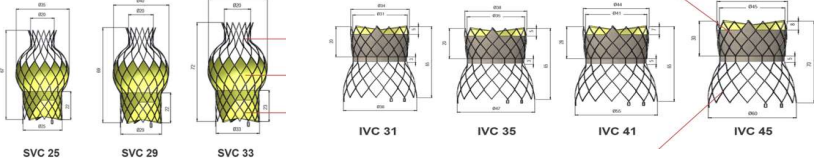
74

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TRICVALVE® MODEL	VALVE SIZE	PROXIMAL DIAMETER	DISTAL DIAMETER	MAXIMAL DIAMETER	LENGTH AFTER DEPLOYMENT
SVC 25	25	25	20	35	66
SVC 29	29	29	20	40	69
IVC 31	31	34	38	38	65
IVC 35	35	38	47	47	65



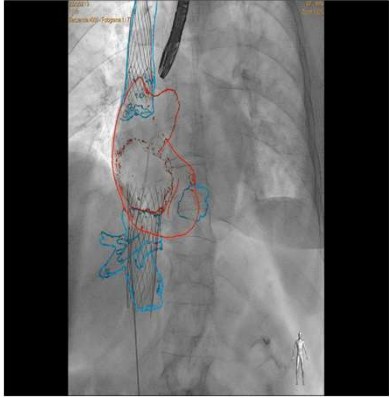
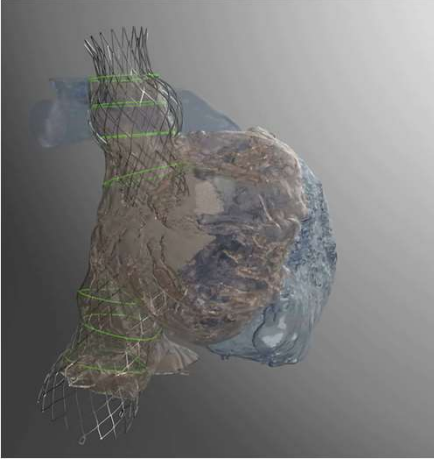
Größen IVC 41, IVC 45 und SVC 33 aktuell nicht CE-Zertifiziert

75

75

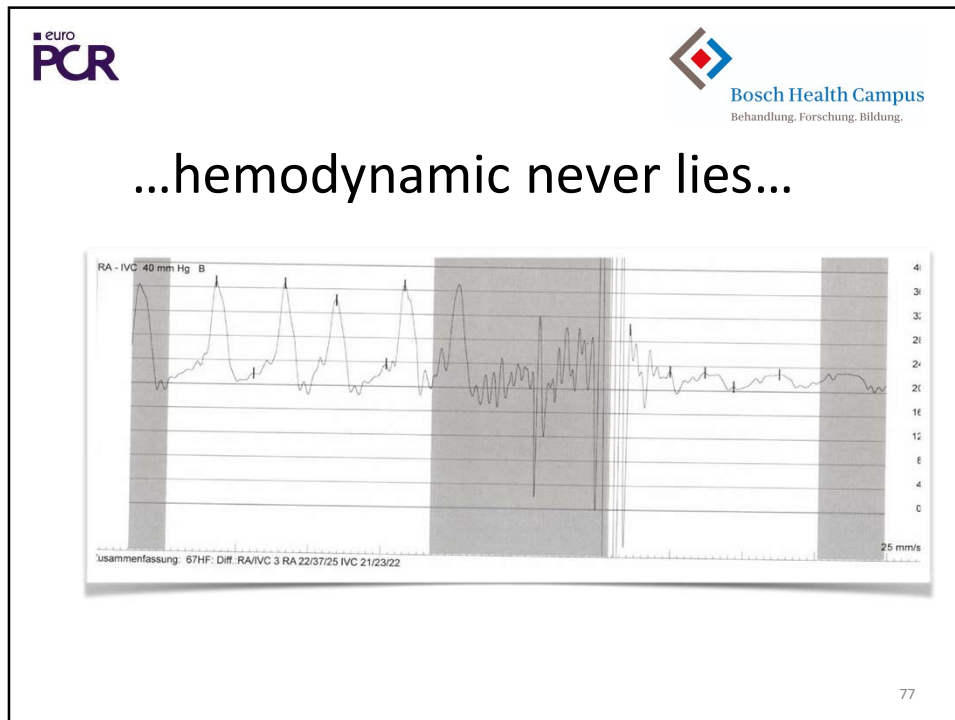
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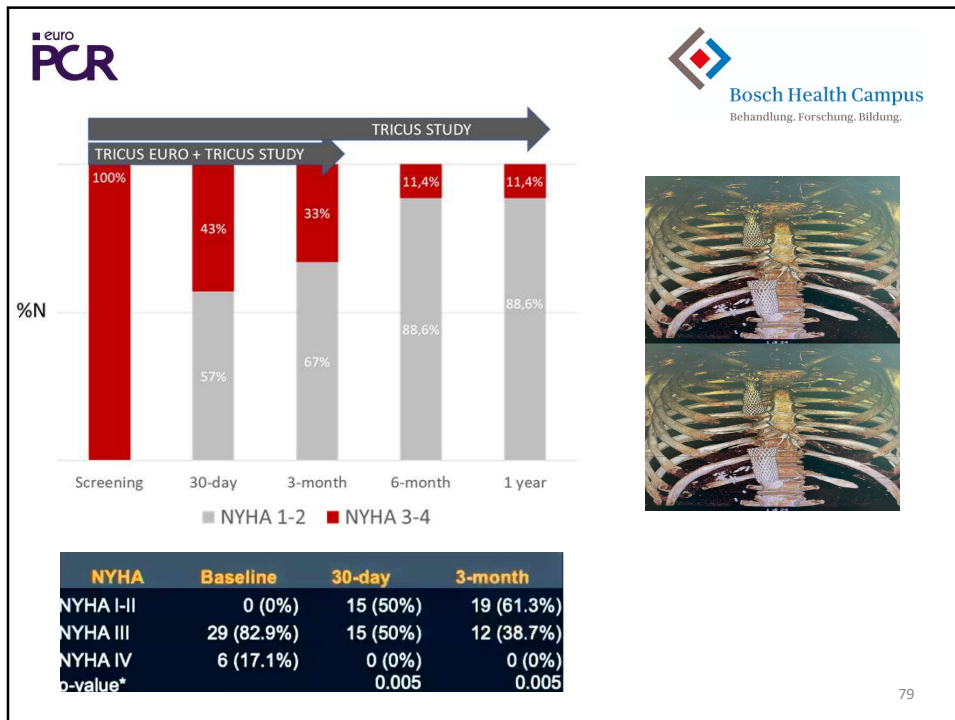
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Variables	TRICUS N = 9 (%)	TRICUSEuro N = 35 (%)
In-Hospital mortality	0	0
Stroke/TIA	0	0
Number of valves implanted	17	70
Procedural success	8 (89)	33 (94)
Device embolization/migration	1 (11)*	1 (3)^
Conversion to surgery	1 (11)*	0 (0)
Cardiac tamponade	0 (0)	0 (0)
Access site bleeding	0 (0)	3 (9)
Non-access site bleeding	0 (0)	0 (0)
New pacemaker implantation	0 (0)	1 (3)^
Length of hospital stay (days)	9 ± 3	9 ± 8

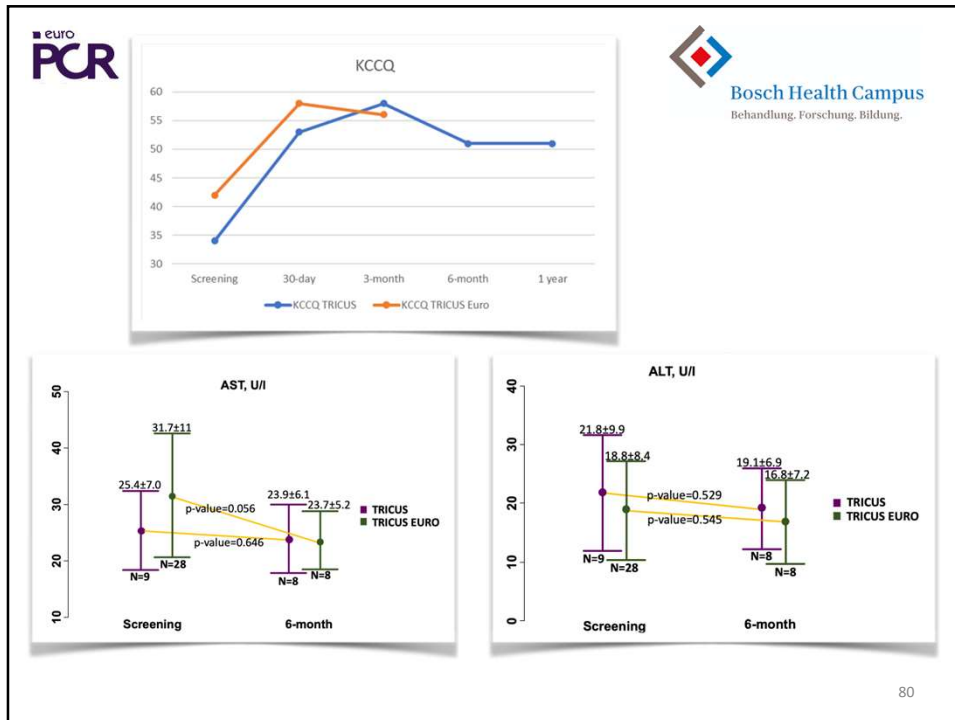
*Immediate embolization + Surgery
^Embolization at 24h + Conservative management

78

78




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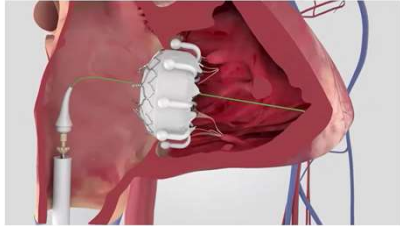
80

TTVR

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Unique valve design
engages leaflets, chords, and annulus to achieve secure placement






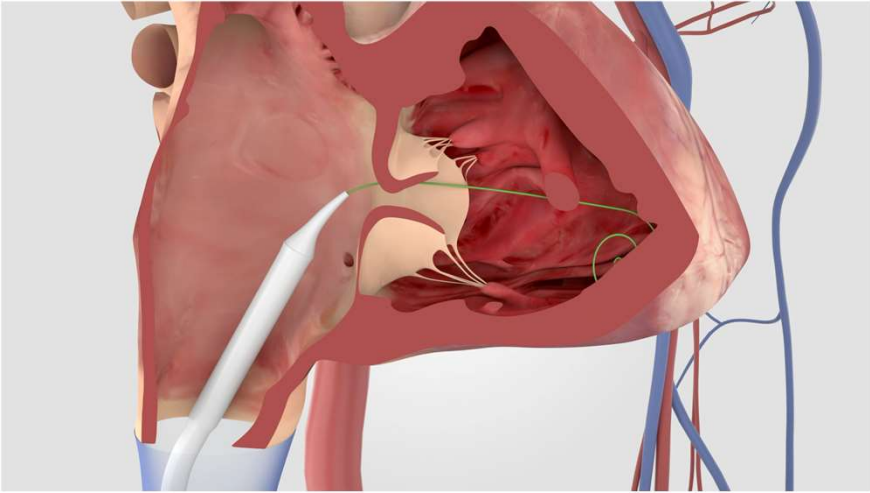
Anchors compatible with pre-existing leads and respect the native anatomy
Conforming frame designed to achieve optimal retention force
Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (44, 48, 52 mm)
28F transfemoral delivery system compatible with all valve sizes

81

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EVOQUE® -Procedure

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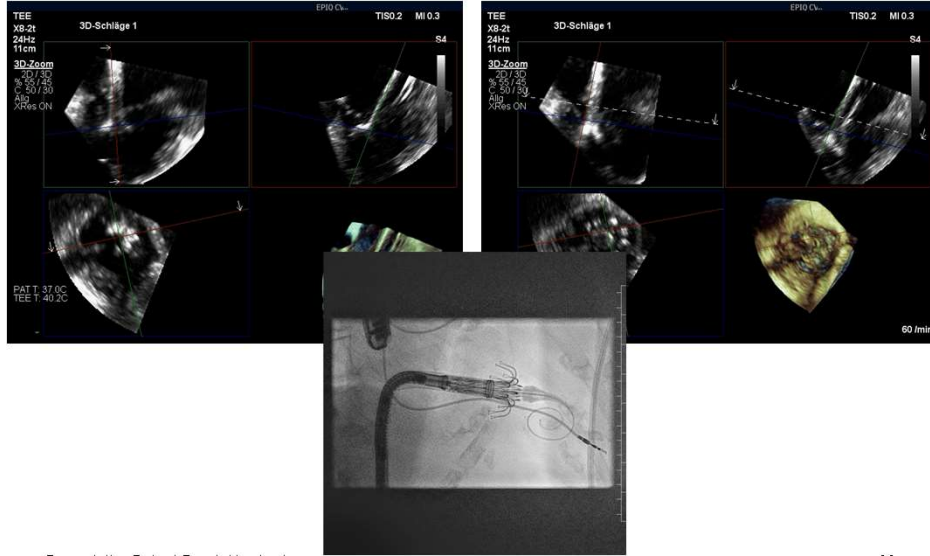
82

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Pat B.D., 85 Jahre, weiblich



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TEE 3D-Schläge 1
XB-2t 24Hz 11cm
3D-Zoom
PAT T: 37.0°C
TEE T: 30.2°C

TEE 3D-Schläge 1
XB-2t 24Hz 11cm
3D-Zoom
PAT T: 37.0°C
TEE T: 30.2°C

60 l/min

Präsentation Robert-Bosch-Krankenhaus

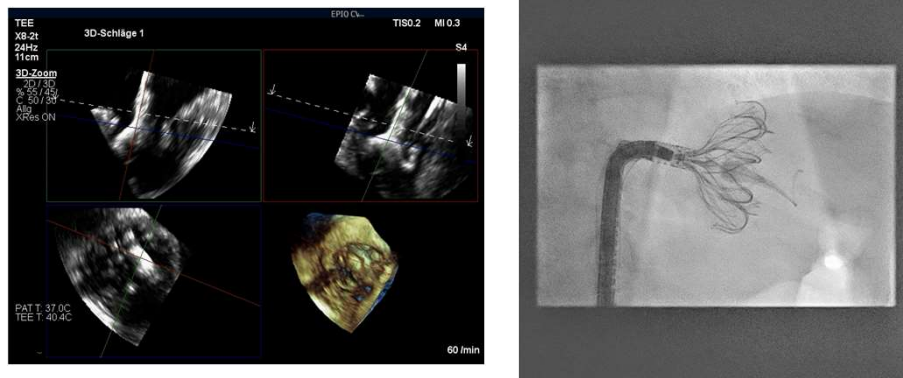
83

83

Pat B.D., 85 Jahre, weiblich



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Behandlung, Forschung, Bildung.



TEE 3D-Schläge 1
XB-2t 24Hz 11cm
3D-Zoom
PAT T: 37.0°C
TEE T: 40.4°C


60 l/min

Präsentation Robert-Bosch-Krankenhaus

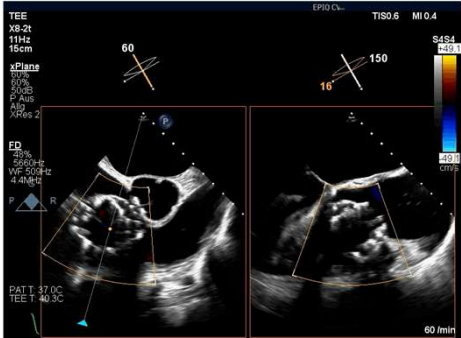
84


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Pat B.D., 85 Jahre, weiblich



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Präsentation Robert-Bosch-Krankenhaus 85

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TTVR - EVOQUE®



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$\Delta = 77.1\%$
 $p < 0.001^a$

Baseline

Group	None/Tra	Mild	Moderate	Severe	Massive	Torrentia
EVOQUE +OMT (n=81)	45.7	22.2	32.1			
OMT Alone (n=37)	45.9	29.7	24.3			

6 Months

Group	None/Tra	Mild	Moderate	Severe	Massive	Torrentia
EVOQUE +OMT ^b (n=81)	77.8	16.0	4.9	1.2		
OMT Alone (n=37)	5.4	16.2	27.0	27.0	24.3	

98.8% ≤ moderate

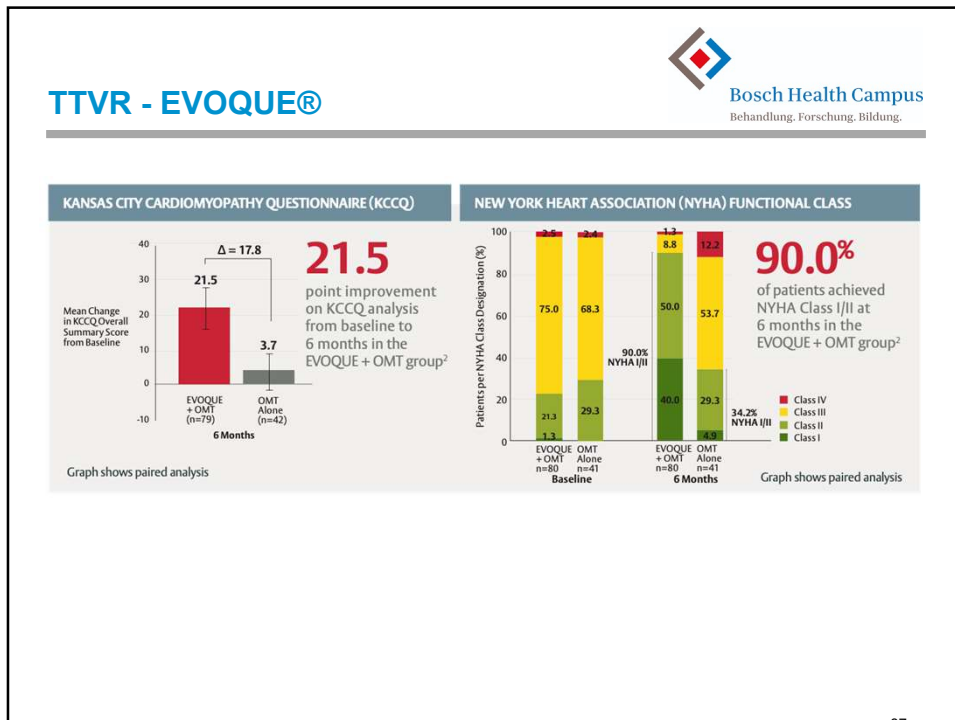
93.8% ≤ mild

21.6% ≤ moderate

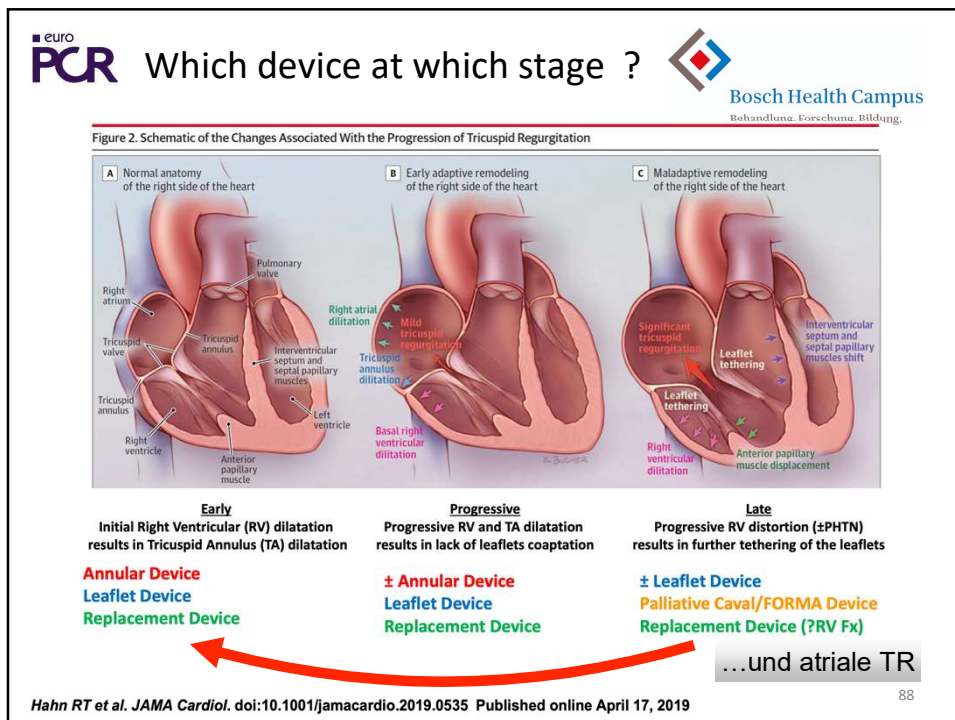
- Torrentia
- Massive
- Severe
- Moderate
- Mild
- None/Tra

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86



87



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Was sollten Sie mitnehmen

Die TAVI setzt sich gegenüber dem SAVR zunehmend als Standardverfahren durch, auch zunehmend bei low-risk-Patienten, auch symptomatische Patienten sollten interveniert werden

Bei hohem Risiko für eine Mitralklappen-OP ist die TEER eine gute Alternative bei primärer Mitralklappeninsuffizienz

Bei sekundärer Mitralklappeninsuffizienz setzt sich die TEER immer mehr als Standardverfahren durch (nach GDMT)

TEER der Trikuspidalklappe ist aktuell die am Besten untersuchte Methode der Intervention

Für sehr selektierte Patienten stehen Klappenersatzverfahren zur Verfügung

Langzeitdaten für alle Interventionen an der Trikuspidalklappe fehlen

Seien Sie nicht zu spät (bei keinem Klappeneingriff)!

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89



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Behandlung, Forschung, Bildung.

Raffi Bekerredjian
Christian Wunder
Bartosz Rylski
Philipp Nikolai
Lisa Kettler
Betül Eker-Dayi
Maria Chatzitofi
Zineb Moussaoui
Yaren Acar
Dominik Bierbaum
Ragi Nagib
Laura Wiedemann



Vielen Dank

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90