



Interventionelle Behandlung der Herzinsuffizienz bei koronaren und strukturellen Herzerkrankung

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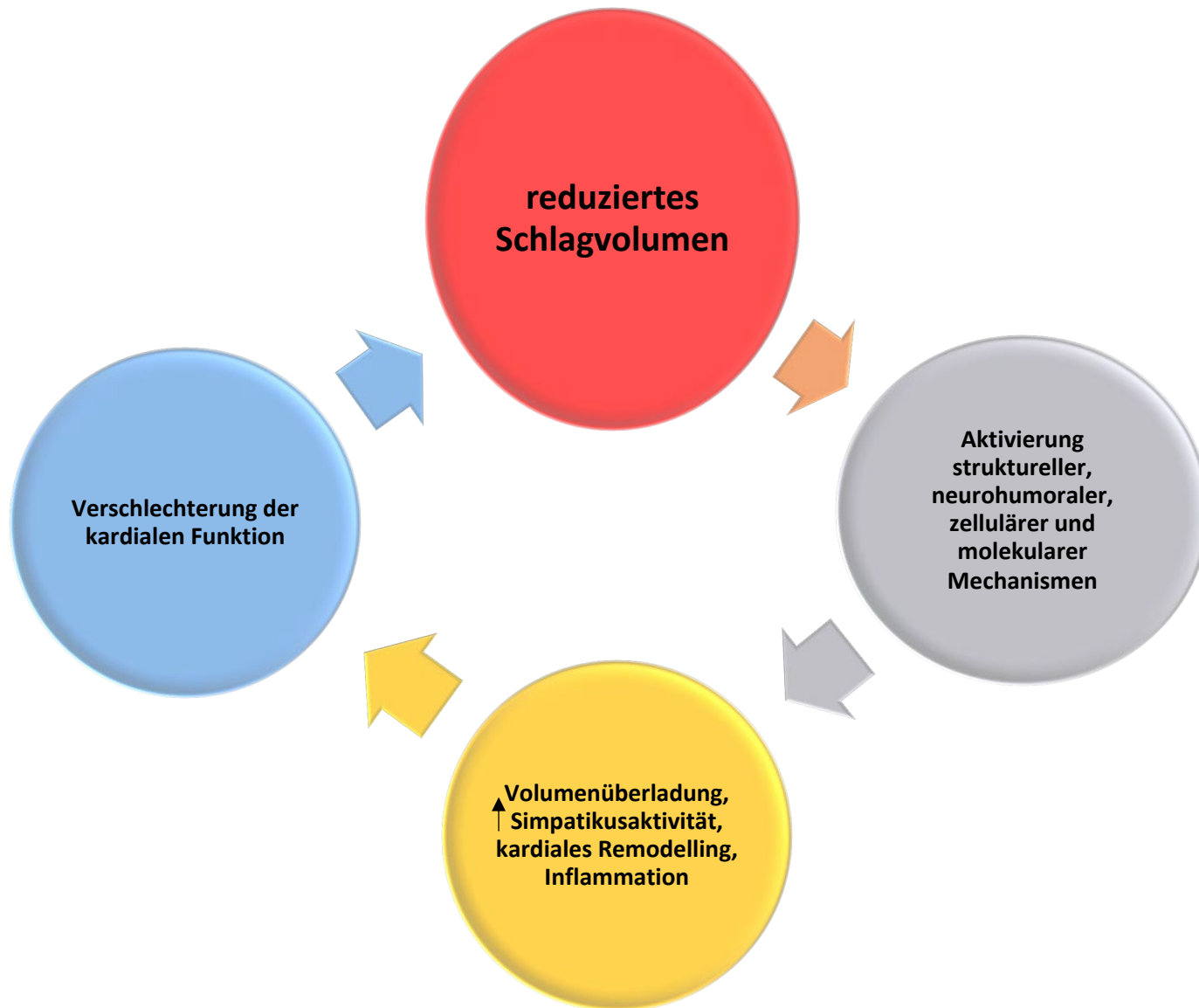


Interessenskonflikte:

keine

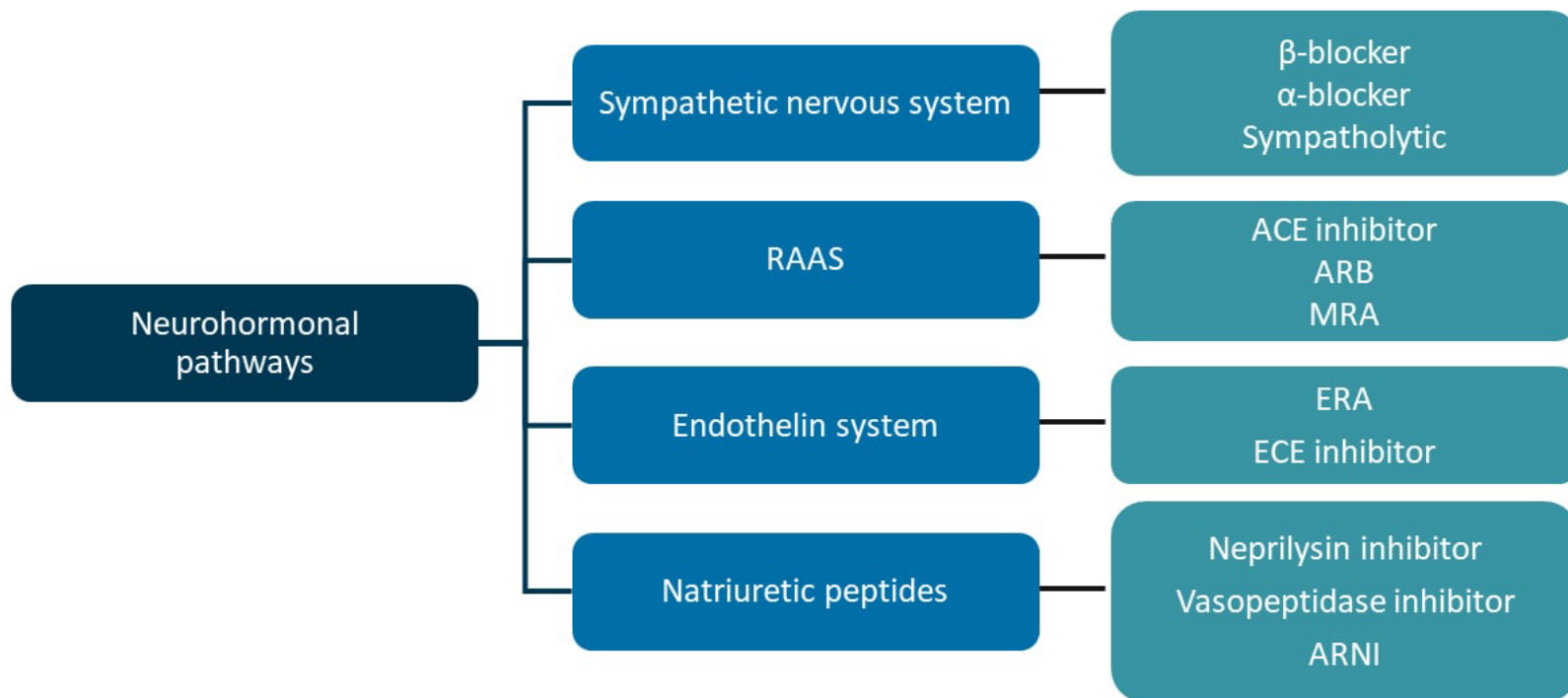


Herzinsuffizienz: Circulus vitiosus



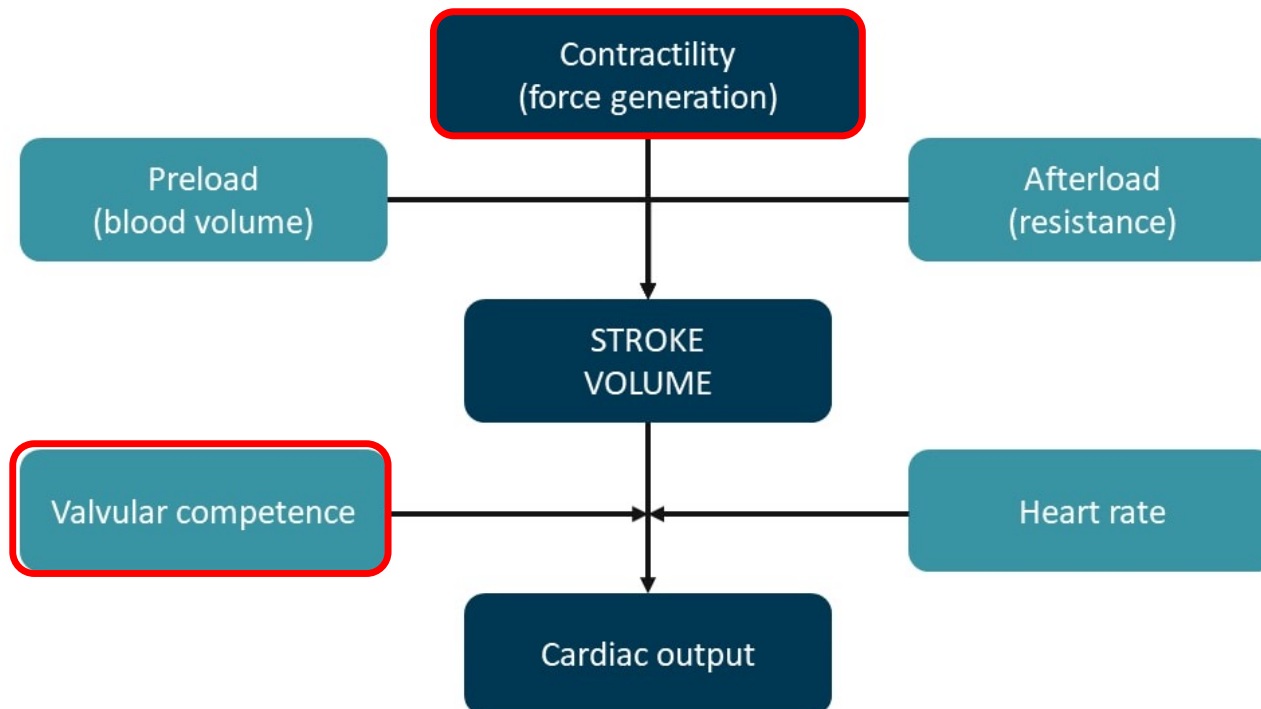


Neurohormonal Pathway in HFrEF





Decreased Contractility Is Central to HFrEF Pathophysiology



Kemp CD, et al. *Cardiovasc Pathol*. 2012;21:365-371.



Intraatrialer Shunt für Druckdekompression bei Herzinsuffizienz

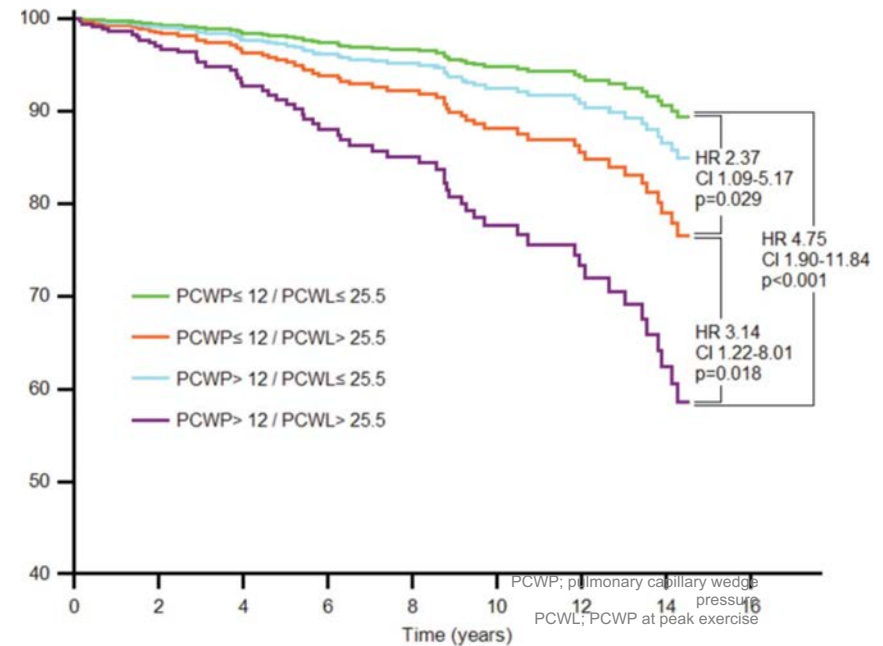
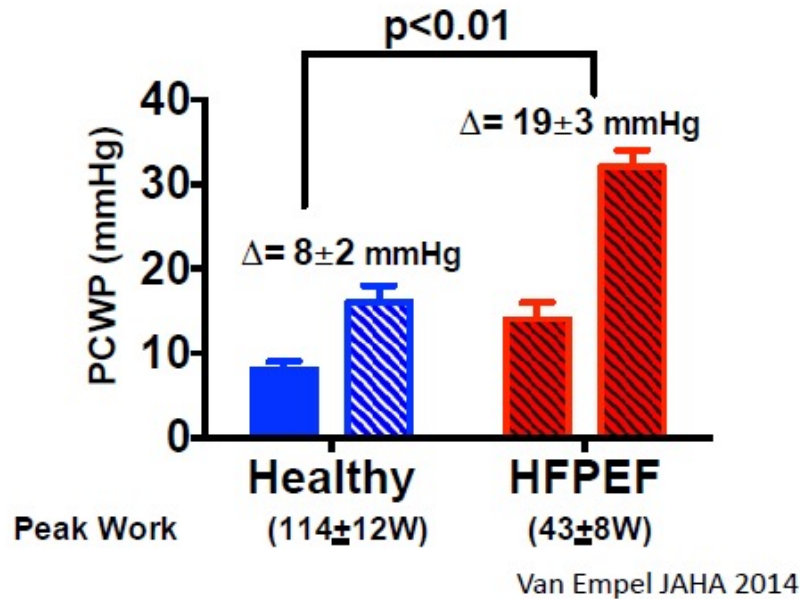
Hintergrund, Technik, erste Ergebnisse

Lebenserwartung und PCWP



Erhöhter LAD (PCWP>25) ist ein häufiger Befund bei Patienten mit HFrEF

Mortalität steigt mit steigendem PCWP, gleich ob in Ruhe oder unter Belastung



*PCWP = LAP = LVEDP

ASD und Herzinsuffizienz

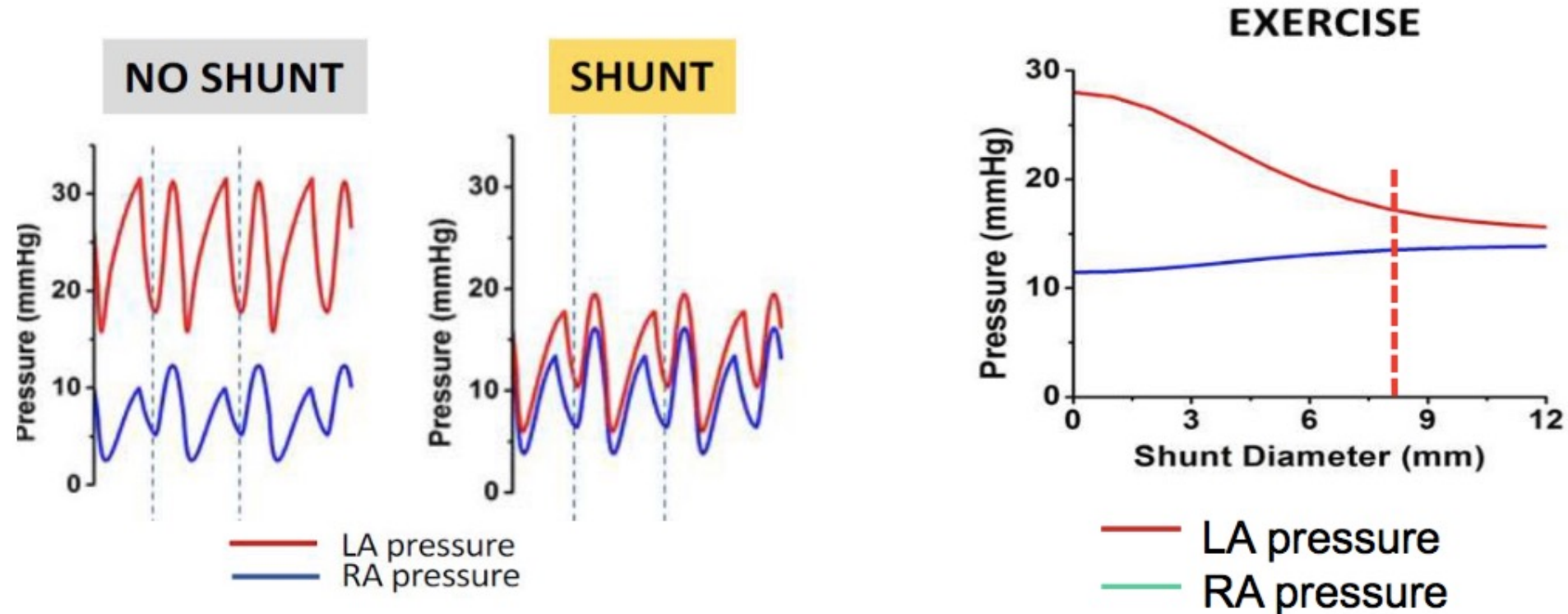


- Lutembacher Syndrom
 - Patienten mit schwerer Mitralklappenstenose und ASD sind weniger symptomatisch als Patienten ohne ASD
- Bei schwerer Mitralklappenstenose hat man für Symptomlinderung einen ASD erzeugt
- Später auch für andere Patienten mit schwerer Linksherzinsuffizienz (auch ECMO-Patienten)

Dekompression des linken Vorhofes



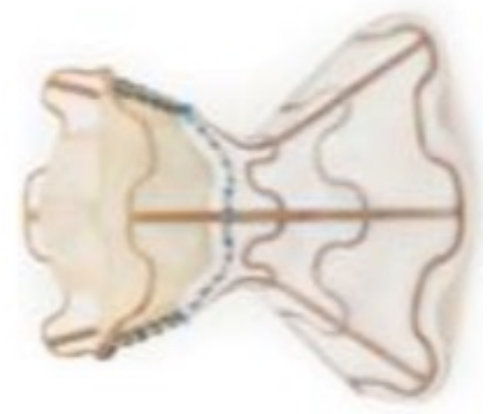
Eine Computersimulation zeigte, wie ein 8 mm großer ASD während der Belastung zu rascher Druckreduktion im LA führt

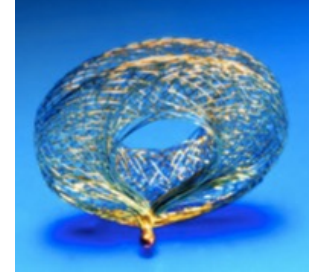


Wie erzeugt man einen ASD?



- Ballondilatation
- Stent
- Corvia Device
- V-Wave
- Occlutech AFR



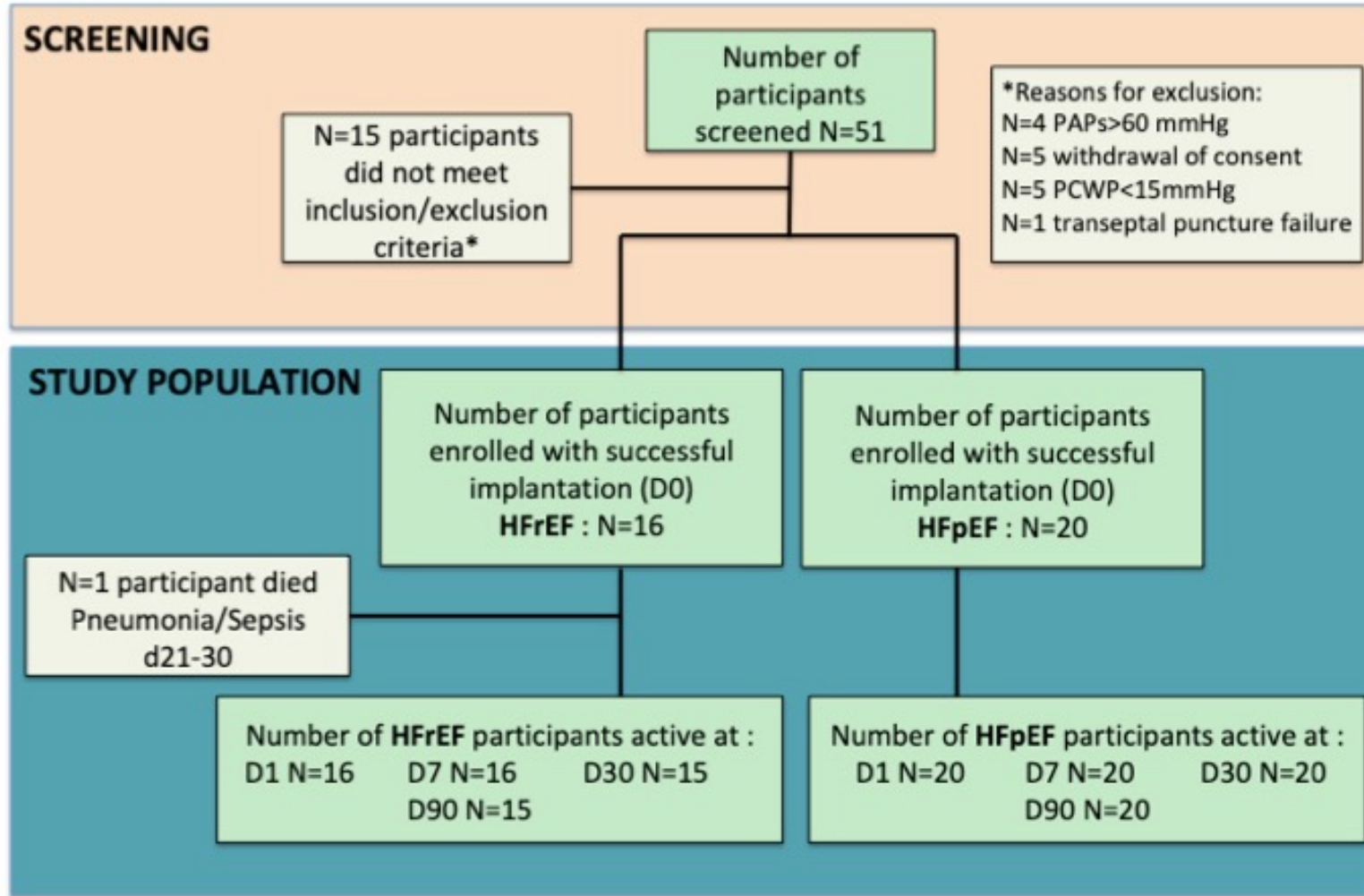


AFR-PRELIEVE- Studie

AFR-Wirkung bei Patienten mit Herzinsuffizienz
(HFrEF u. HFpEF)

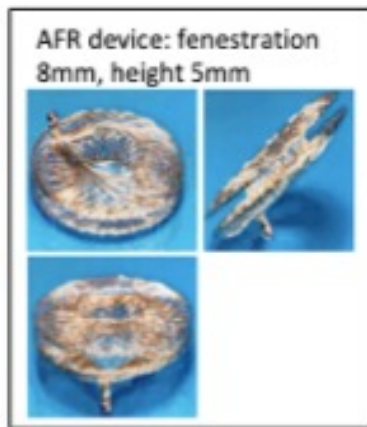
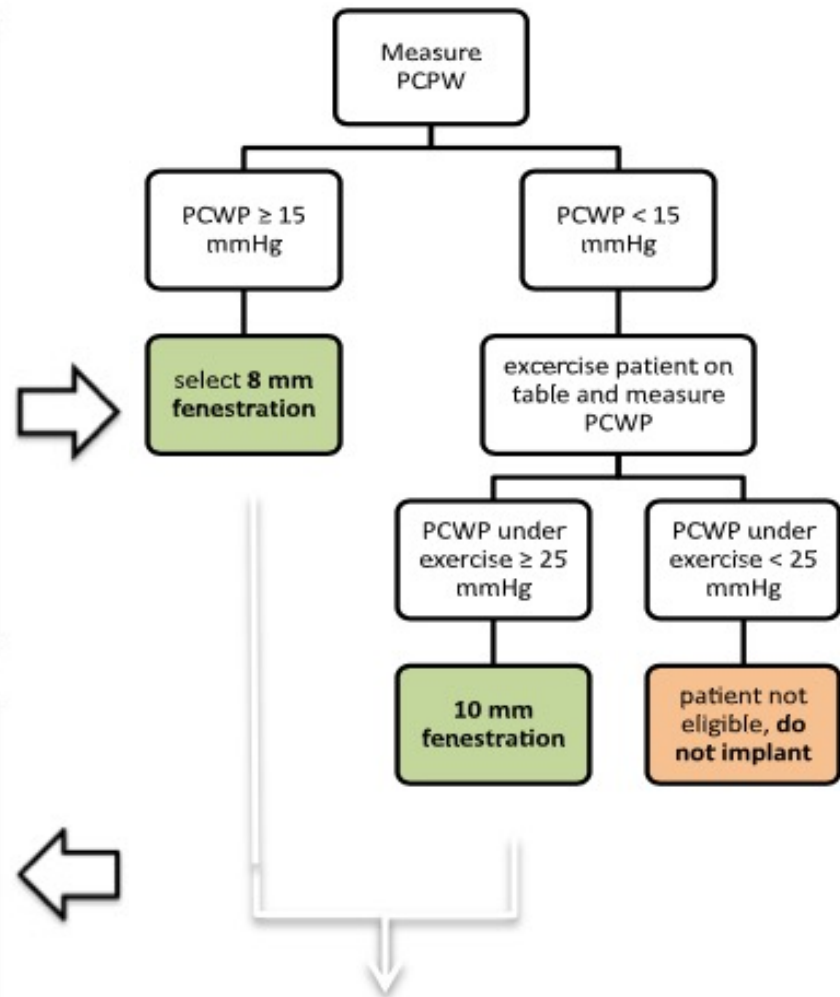
- Prospektive, multizentrische nicht randomisierte Pilot-Studie:
- Primärer Endpunkt
 - Sicherheit 3 Monate nach Implantation
- Sekundäre Endpunkte
 - Sicherheit 12 Monate nach Implantation
- Effektivität wird durch Offenheit, Hämodynamik und Symptome beurteilt
- Kontrolluntersuchungen am Tag 1,7,30,90,180,360

AFR-PRELIEVE- Studie





AFR-PRELIEVE- Studie



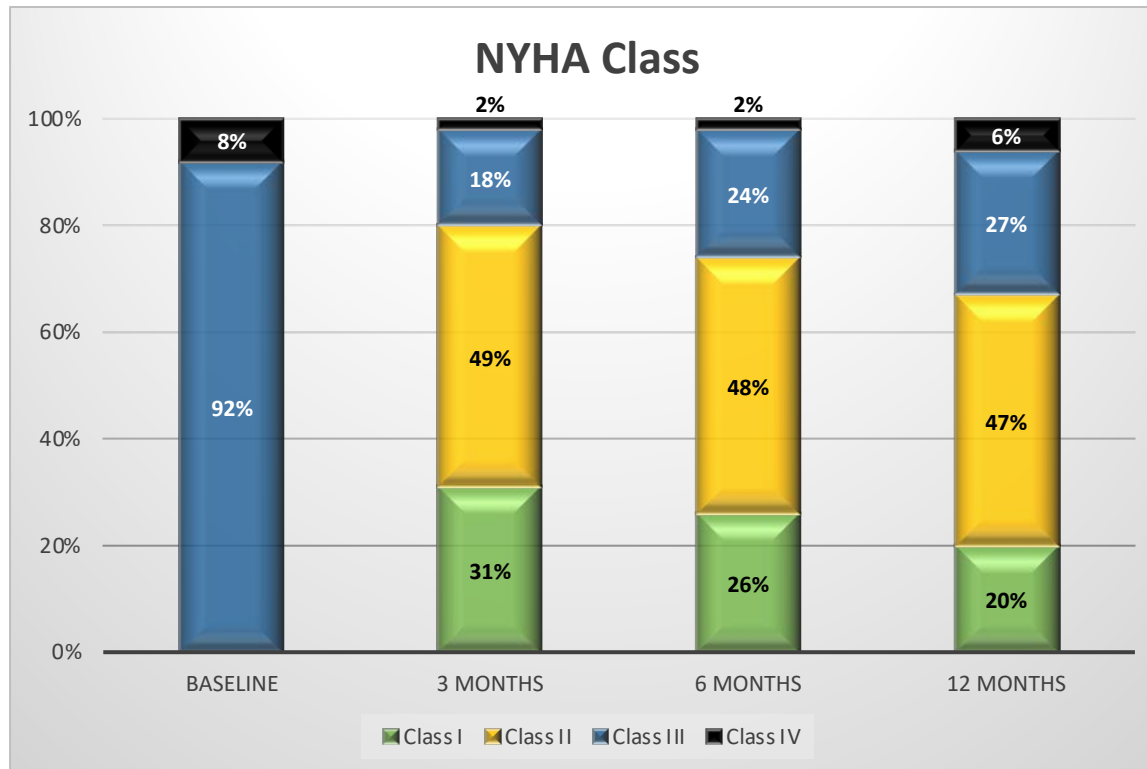
Septal thickness	Height of the device (h)
≤ 5 mm	5mm
≥ 6 up to 10mm	10mm

AFR-PRELIEVE- Studie



NYHA Class at 1-year

PRELIEVE Trial – AFR in HFrEF and HFpEF patients



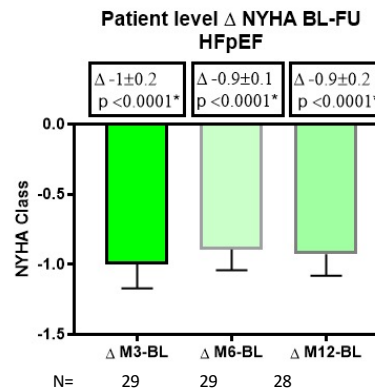
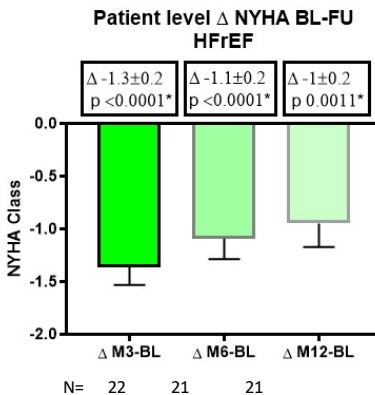
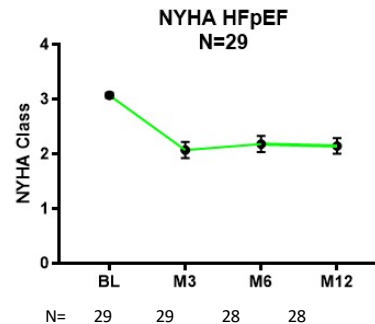
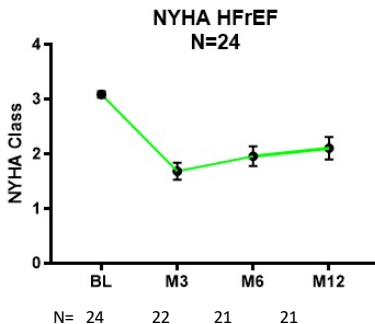
(1) Paitazoglou C, et al. *European Journal of Heart Failure* 2021 doi:10.1002/ehjhf.2119



AFR-PRELIEVE- Studie

NYHA Class at 1-year

PRELIEVE Trial – AFR in HFrEF and HFpEF patients



Besserung der NYHA Klasse sowohl
für HFrEF als auch für HFpEF

(1) Paitazoglou C, et al. European Journal of Heart Failure 2021 doi:10.1002/ehj.2119

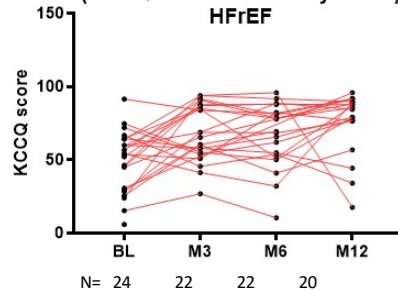
AFR-PRELIEVE- Studie



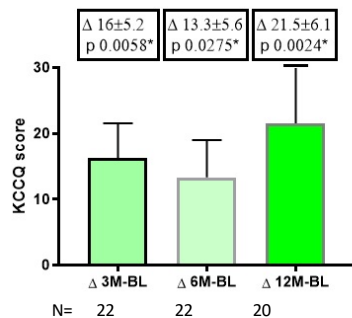
Quality of Life (QoL) at 1-year

PRELIEVE Trial – AFR in HFrEF and HFpEF patients

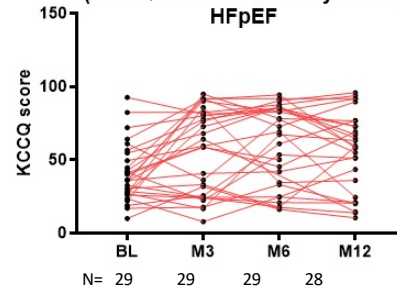
Kansas City Cardiomyopathy Questionnaire
(KCCQ overall summary score)



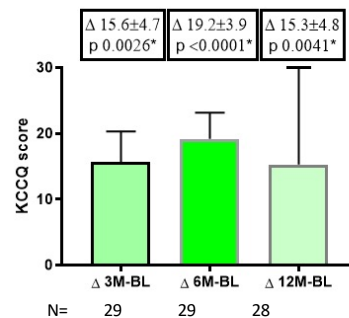
Individual patient level
 Δ KCCQ score FU vs. baseline
HFrEF



Kansas City Cardiomyopathy Questionnaire
(KCCQ overall summary score)



Individual patient level
 Δ KCCQ score FU vs. baseline
HFpEF



Besserung der QoL sowohl für
HFrEF als auch für HFpEF

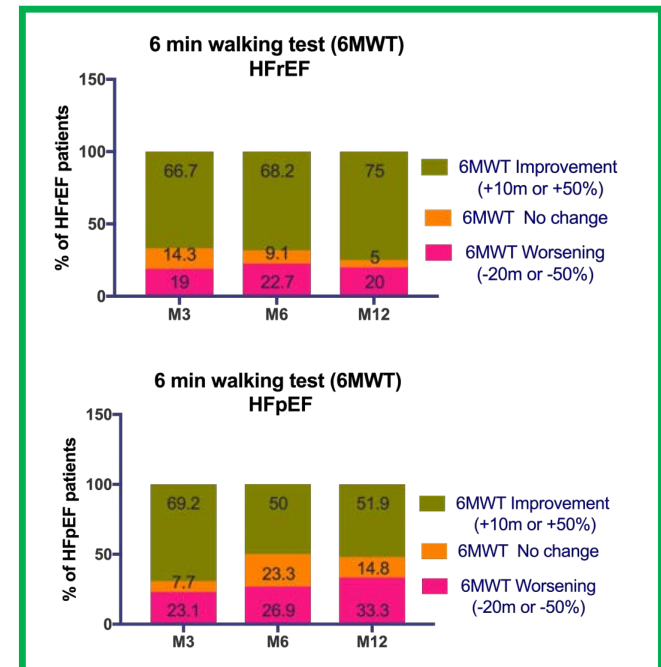
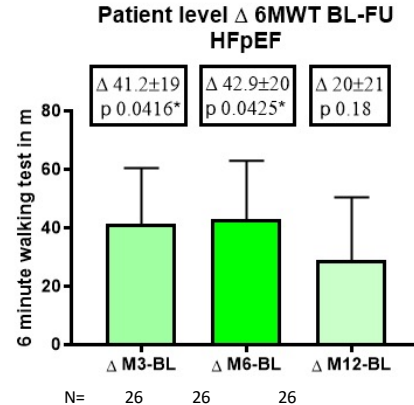
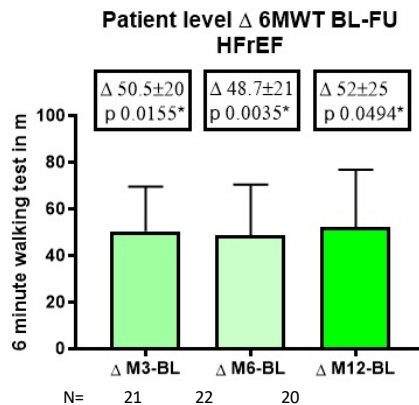
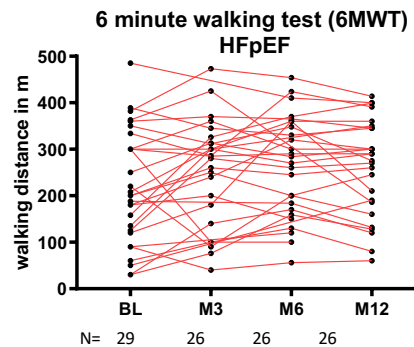
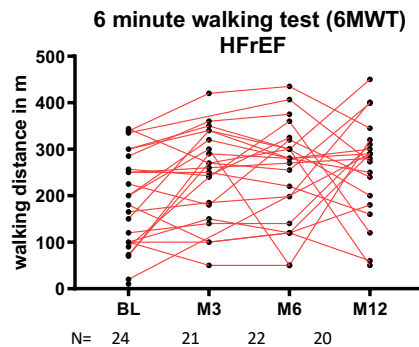
(1) Paitazoglou C, et al. European Journal of Heart Failure 2021 doi:10.1002/ehjhf.2119

AFR-PRELIEVE- Studie



6 Minute Walking Distance (6MWD) at 1-year

PRELIEVE Trial – AFR in HFrEF and HFpEF patients





- IAS führt bei Patienten mit Herzinsuffizienz zu Druckreduktion im LA, Besserung der Dyspnoe, Belastbarkeit und ihrer Lebensqualität
- Dieses Konzept funktioniert bei Patienten mit reduzierter LVEF
- Es scheint auch bei Patienten mit erhaltener LV Funktion zu funktionieren
- Weitere Studien sind notwendig

Interventionelle Therapie der Aortenklappenstenose

Randomized Trials of TAVI in Low Risk Patients

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

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

Hans Gustav Flörke Thynegod, MD,* Daniel Andreas Steinbrüchel, MD, DMSc,* Nikolaj Blomhøj, MD, PhD,* Henrik Nissen, MD, PhD,* Bo Juel Kjeldsen, MD, PhD,* Peter Petursson, MD,* Yanping Chang, MS,* Olaf Walter Fransen, MD,* Thomas Engström, MD, DMSc,* Peter Clemmensen, MD, DMSc,* Peter Bo Hansen, MD,* Lars Willy Andersen, MD, DMSc,* Peter Skov Olsen, MD, DMSc,* Lars Søndergaard, MD, DMSc



NOTION



UK TAVI

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

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. Goldman, 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*

PARTNER 3

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubasher Muntaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Meeks, D.O., Neal S. Kleiman, M.D., Judith Aschew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn, III, M.D., John K. Forrest, M.D., Didier Tchiksché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Bouhassira, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*

EVOLUT LR



Summary of Low Risk Trials in TAVI

	Evolut LR	Partner 3	Notion	UK TAVI
Years	2016-2018	2016-2017	2009-2013	2014-2018
N	1468	1000	280	913
Age	74	73	79.1	81
Valve	CoreValve/ Evolut R/ PRO	Sapien 3	CoreValve	12 Valves/ Models
Inclusion	STS PROM <3	STS PROM <4	Age >70	Age >80 > 70 Int/High Risk
Bicuspid	0	0	0	Not Excluded
STS PROM	1.9%	1.9%	3.0%	2.6%
Primary Endpoint	Two Year Death/Disabling Stroke	One Year Death/Stroke/ Rehospitalization	One Year Death/Stroke/MI	One Year Mortality



Summary of Low Risk Trials in TAVI

	Evolut LR	Partner 3	Notion	UK TAVI
Primary Endpoint	Two Year Death/Disabling Stroke	One Year Death/Stroke/Rehospitalization	One Year Death/Stroke/MI	One Year Mortality
Results	TAVR non-inferior to surgery at 24 months	Rate of primary endpoint significantly lower with TAVR	No significant difference TAVR/SAVR at one year	TAVR is not inferior to surgery

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

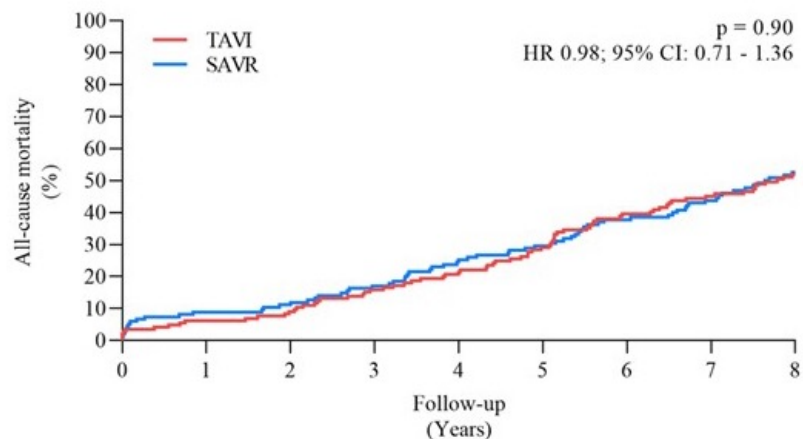
Troels Højsgaard Jørgensen^{1*†}, Hans Gustav Hørsted Thyregod^{2†}, Nikolaj Ihlemann³, Henrik Nissen ³, Petur Petursson⁴, Bo Juel Kjeldsen⁵, Daniel Andreas Steinbrüchel⁶, Peter Skov Olsen², and Lars Søndergaard¹

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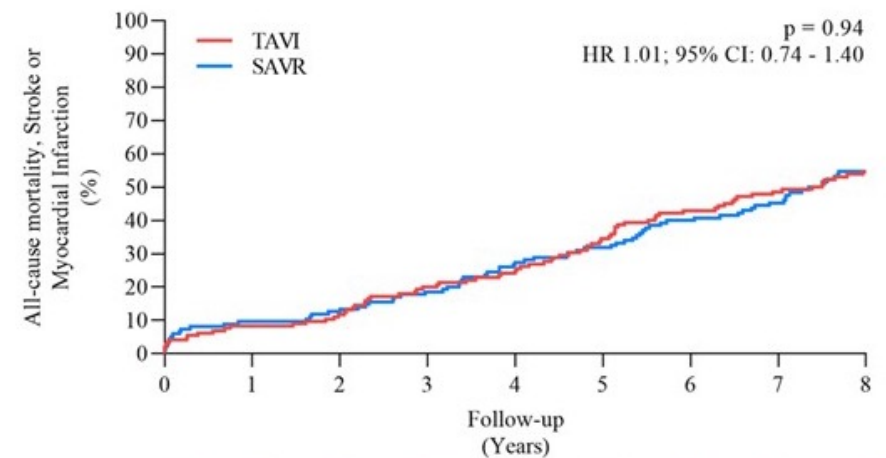
Received 15 February 2021; revised 14 April 2021; editorial decision 25 May 2021; accepted 4 June 2021; online publish-ahead-of-print 28 June 2021

See page 2920 for the editorial comment on this article (doi: [10.1093/eurheartj/ehab393](https://doi.org/10.1093/eurheartj/ehab393))

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement



TAVI	145	136	132	122	115	101	86	78	64
SAVR	135	123	120	112	102	95	83	74	57



TAVI	145	133	128	116	110	93	81	73	60
SAVR	135	122	118	110	99	92	80	73	54

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

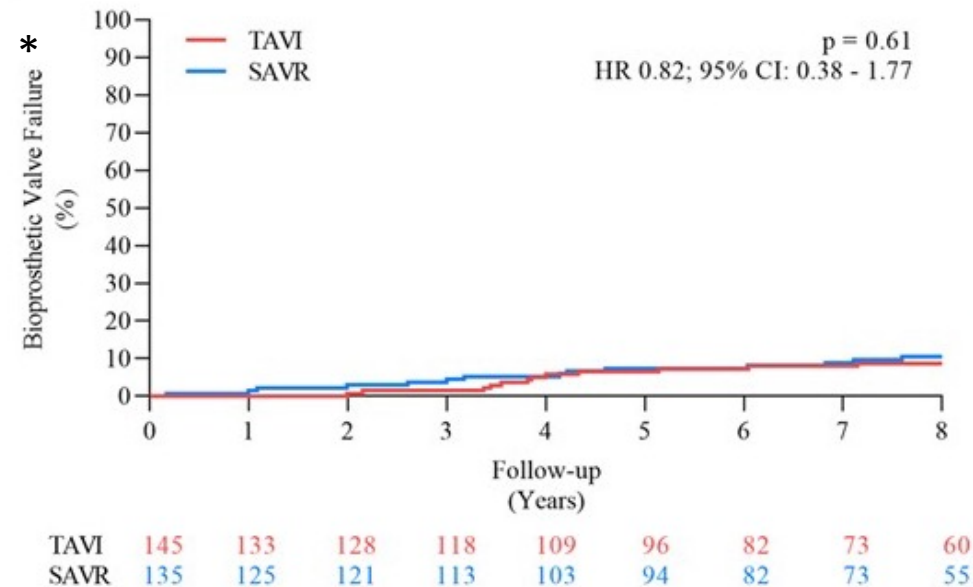
	TAVI (n = 145)	SAVR (n = 135)	P-value
All-cause mortality	51.8 (8.5)	52.6 (8.7)	0.90
Cardiovascular death	40.6 (6.6)	43.6 (7.2)	0.64
Stroke	8.3 (1.4)	9.1 (1.7)	0.90
Transient ischaemic attack	7.6 (1.3)	5.3 (0.9)	0.41
Myocardial Infarction	6.2 (1.1)	3.8 (0.6)	0.33
New-onset atrial fibrillation	50.0 (18.5)	74.1 (<u>53.1</u>)	<0.0001
New permanent pacemaker	42.5 (<u>11.0</u>)	10.9 (1.9)	<0.0001

Risk estimates are % and (per 100 person-years).

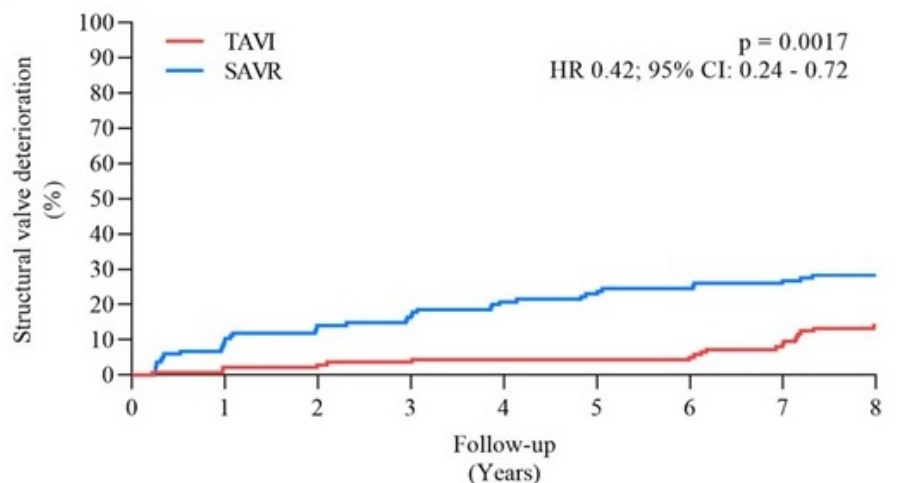
SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation

Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement

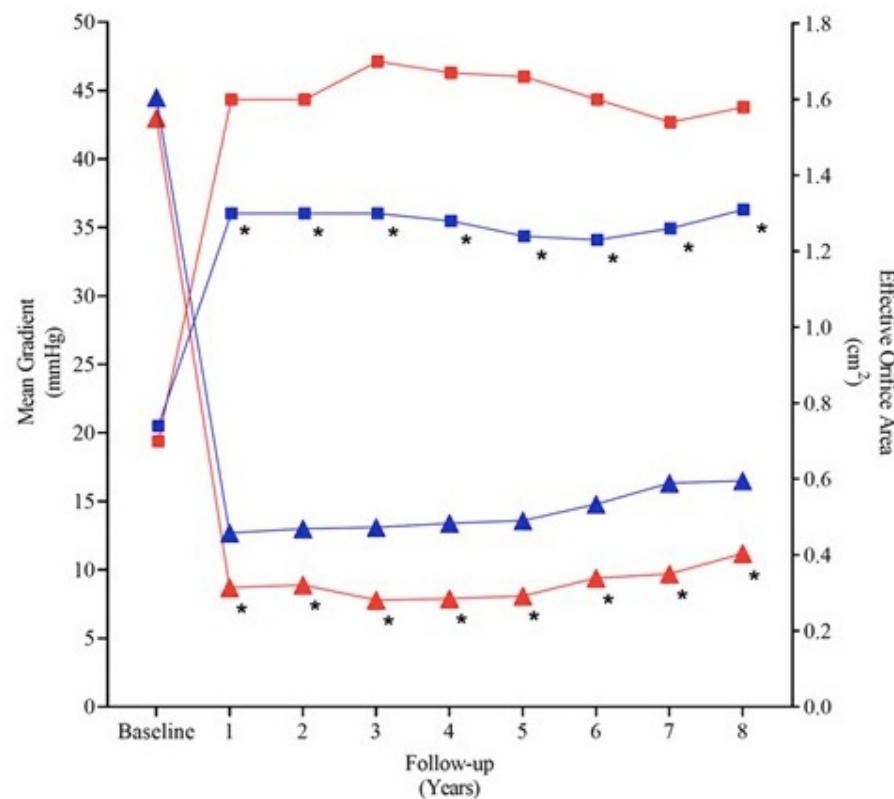
	TAVI (n = 139)	SAVR (n = 135)	P-value
Bioprosthetic valve failure	8.7	10.5	0.61
– Valve-related death	5.0	3.7	0.60
– Severe structural valve deterioration	2.2	6.8	0.068
– Aortic valve re-intervention	3.6	2.3	0.51



Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement



TAVI	145	130	126	115	107	94	80	68	50
SAVR	135	113	105	97	84	75	62	54	40



▲ TAVI - Gradient	124	122	105	107	96	79	67	58	44
▲ SAVR - Gradient	117	116	109	106	96	84	70	56	46
■ TAVI - EOA	125	118	118	87	82	76	56	47	44
■ SAVR - EOA	118	116	111	95	77	83	61	51	42

St Jude Medical Epic®, 29%;
Medtronic Mosaic®, 27%;
St Jude Medical Trifecta®, 24%;
Carpentier-Edwards Perimount®, 10%;
Sorin Mitroflow®, 10%
vs. I Generation CoreValve

Konsensuspapier der Deutschen Gesellschaft für Kardiologie (DGK) und der Deutschen Gesellschaft für Thorax-, Herz- und Gefäßchirurgie (DGTHG) zur kathetergestützten Aortenklappenimplantation (TAVI) 2020

Der Kardiologe

Konsensuspapiere

Kardiologie 2020 · 14:182–204

<https://doi.org/10.1007/s12181-020-00398-w>

Online publiziert: 27. Mai 2020

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Tab. 4 Vom Herz-Team zu berücksichtigende Aspekte für die Entscheidung zwischen AKE und TAVI

	Favorisiert TAVI	Favorisiert AKE
<i>Klinische Charakteristika</i>		
Schwere Komorbidität (nicht adäquat im Score abgebildet)	+	
Früherer herzchirurgischer Eingriff	+	
Gebrechlichkeit	+	
Eingeschränkte Mobilität und Umstände, die den Rehabilitationsprozess nach dem Eingriff beeinträchtigen können	+	
Verdacht auf Endokarditis		+
<i>Anatomische und technische Aspekte</i>		
Günstiger Zugang für eine transfemorale TAVI	+	
Ungünstiger Zugang (jeglicher) für eine TAVI		+
Folgeschäden einer Thoraxbestrahlung	+	
Porzellanaorta	+	
Vorhandensein intakter koronarer Bypass-Grafts, die durch eine Sternotomie gefährdet sind	+	
Patienten-Prothesen-Mismatch wird erwartet	+	
Schwere Thoraxdeformation oder Skoliose	+	
Geringer Abstand zwischen Koronarostien und Aortenklappenannulus		+
Größe des Aortenklappenannulus „out of range“ für eine TAVI		+
Aortenwurzelmorphologie ungünstig für eine TAVI		+
Klappenmorphologie (bikuspid, Kalzifizierungsgrad und -muster) ungünstig für eine TAVI		+
Thromben in der Aorta oder dem LV vorhanden		+
<i>Herzerkrankungen zusätzlich zur AS, für die eine gleichzeitige Intervention in Betracht zu ziehen sind</i>		
Schwere KHK, die Revaskularisation mittels ACB-OP erfordert		+
Schwere primäre Mitralklappenerkrankung, die operativ behandelt werden könnte		+
Schwere Trikuspidalklappenerkrankung		+
Aneurysma der Aorta ascendens		+
Septumhypertrophie, die eine Myektomie erfordert		+

Recommendations on indications for intervention in asymptomatic aortic stenosis (1)

Recommendations	Class	Level
Intervention is recommended in <u>asymptomatic</u> patients with severe aortic stenosis and systolic LV dysfunction (<u>LVEF <50%</u>) without another cause.	I	B
Intervention is recommended in asymptomatic patients with severe aortic stenosis and <u>demonstrable symptoms on exercise testing</u> .	I	C
Intervention should be considered in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (<u>LVEF <55%</u>) without another cause.	IIa	B
Intervention should be considered in asymptomatic patients with severe aortic stenosis and a sustained <u>fall in BP (>20 mmHg) during exercise testing</u> .	IIa	C

Recommendations on indications for intervention in asymptomatic aortic stenosis (2)

Recommendations	Class	Level
Intervention should be considered in asymptomatic patients with LVEF >55% and a normal exercise test if the procedural risk is low and one of the following parameters is present: • Very severe aortic stenosis (mean gradient ≥ 60 mmHg or $V_{\max} > 5$ m/s). • Severe valve calcification (ideally assessed by <u>CCT</u>) and $V_{\max}$ progression ≥ 0.3 m/s/year. • Markedly elevated <u>BNP levels</u> ($> 3 \times$ age- and sex-corrected normal range) confirmed by repeated measurements and without other explanation.	IIa	B

Recommended mode of intervention on aortic stenosis (2)

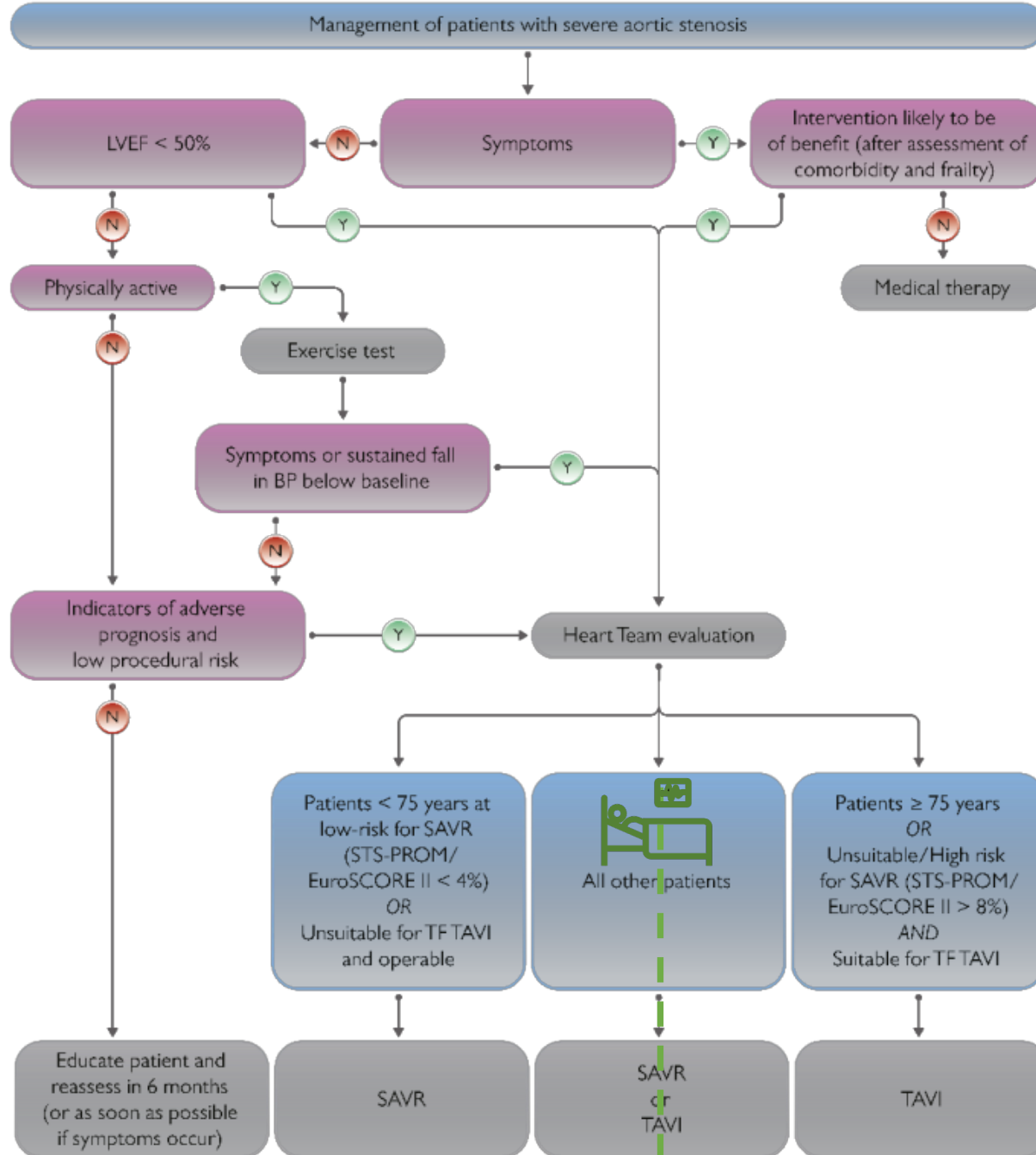
Recommendations	Class	Level
SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/EuroSCORE II <4%), or in patients who are operable and unsuitable for transfemoral TAVI.	I	B
TAVI is recommended in older patients (≥75 years), or in those who are high risk (STS-PROM/EuroSCORE II >8%) or unsuitable for surgery.	I	A
SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical, and procedural characteristics.	I	B
Non-transfemoral TAVI may be considered in patients who are inoperable and unsuitable for transfemoral TAVI.	IIb	C
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients and (if feasible) in those with severe aortic stenosis who require urgent high-risk NCS.	IIb	C

Recommended concomitant aortic valve surgery at the time of other cardiac/ascending aorta surgery

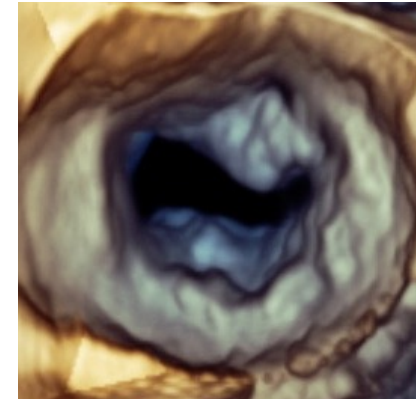


Recommendations	Class	Level
SAVR is recommended in patients with severe aortic stenosis undergoing CABG or surgical intervention on the ascending aorta or another valve.	I	C
SAVR should be considered in patients with moderate aortic stenosis* undergoing CABG or surgical intervention on the ascending aorta or another valve after Heart Team discussion.	IIa	C

** Moderate aortic stenosis is defined as a valve area of 1.0–1.5 cm² (or mean aortic gradient of 25–40 mmHg) in normal flow conditions—clinical assessment is essential to determine whether SAVR is appropriate for an individual patient.*



Interventionelle Therapie der Mitralklappeninsuffizienz



Recommendations on indications for intervention in severe primary mitral regurgitation (1)



Recommendations	Class	Level
Mitral valve repair is the recommended surgical technique when the results are expected to be durable.	I	B
Surgery is recommended in symptomatic patients who are operable and not high risk.	I	B
Surgery is recommended in <u>asymptomatic</u> patients with LV dysfunction (LVESD <u>≥40</u> mm and/or LVEF ≤60%).	I	B
Surgery should be considered in asymptomatic patients with preserved LV function (LVESD <40 mm and LVEF >60%) and AF secondary to mitral regurgitation or pulmonary hypertension (SPAP at rest >50 mmHg).	IIa	B

Recommendations on indications for intervention in severe primary mitral regurgitation (2)

Recommendations	Class	Level
Surgical mitral valve repair should be considered in low-risk asymptomatic patients with LVEF >60%, LVESD <40 mm* and significant <u>LA dilatation</u> (volume index ≥ 60 mL/m ² or diameter ≥ 55 mm) when performed in a Heart Valve Centre and a durable repair is likely.	IIa	B
<u>TEER</u> may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are <u>judged inoperable or at high surgical risk</u> by the Heart Team and for whom the procedure is not considered futile.	IIb	B

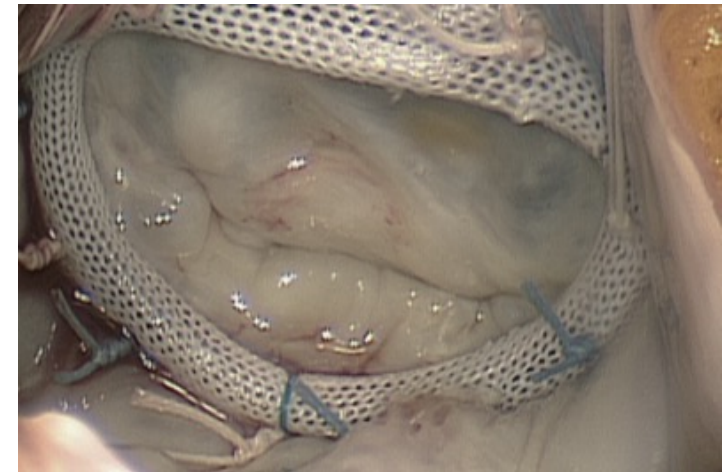
* Cut-offs refer to average-size adults and may require adaptations in patients with unusually small or large stature.



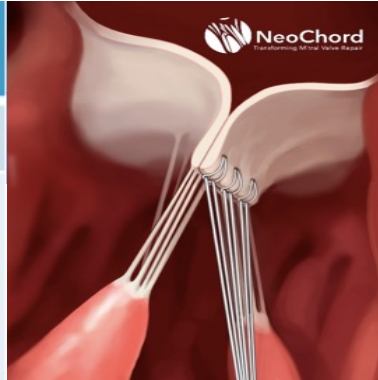
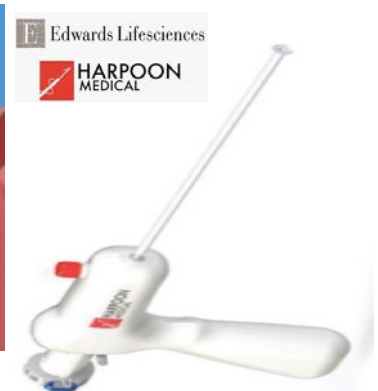
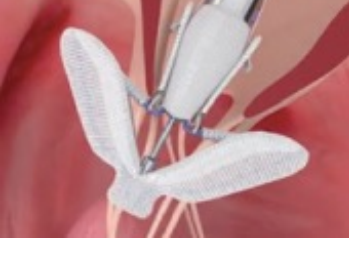
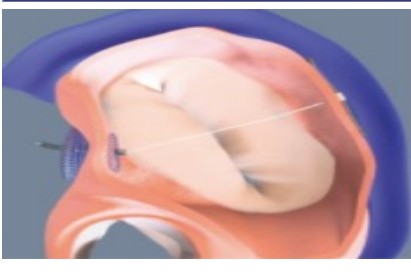
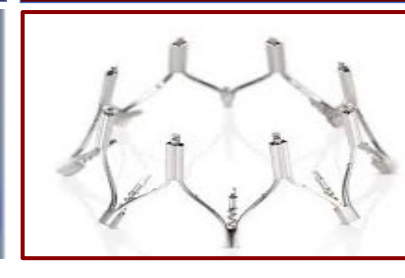
Sekundäre Mitralklappeninsuffizienz: Chirurgische Annuloplastie

Implantation eines unterdimensionierten Ringes:

- gute Akutergebnisse
- Rezidiv Rate für MI 2+
 - nach 6-12 Mo 15-33%
 - nach 5 Jahren 70%
- Prädiktoren für ein Rezidiv:
 - offener oder flexibler Ring
 - LV Dilatation (LVEDD >65 mm)
 - Segeltenting >11mm, PML-Winkel >45°
 - schwere präoperative MI
 - basales Aneurysma oder Dyskinesie



Interventionelle Behandlungsmethoden der Mitralklappeninsuffizienz

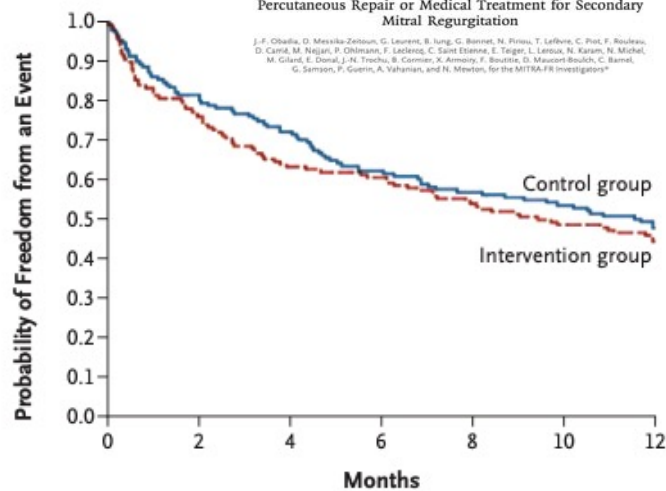
Abbott		CardiacDim	Valtech/Edwards	AccuCinch
MitraClip		Carillon	CardioBand TA and TF	Ancora
				
Zusammen- klammern der Segel	Ersatz der Chordae	Ringreduktion zum Annähern der Klappensegel		
Edwards Pascal		MVRx ARTO	IRIS Millipede	
				



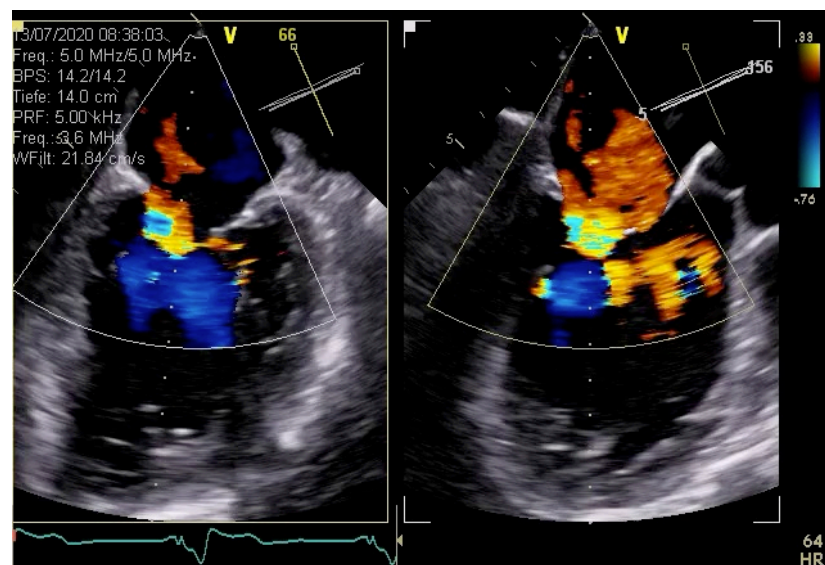
The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1922 DECEMBER 15, 2018 VOL. 379 NO. 24

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

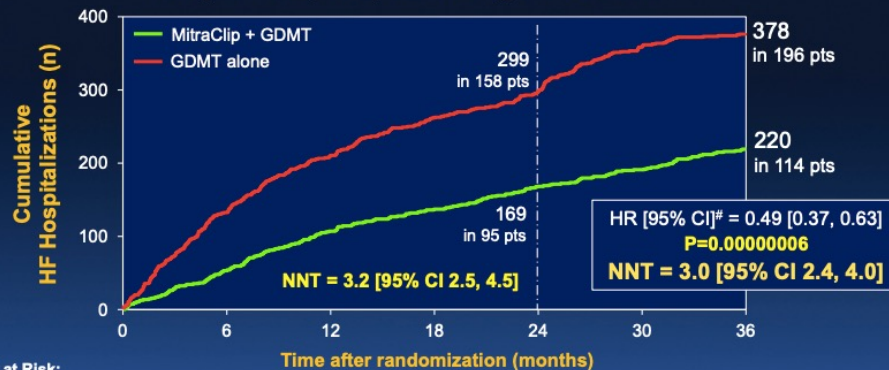
J.-F. Obadia, D. Messika-Zetoun, C. Leclercq, B. Jung, G. Barot, N. Piro, T. Lellouche, C. Pelt, F. Boucly, D. Comé, M. Najari, P. Ohlmann, F. Leclercq, C. Saint-Etienne, E. Teger, L. Lenoir, N. Karam, N. Michel, M. Gilard, E. Dorval, J.-N. Treche, B. Cormier, X. Amoury, F. Boucly, D. Maunier-Bouché, C. Barot, G. Samson, P. Guerin, A. Vahanian, and N. Mesier, for the MITRA-FR Investigators*



No. at Risk							
Control group	152	123	109	94	86	80	73
Intervention group	151	114	95	91	81	73	67



Primary Effectiveness Endpoint
All Hospitalizations for HF within 36 months
All patients, ITT, including crossovers



# at Risk:							
MitraClip + GDMT	302	269	238	219	189	128	93
GDMT alone	312	272	223	185	144	89	68



#Joint frailty model



Functional Mitral Regurgitation: Learnings and Limits of the COAPT and MITRA-FR Trials



Possible explanations for the different results between the MITRA-FR and COAPT trials.

By Daniel Grinberg, MD, PhD; Xavier Armoiry, PharmD, PhD;
and Jean-François Obadia, MD, PhD

TABLE 1. COMPARISON OF THE MAIN DIFFERENCES BETWEEN MITRA-FR AND COAPT STUDIES

	MITRA-FR (n = 304)	COAPT (n = 614)
Roll-in period	5 patients/center	3 patients/center
Enrollment (inclusions/center)	3.2 y: 8.2/center → 2.6/y	4.8 y: 7.8/center → 1.6/y
Technical implantation success	96%	98%
EROA (mean ± SD)	31 ± 10 mm ²	41 ± 15 mm ²
LVEDV (mean ± SD)	135 ± 35 mL/m ²	101 ± 34 mL/m ²
GDMT at baseline and follow-up	- Stable for 3 mo before randomization - Under center control all along the study	Central eligibility committee and limited changes during follow-up
Mortality at 1 y and 2 y	≈ 23% and 34%	≈ 20% and 46% vs 29%
MR ≥ 3+ at discharge → 12 mo → 24 mo	8% → 17% → Not recorded	7.4% → 5% → 0.9%

Abbreviations: EROA, effective regurgitant orifice area; GDMT, guideline-directed medical therapy; LVEDV, left ventricle end-diastolic volume; MR, mitral regurgitation.

Functional Mitral Regurgitation: Learnings and Limits of the COAPT and MITRA-FR Trials



Possible explanations for the different results between the MITRA-FR and COAPT trials.

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TABLE 2. THE COAPT-LIKE DEFINITION APPLIED TO THE MITRA-FR POPULATION*

	MITRA-FR			COAPT	
	COAPT-Ineligible (n = 77)	COAPT-Eligible (n = 189)	P value	Total (n = 614)	P value
Characteristics					
Age, y	69.5 ± 10.1	6.9 ± 10.2	.65	72.2	NA
Male sex	61 (79.2)	142 (75.1)	.53	393 (64)	.005
LV ejection fraction, %	30 ± 8.5	34.1 ± 5.5	.0002	31.3 ± 9.3	< .0001
LV end-diastolic volume, mL	259.7 ± 98.5	246.9 ± 64.6	.56	192.7 ± 71	< .0001
Effective regurgitant orifice area, cm ²	0.27 ± 0.1	0.34 ± 0.11	< .0001	0.41 ± 0.15	< .0001
Tricuspid regurgitation grade ≥ 2	32/70 (45.7)	85/175 (48.6)	.69	98/599 (16.4)	< .0001
Procedure and Outcome "Composite Endpoint"					
Randomized to TMVr	41 (53.2)	96 (50.8)	.79	302 (49.2)	.7
Death or hospitalization for heart failure at 24 mo	57 (74)	121 (64)	.18	320 (52.1)	.004
TMVr	30/41 (73.2)	60/96 (62.5)	.23	129/302 (42.7)	.0007
Medical therapy alone	27/36 (75)	61/93 (65.6)	.30	191/312 (61.2)	.45

*The COAPT-like definition applied to the MITRA-FR population was unsuccessful to select a population with any benefit of the MR correction. Conversely and not surprisingly, the COAPT-like patients of MITRA-FR were by definition less severe than the others. Abbreviations: LV, left ventricle; TMVr, transcatheter mitral valve repair. Reprinted from lung B, Messika-Zeitoun D, Boutitie F, et al. Characteristics and Outcome of COAPT-Eligible Patients in the MITRA-FR Trial. Circulation. 2020;2482-2484.

Severe mitral regurgitation criteria based on 2D echocardiography (3)



	Primary MR	Secondary MR
Quantitative		
EROA (2D PISA, mm ²)	≥40 mm ²	≥40 mm ² (may be ≥30 mm ² if elliptical regurgitant orifice area)
Regurgitant volume (mL/beat)	≥60 mL	≥60 mL (may be ≥45 mL if low flow conditions)
Regurgitant fraction (%)	≥50%	≥50%
Structural		
Left ventricle	Dilated (ESD ≥40 mm)	Dilated
Left atrium	Dilated (diameter ≥55 mm or volume ≥60 mL/m ²)	Dilated

Adapted from Lancellotti et al., *Eur Heart J Cardiovasc Imaging* (2013). DOI: 10.1093/ehjci/jet105 and Zoghbi et al., *J Am Soc Echocardiogr* (2017). DOI: 10.1016/j.echo.2017.01.007.

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

www.escardio.org/guidelines (European Heart Journal; 2021 – doi: 10.1093/eurheartj/ehab395; European Journal of Cardio-Thoracic Surgery; 2021 – doi: 10.1093/ejcts/ezab389)

Recommendations on indications for mitral valve intervention in chronic severe secondary mitral regurgitation (1)

Recommendations	Class	Level
Valve surgery/intervention is recommended only in patients with severe SMR who remain symptomatic despite GDMT (including CRT if indicated) and has to be decided by a structured collaborative Heart Team.	I	B
<i>Patients with concomitant coronary artery or other cardiac disease requiring treatment</i>		
Valve surgery is recommended in patients undergoing CABG or other cardiac surgery.	I	B
In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics, PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.	IIa	C

Recommendations on indications for mitral valve intervention in chronic severe secondary mitral regurgitation (2)

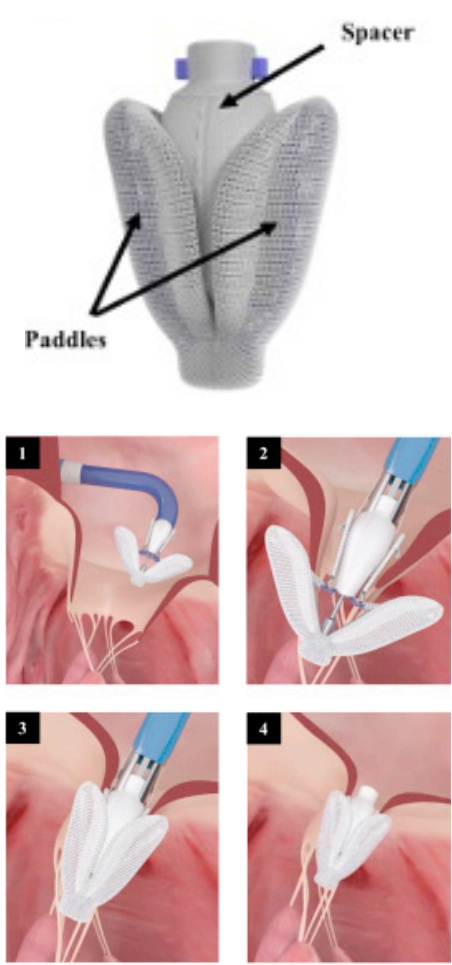
Recommendations	Class	Level
<i>Patients without concomitant coronary artery or other cardiac disease requiring treatment</i>		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment.	IIa	B
Valve surgery may be considered in symptomatic patients judged appropriate for surgery by the Heart Team.	IIb	C
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.	IIb	C



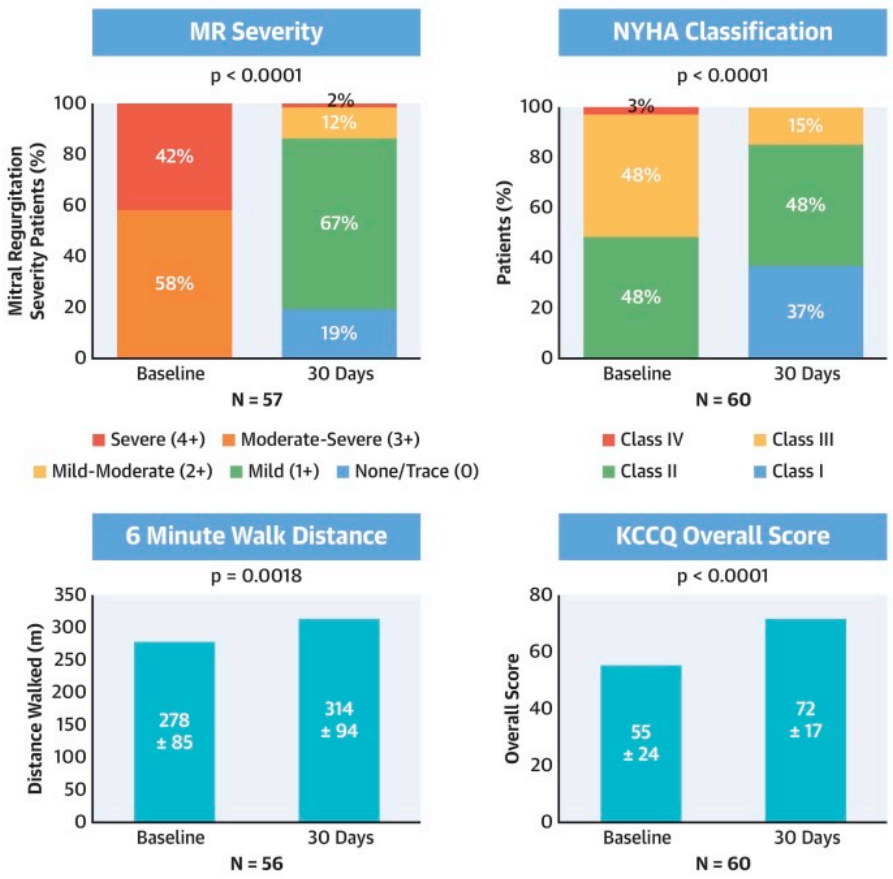
Transcatheter Valve Repair for Patients With Mitral Regurgitation

30-Day Results of the CLASP Study

D. Scott Lim, MD,^a Saibal Kar, MD,^b Konstantinos Spargias, MD,^c Robert M. Kipperman, MD,^d
William W. O'Neill, MD,^e Martin K.C. Ng, MBBS, PhD,^f Neil P. Fam, MD,^g Darren L. Walters, MBBS, MPhil,^h
John G. Webb, MD,ⁱ Robert L. Smith, MD,^j Michael J. Rinaldi, MD,^k Azeem Latib, MD,^l Gideon N. Cohen, MD,^m
Ulrich Schäfer, MD,ⁿ Leo Marcoff, MD,^d Prashanthi Vandrangi, PhD,^o Patrick Verta, MD, DVM, MS STAT,^o
Ted E. Feldman, MD^{o,p}



CENTRAL ILLUSTRATION: Echocardiographic, Functional, and Clinical Results at Baseline and 30 Days for the PASCAL Transcatheter Valve Repair System



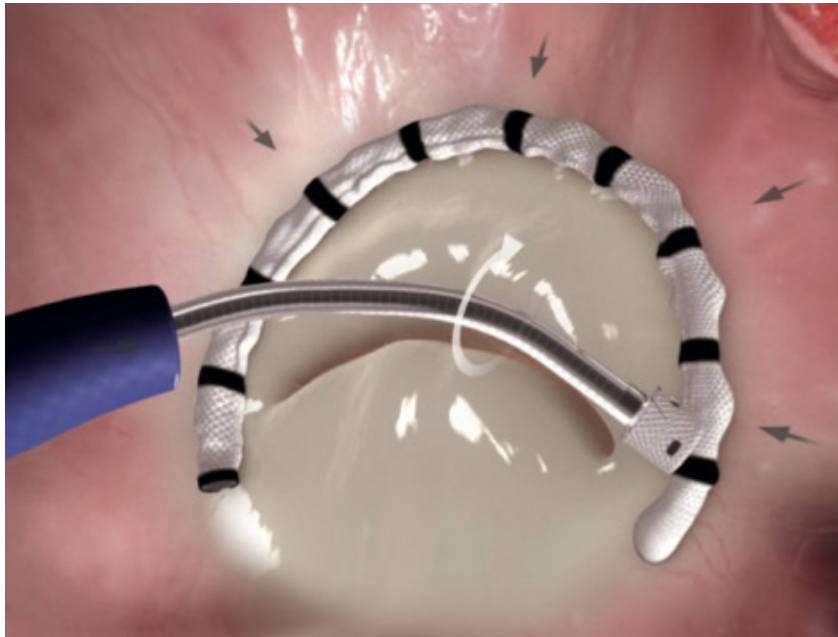


Edwards Cardioband Mitral Reconstruction System

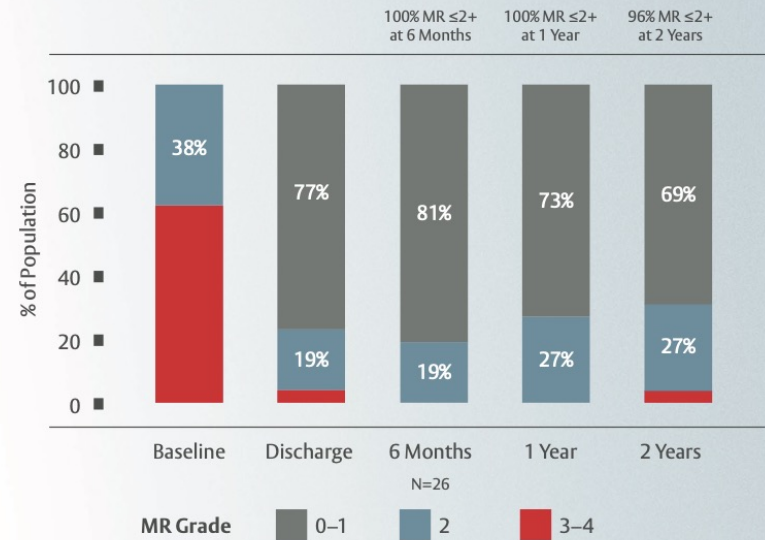
A New Era for Transcatheter Mitral Repair

European CE mark trial – two-year results

Single-arm, multicentre prospective study designed to evaluate the performance and safety of the Cardioband mitral system for treatment of functional mitral regurgitation.



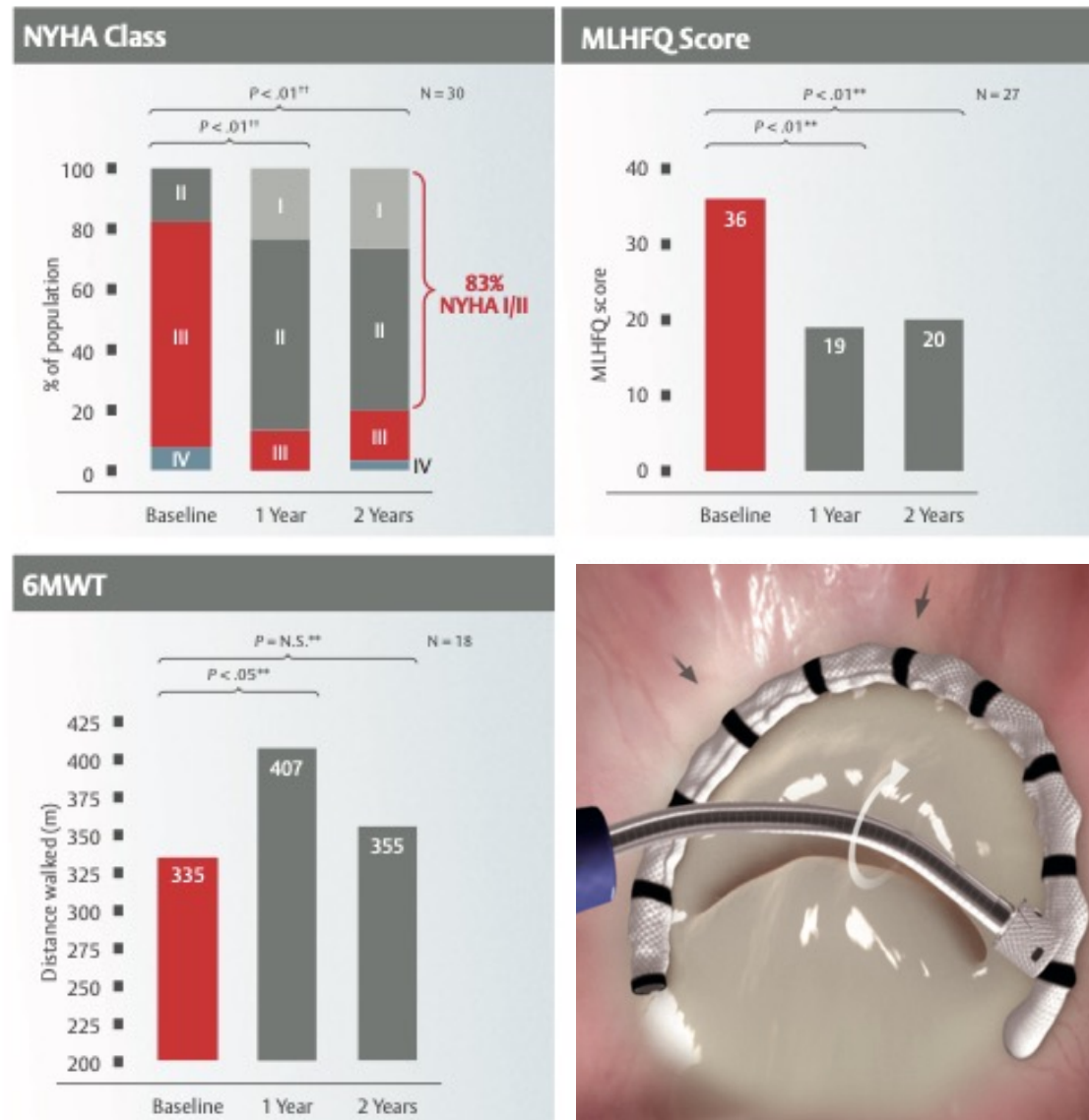
96% of patients with MR $\leq$ 2+ at 2 years by core lab* in paired analysis¹



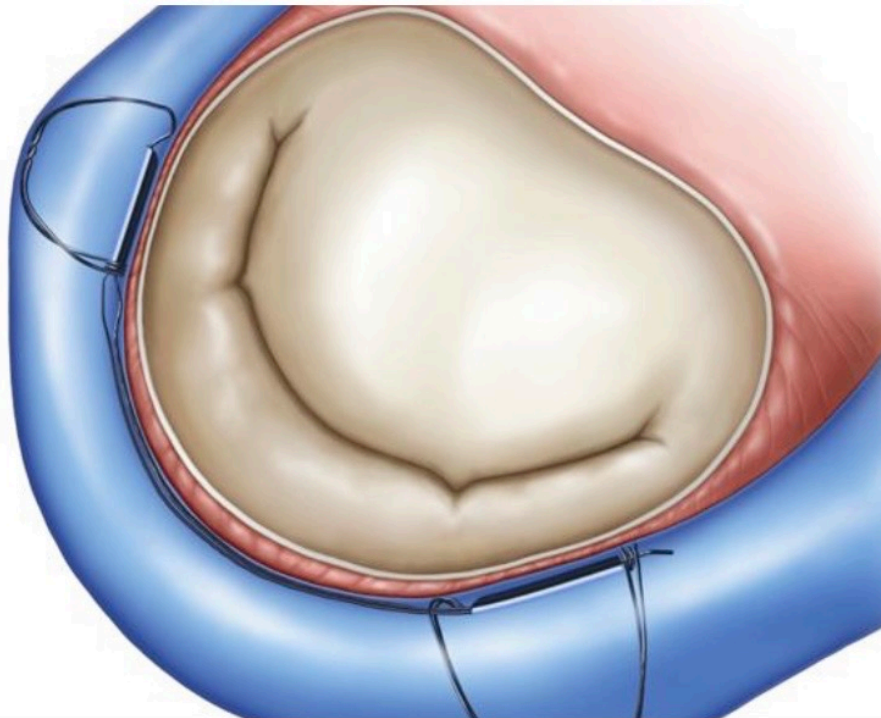
Edwards Cardioband Mitral Reconstruction System



Functional improvement at 2 years¹



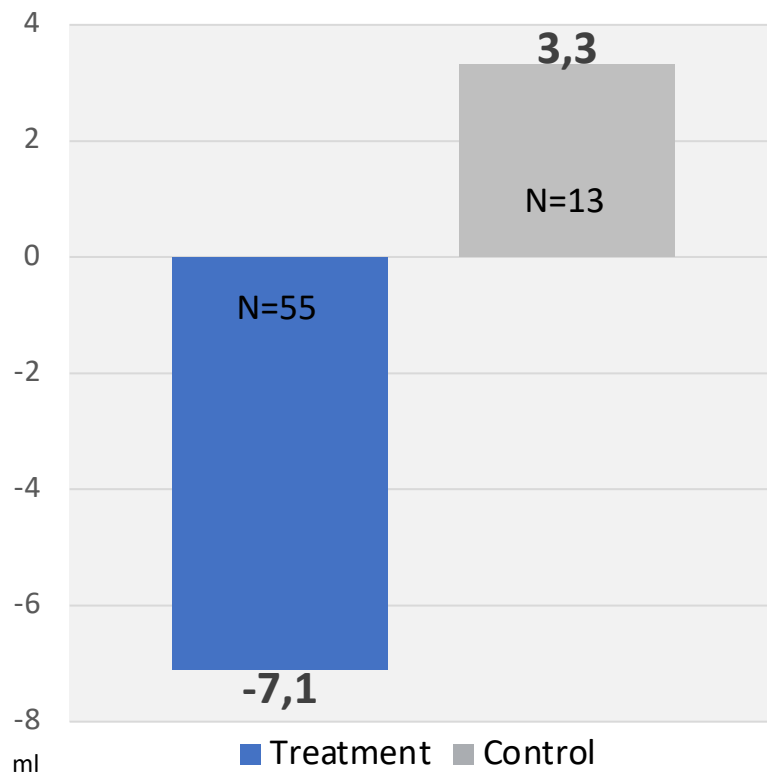
Mitralklappenringverkleinerung mit Carillon™-Spange





REDUCE FMR – Primary Endpoint

Change in Regurgitant Volume (RV) at 1-year (ITT)



$p = 0.03$

- 22% reduction in treatment group
- 8% increase in control group
- Absolute difference 10.4 ml

Mean RV Change – Paired data (ml)

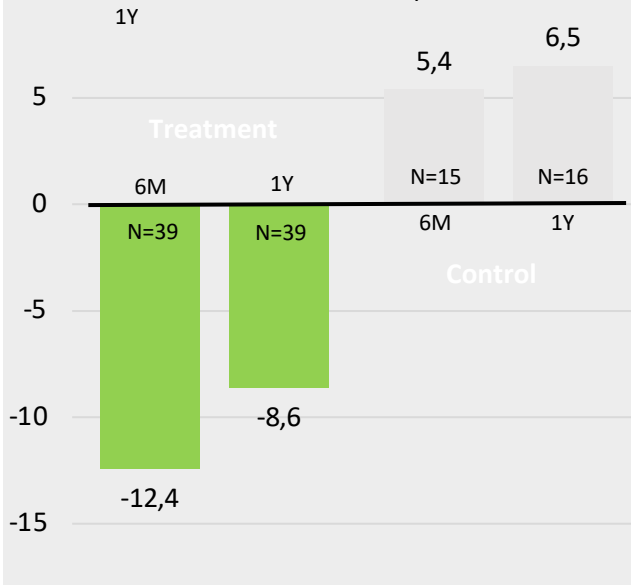


REDUCE FMR – Secondary Endpoint Analysis

Change in LVEDV and LVESV 1-Year (AT – As Treated)

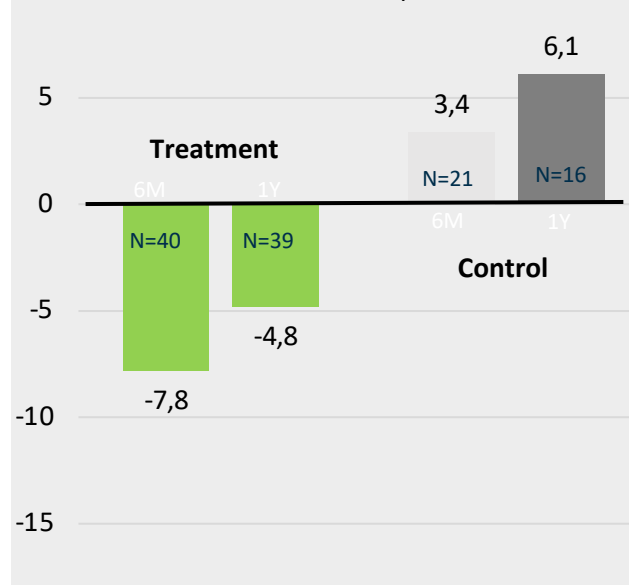
Change in LVEDV (ml)

P= 0.02 at 6-months
P= 0.06 at 1-year



Change in LVESV (ml)

P= 0.06 at 6-months
P= 0.07 at 1-year



- Secondary endpoints included change in LVEDV and LVESV at 1-year
- A volume reduction at 6-months and 12-months was observed in the treatment group
- The control group showed increased volumes at 6-months with further increased volumes at 1-year



Carillon™ Mitral Contour System™

- Indirekte Annuloplastie mit Carillon-Spange führt zur Reduktion des Regurgitationsvolumens und zur Besserung der Symptome
- In gut ausgewählten Fällen, Carillon kann sehr effektiv sein
- Beginn einer randomisierten EMPOWER Studie in USA

Perkutaner Mitralklappenersatz



Native leaflet engagement



Tiara (Neovasc)

Mitral annulus clamping



EVOQUE (Edwards)

Radial force



Intrepid (Medtronic)

Apical tether



Tendyne (Abbott)

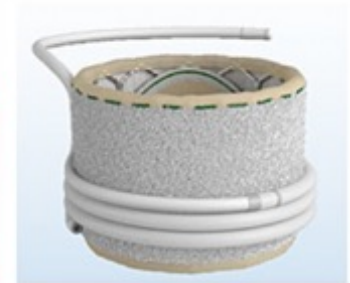
External anchor



Caisson (LivaNova)



HighLife (HighLife)

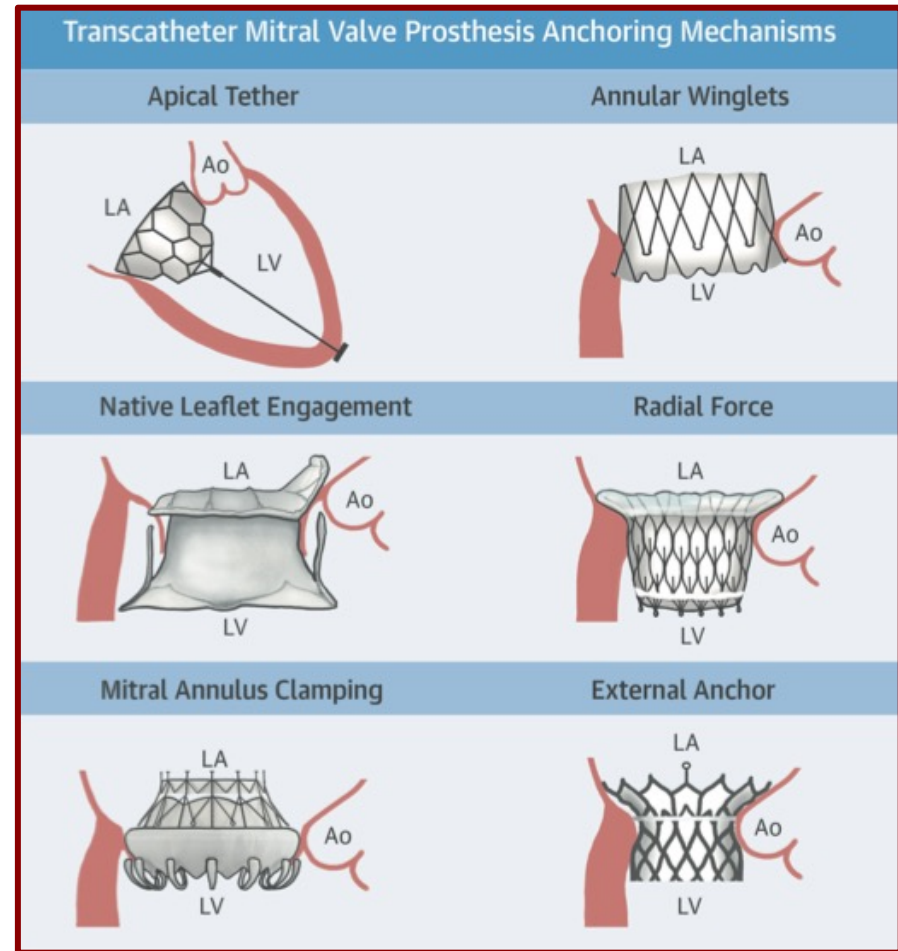


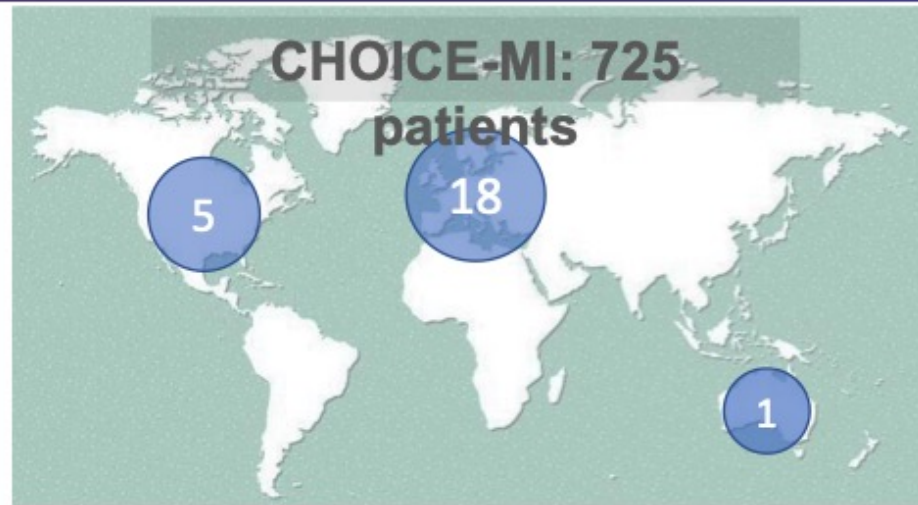
Sapien M3 (Edwards)

Herausforderungen:



- Komplexe Anatomie
- Verankerung der Prothese
- LVOT-Obstruktion
- Abdichtung/PVL
- Einführungssystem
- Thrombogenität/ Langhaltigkeit





The CHOICE of Optimal transCatheter trEatment for Mitral Insufficiency (CHOICE-MI) Registry

- investigator-initiated
- global
- multicentric
- retrospective
- device-independent

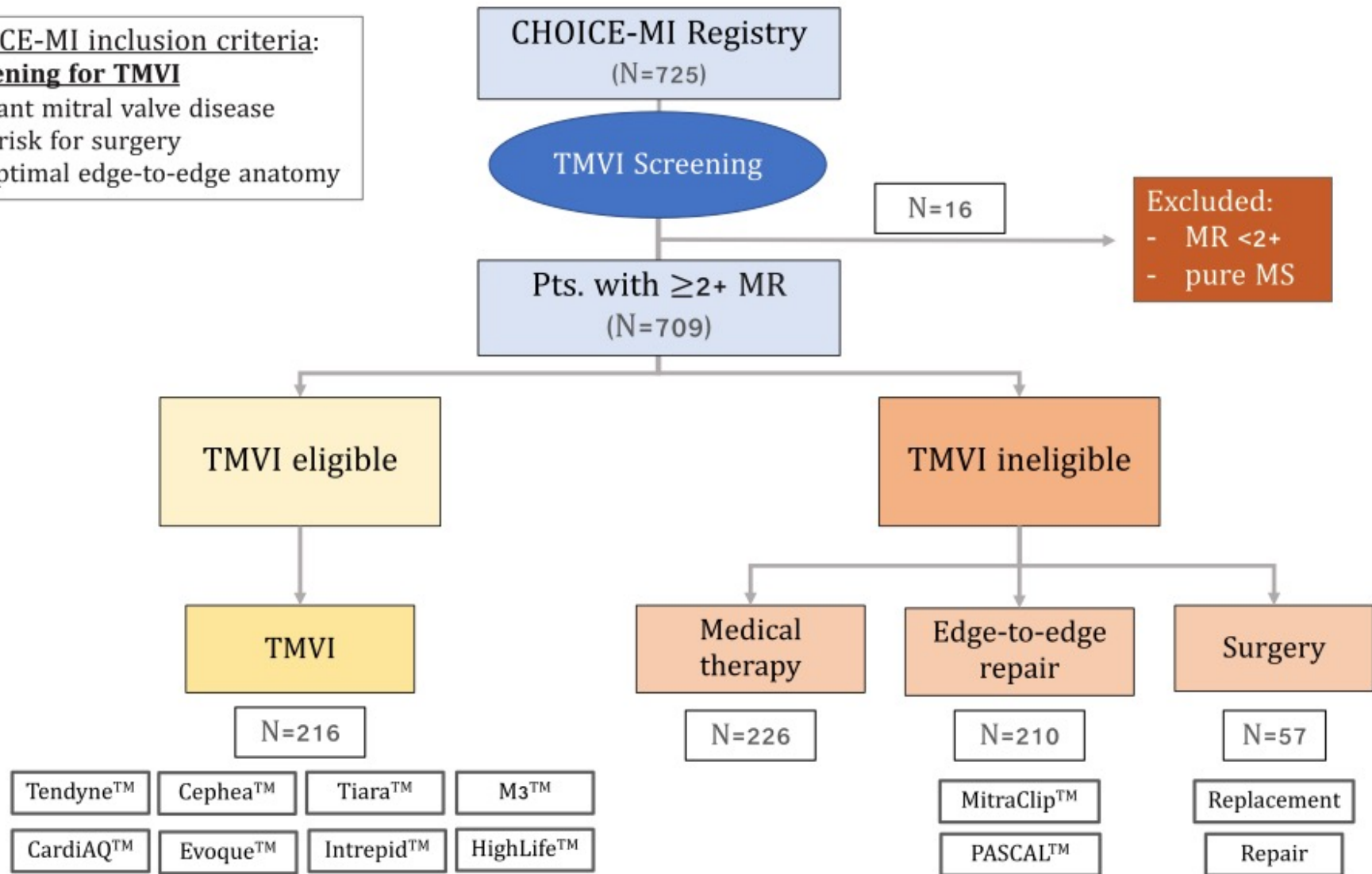
CHOICE-MI inclusion criteria:

- screening for TMVI
- relevant mitral valve disease
- high risk for surgery
- suboptimal edge-to-edge anatomy

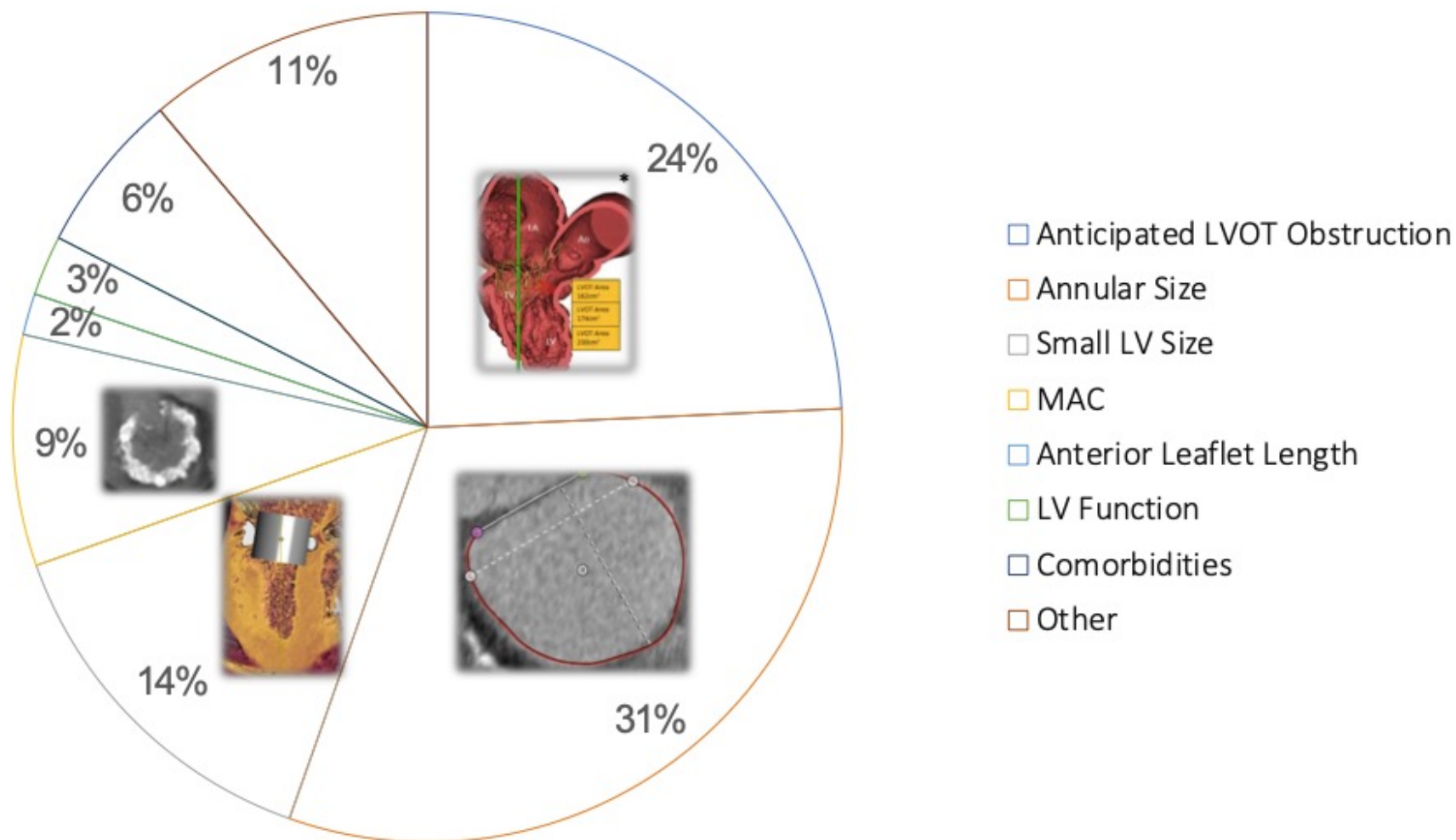
How was the study executed?

CHOICE-MI inclusion criteria:

- **screening for TMVI**
- relevant mitral valve disease
- high risk for surgery
- suboptimal edge-to-edge anatomy

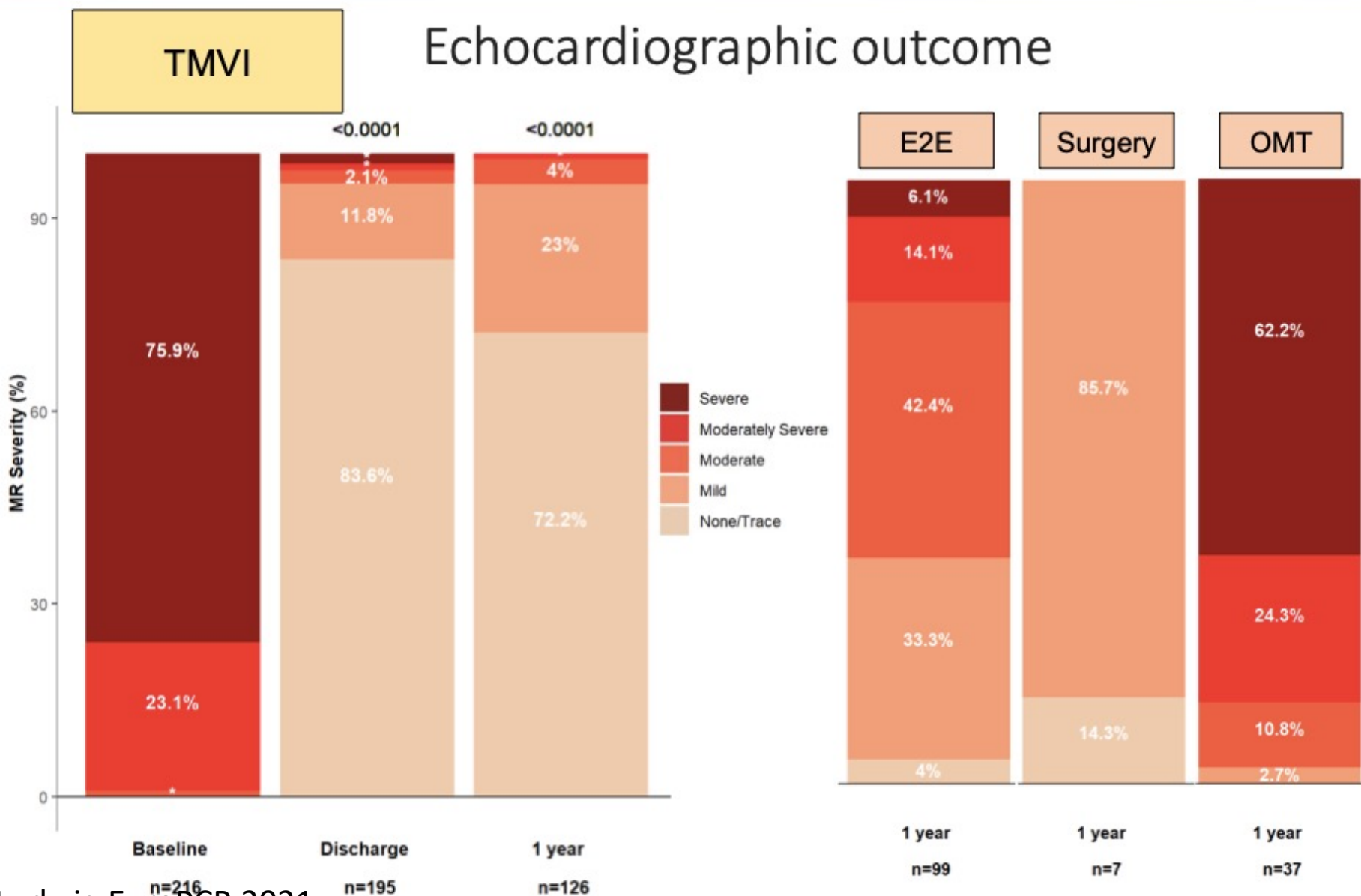


Reasons for screen failure



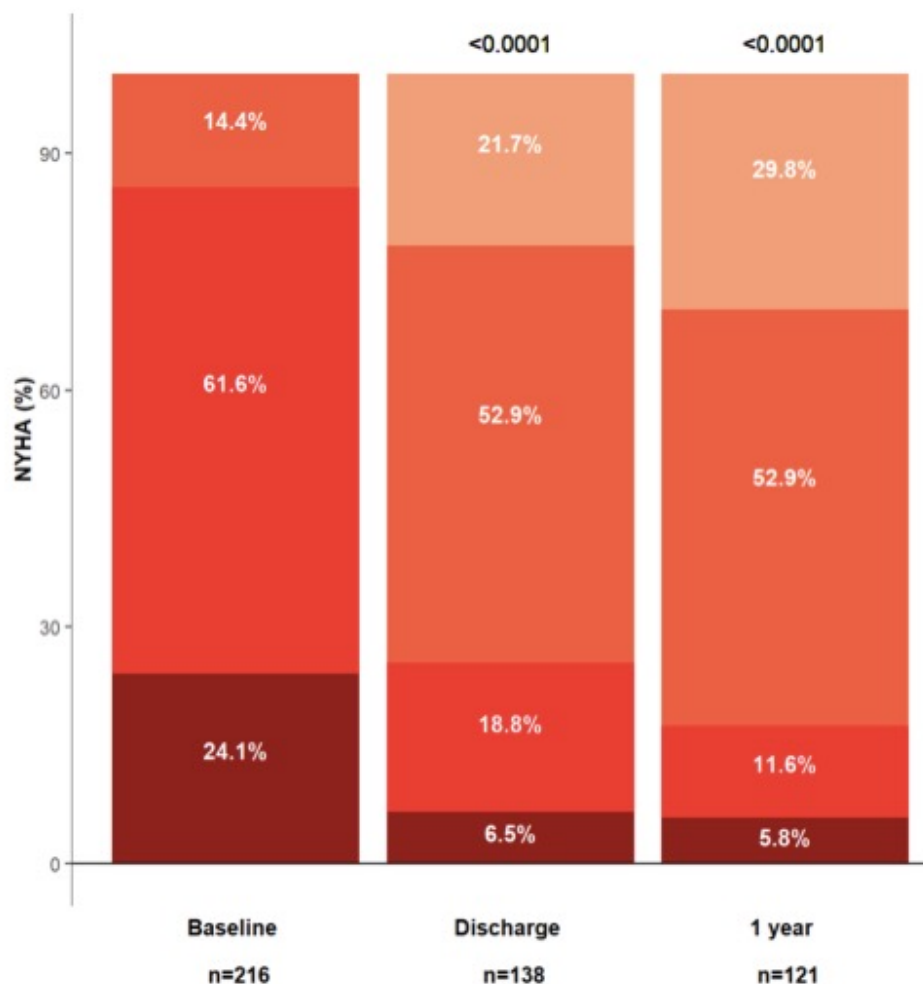
What are the essential results?

	TMVI (N=216)	OMT (N=226)	Edge-to-edge (N=210)	Surgery (N=57)	p-value
Age (years)	76.0 (71.0, 81.0)	79.5 (74.0, 83.0)	79.0 (74.0, 83.0)	77.0 (68.7, 82.3)	<0.001
Female gender	82 (38.0)	123 (54.4)	90 (42.9)	30 (52.6)	0.0030
STS PROM (%)	5.6 (3.2, 8.5)	5.0 (2.8, 7.7)	4.1 (3.0, 6.7)	3.7 (2.1, 5.7)	0.0058
EuroSCORE II (%)	6.3 (3.6, 13.5)	4.3 (2.5, 9.4)	4.3 (2.6, 7.9)	3.0 (2.1, 6.2)	<0.001
Chronic kidney disease	110 (54.5)	105 (51.7)	94 (46.8)	14 (29.8)	0.016
Diabetes	55 (25.5)	67 (30.0)	34 (16.2)	11 (19.3)	0.0058
NYHA stage IV	52 (24.1)	30 (13.5)	44 (21.1)	3 (5.4)	0.0013
previous CABG	78 (36.1)	44 (19.6)	43 (20.5)	13 (22.8)	<0.001
EF (%)	40.0 (35.0, 54.0)	55.0 (41.7, 60.0)	55.5 (40.0, 61.9)	58.5 (50.0, 62.1)	<0.001
LVEDV (mL)	152.6 (115.5, 196.2)	133.9 (90.7, 174.1)	118.6 (90.7, 160.6)	95.6 (74.6, 121.1)	<0.001
TAPSE (mm)	15.0 (12.0, 19.0)	18.0 (14.9, 21.0)	17.0 (14.0, 21.0)	17.5 (15.0, 21.6)	<0.001
Primary MR	59 (28.6)	129 (58.1)	94 (47.0)	34 (69.4)	<0.001
Secondary MR	122 (59.2)	71 (32.0)	81 (40.5)	8 (16.3)	<0.001



TMVI

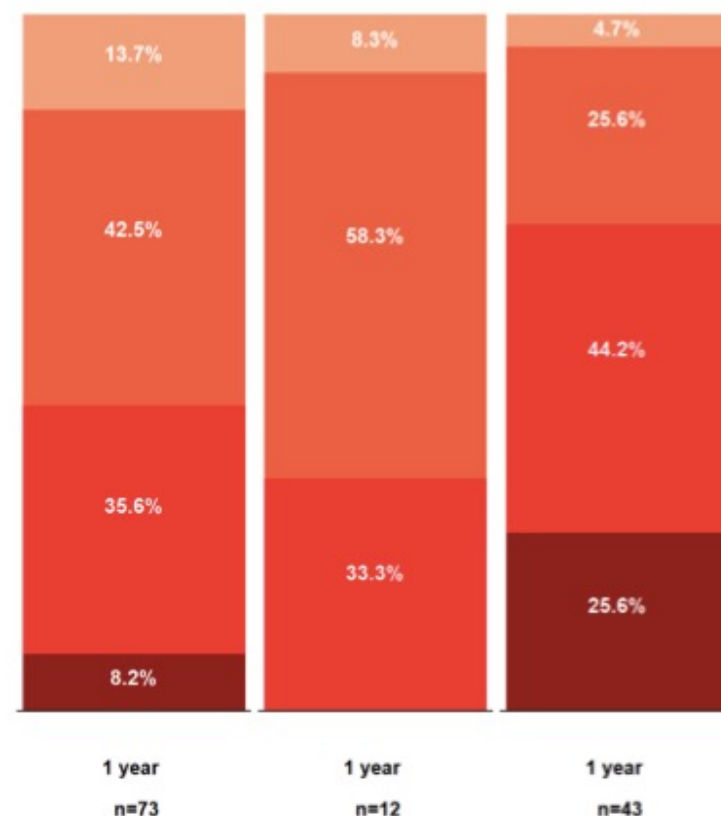
Functional outcome



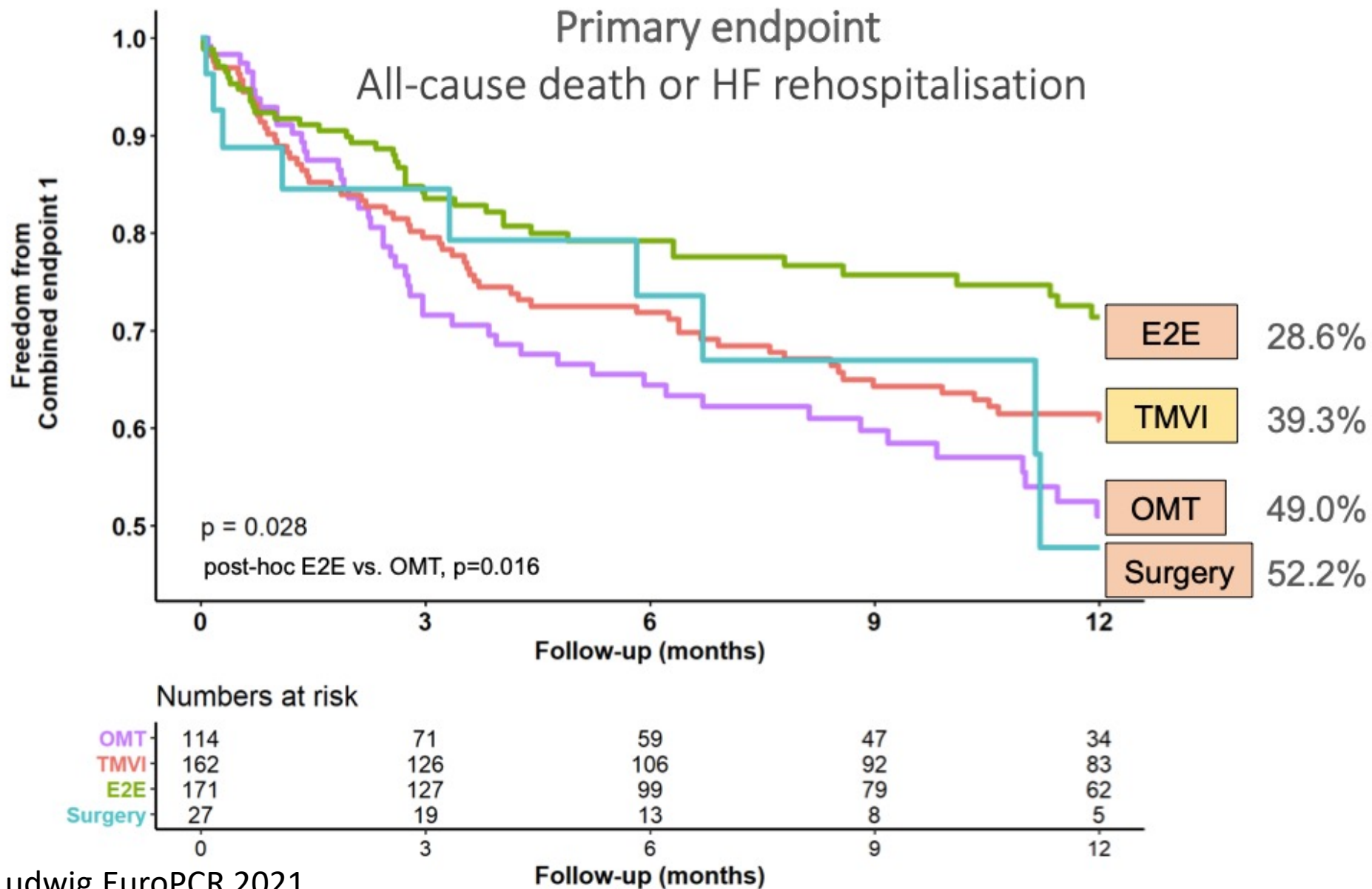
E2E

Surgery

OMT



What are the essential results?

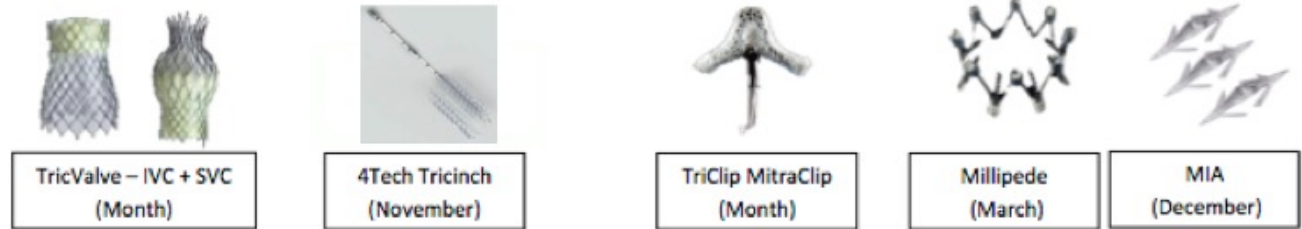


Interventionelle Therapie der Trikuspidalklappeninsuffizienz

Interventionelle Therapie der Trikuspidalklappeninsuffizienz



First - In - Man



2010

2011

2012

2013

2014

2015

2016

2017

TricValve - IVC
(Month)



Trialign
(September)



FORMA
(Jan-Feb)



CardioBand
(September)



Navigate
(December)

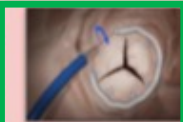


Mitralix



Interventionelle Therapie der Trikuspidalklappeninsuffizienz



Mechanism	New Technologies						
Annuloplasty (Direct and Indirect) Device	 TriAlign	 Cardioband	 4 Tech	 Millepede	 Pasta	 Cardiac Implants	 MIA
Leaflet Device	 Forma	 MitraClip	 PASCAL	 Mistral			
Heterotopic Valve (in IVC/SVC)	 Trinity /Sapien	 TriCentro	 SAPIEN in IVC				
Orthotopic Valve Replacement	 Navigate	 Evoque	 Intrepid	 Trisol	 LUX	 Tri-Cares	



Neue Graduierung der Trikuspidalklappeninsuffizienz

Parameter	leichtgradig	mittelgradig	hochgradig	massiv	torrential
qualitativ					
TK-Morphologie	normal/abnormal		flail leaflet/großer Koaptationsdefekt/ausgeprägtes Segeltethering		
Farbdoppler-Jet	klein, zentral	intermediär	sehr großer zentraler oder exzentrischer Jet, rotierender Jet		
CW-Doppler-Signal			triangulär mit frühsystolischem Maximum		
Konvergenzzone	keine	intermediär	groß	sehr groß	
semiquantitativ					
Vena contracta		< 7 mm	7–13 mm	14–20 mm	≥ 21 mm
Fluss in den Lebervenen	systolisch > diastolisch	systolische Dämpfung, systolisch < diastolisch	systolische Flussumkehr		
quantitativ					
EROA	< 20 mm ²	20–39 mm ²	40–59 mm ²	60–79 mm ²	≥ 80 mm ²
Regurgitationsvolumen	< 30 ml	31–44 ml	≥ 45 ml		
3-D VC area			75–94 mm ²	95–114 mm ²	≥ 115 mm ²
supportiv					
			Vena cava inferior dilatiert, nicht atemvariabel RA/RV Dilatation		



Trikuspidalklappeninsuffizienz: Katheter- gestützte Behandlungsmethoden

Anuloplastie



Edge-to-Edge

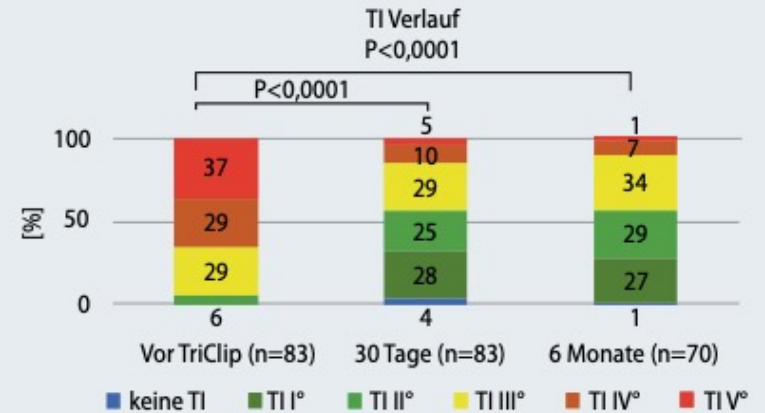
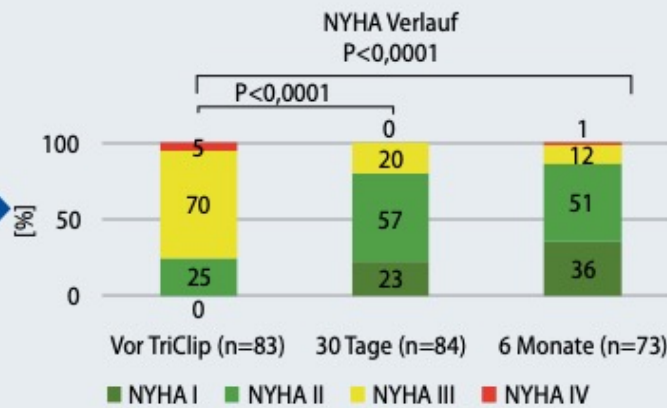


Klappenersatz

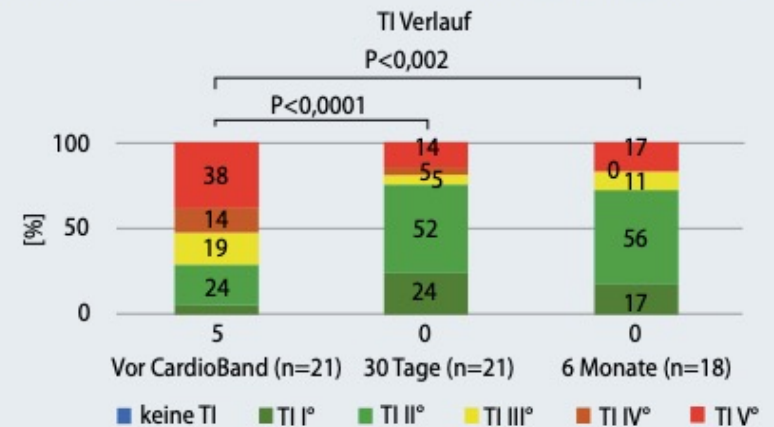
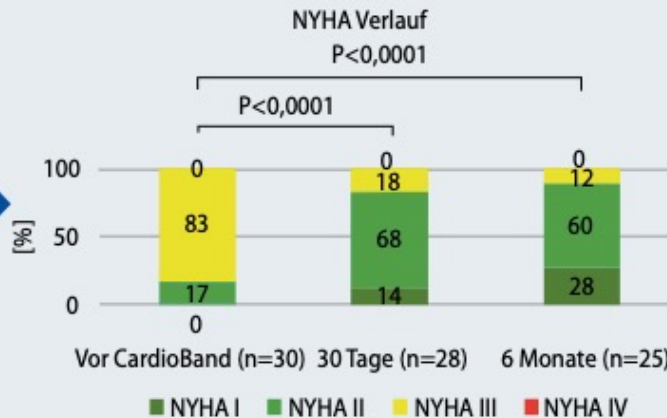




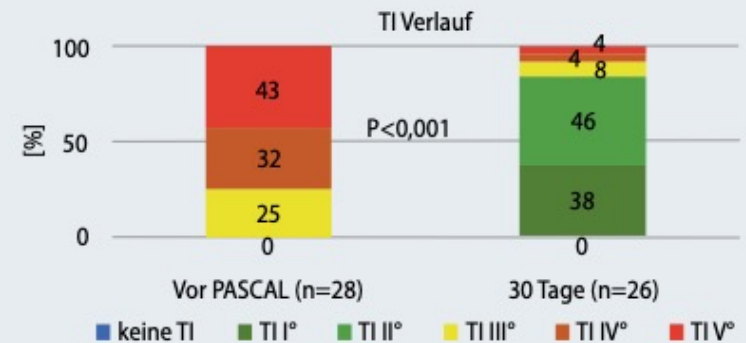
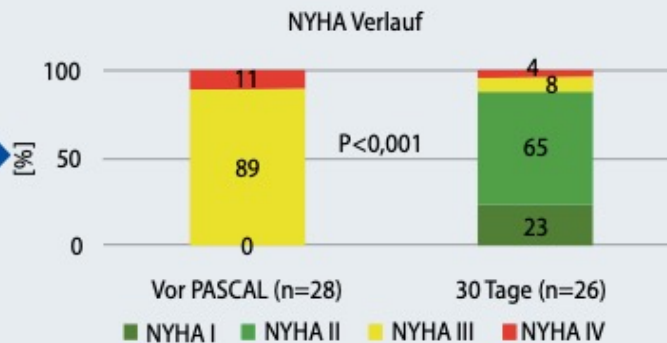
TriClip



Trikuspidales CardioBand



Trikuspidaler PASCAL

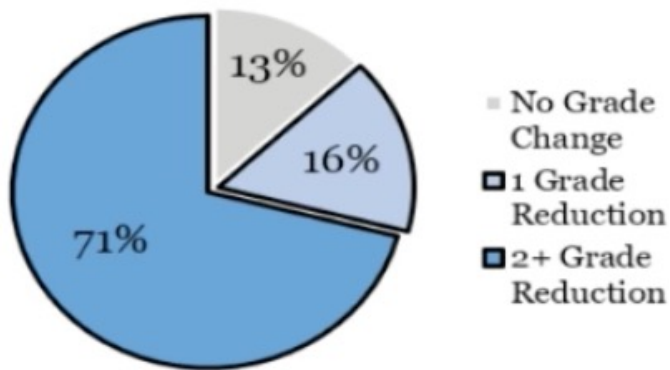




TRILUMINATE:

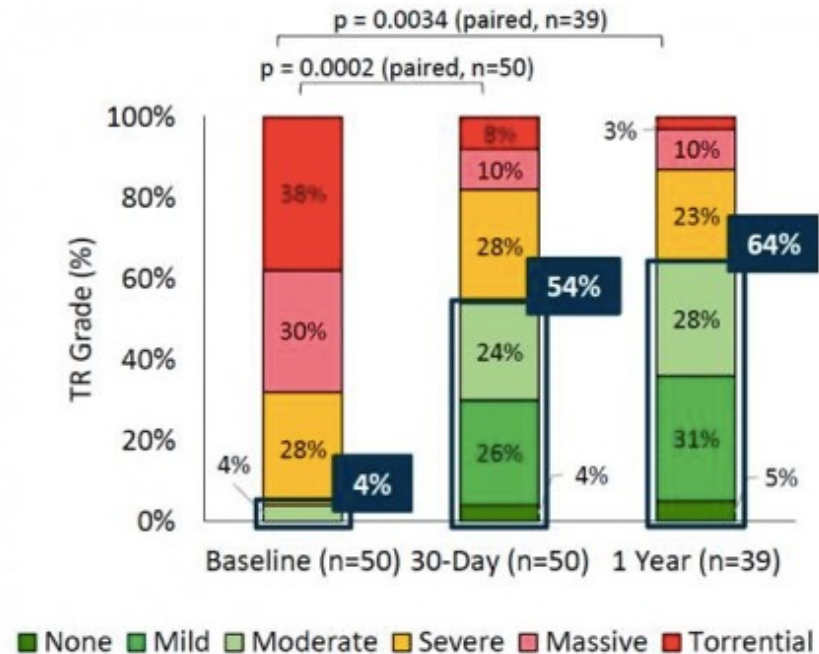
Anhaltende TI Reduktion nach 1 Jahr

TR Reduction Sustained at 1 Year (n=62)



87.1% showed at least 1 grade improvement at 1 Year

70% Moderate or less at 1Y



N=87



TRILUMINATE:

Ein sicherer und komplikationsarmer Eingriff

Low Occurrence of Major Adverse Events

Event	(n)*
Major Adverse Event (MAE) through 1 Year	6
Cardiovascular Mortality	4
Myocardial Infarction	1
Stroke	1
New Onset Renal Failure	1
Non-elective CV surgery, TVRS	0
Device-related AE	0

¹ Subjects were reported drop in hemoglobin of 3-5 g/dl (BARC Type 3a)

² Subjects TR severity and clinical symptoms did not worsen, as compared to baseline. No additional intervention was needed.

*n=total number of subjects

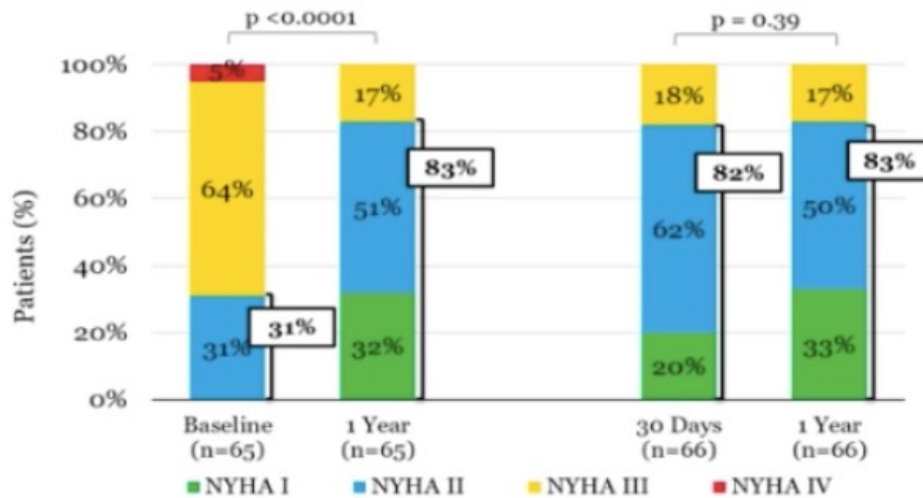
Minimal Safety Concerns

Event	(n)*
Other Clinical Safety Endpoints	
All-cause Mortality	6
Major Bleeding ¹	10
Pulmonary Thromboembolism	0
New Onset Liver Failure	0
New Onset Atrial Fibrillation	1
Single Leaflet Device Attachment ²	5
Embolization	0
Tricuspid Valve Mean Gradient $\geq$ 5mmHg	4

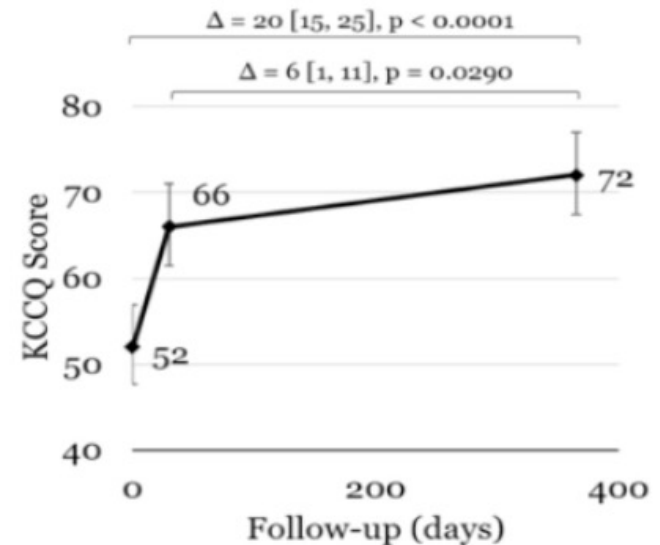


TRILUMINATE: Anhaltende Symptombesserung

Sustained Symptomatic Improvement



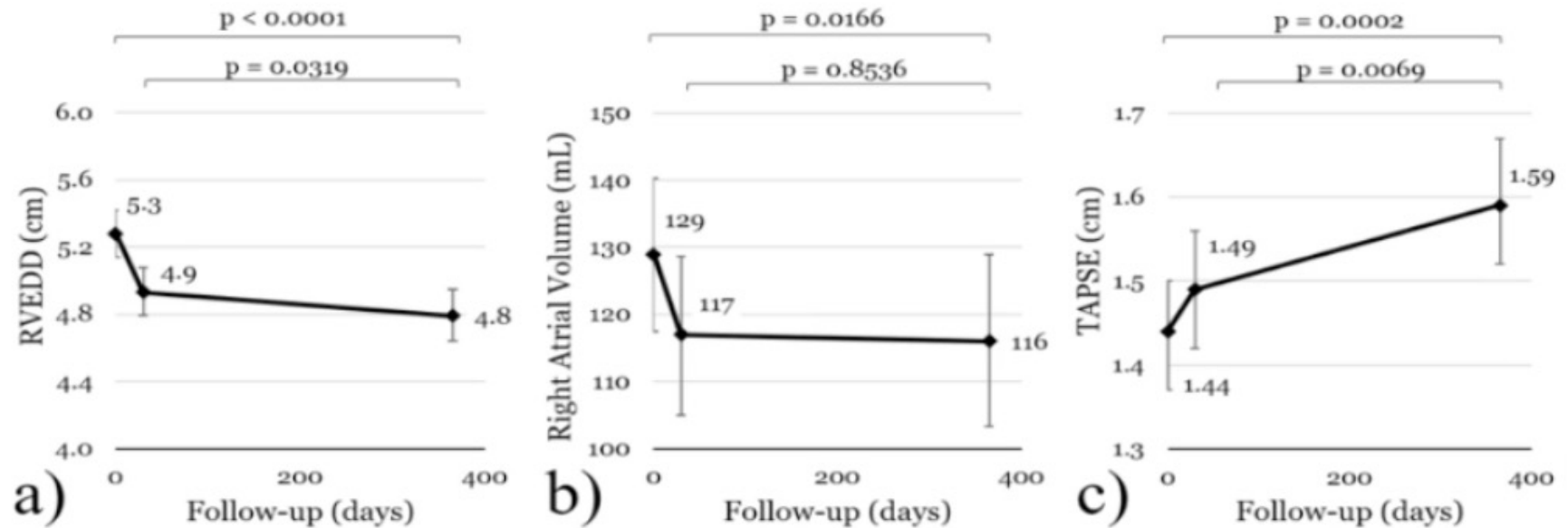
Continued KCCQ Improvement





TRLIMINATE: TI -Reduktion führt zu einem positiven RV- Remodelling

Reduction in TR → Reverse RV Remodeling

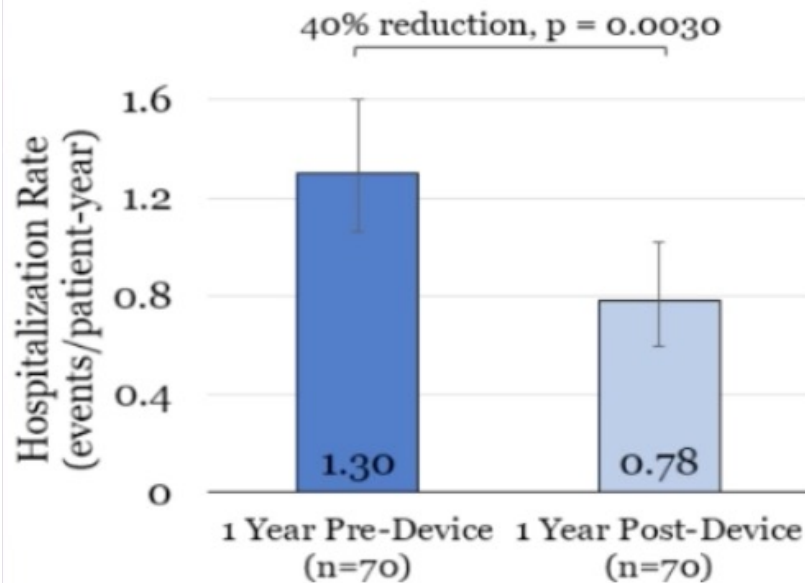




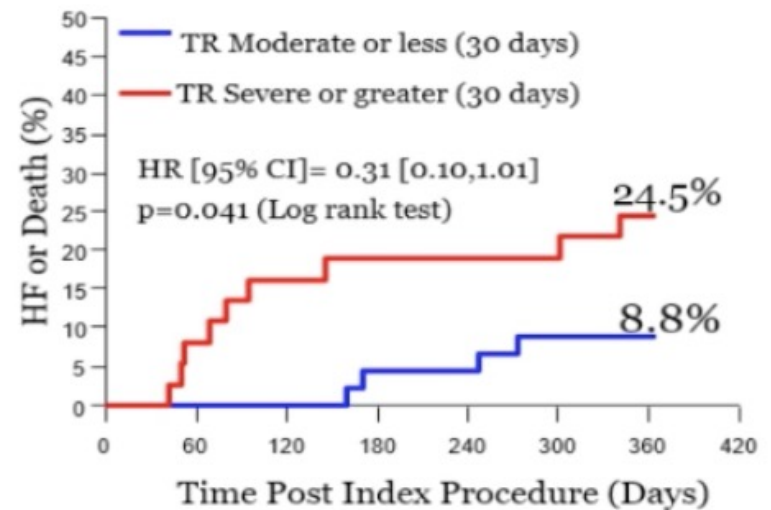
TRILUMINATE:

TI-Reduktion führt zu Abnahme der Krankenhausaufenthalte

Reduced Hospitalization Rate



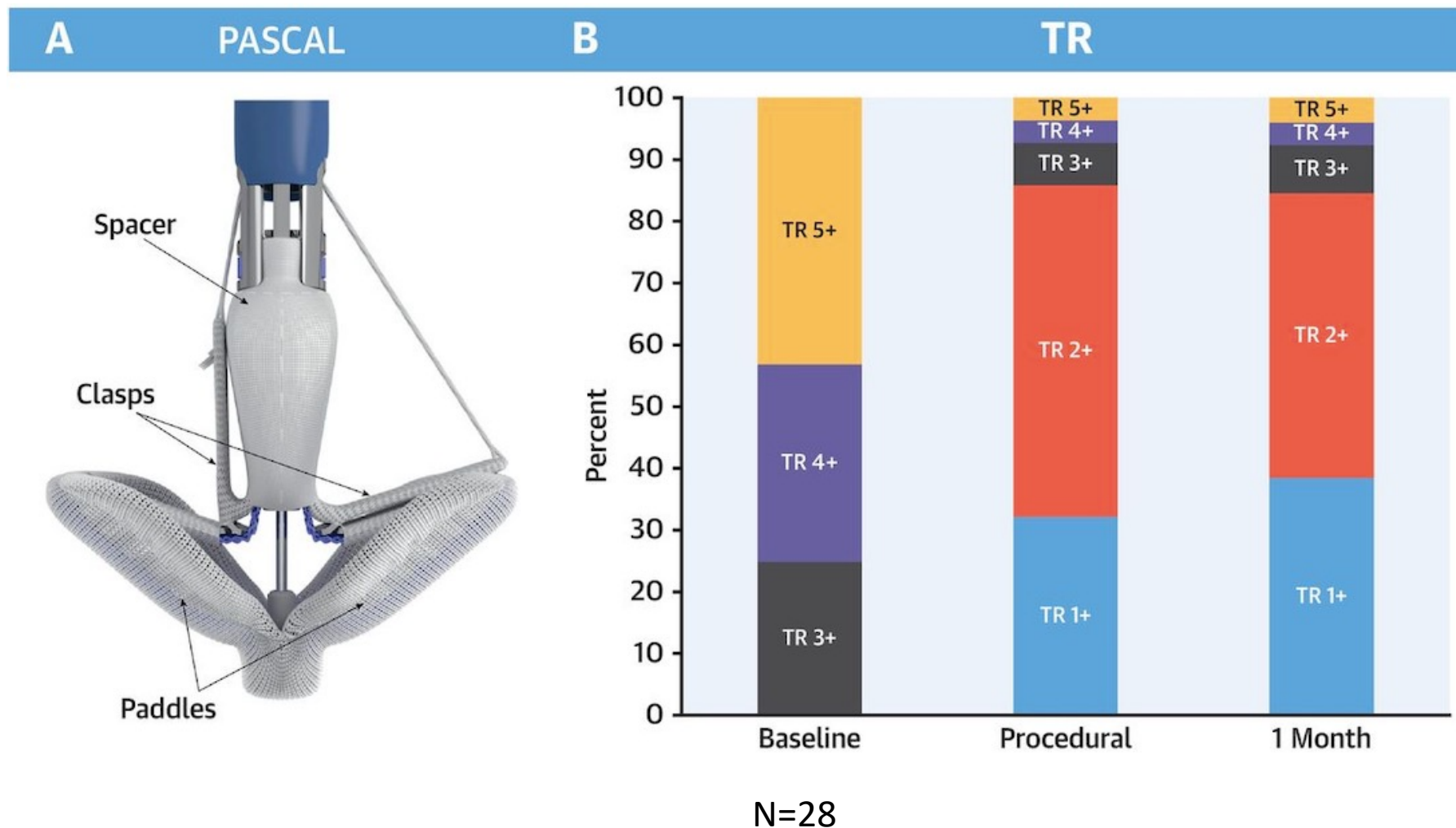
Procedural Success Predictive of Mortality and Heart Failure Hospitalizations at 1Y



Compassionate Use of the PASCAL Transcatheter Valve Repair System for Severe Tricuspid Regurgitation

A Multicenter, Observational, First-in-Human Experience

Neil P. Fam, Daniel Braun, Ralph Stephan von Bardeleben, Michael Nabauer, Tobias Ruf, Kim A. Connelly, Edwin Ho, Holger Thiele, Philipp Lurz, Marcel Weber, Georg Nickenig, Akhil Narang, Charles J. Davidson and Jörg Hausleiter



12-Month outcomes of transcatheter tricuspid valve repair with the PASCAL system for severe tricuspid regurgitation

Mitsunobu Kitamura MD¹ | Neil P. Fam MD² | Daniel Braun MD³ | Tobias Ruf MD⁴ | Atsushi Sugiura MD⁵ | Akhil Narang MD⁶ | Kim A. Connelly MD² | Edwin Ho MD² | Michael Nabauer MD³ | Jörg Hausleiter MD³ | Marcel Weber MD⁵ | Georg Nickenig MD⁵ | Charles J. Davidson MD⁶ | Holger Thiele MD¹ | Ralph Stephan von Bardeleben MD⁴ | Philipp Lurz MD, PhD¹

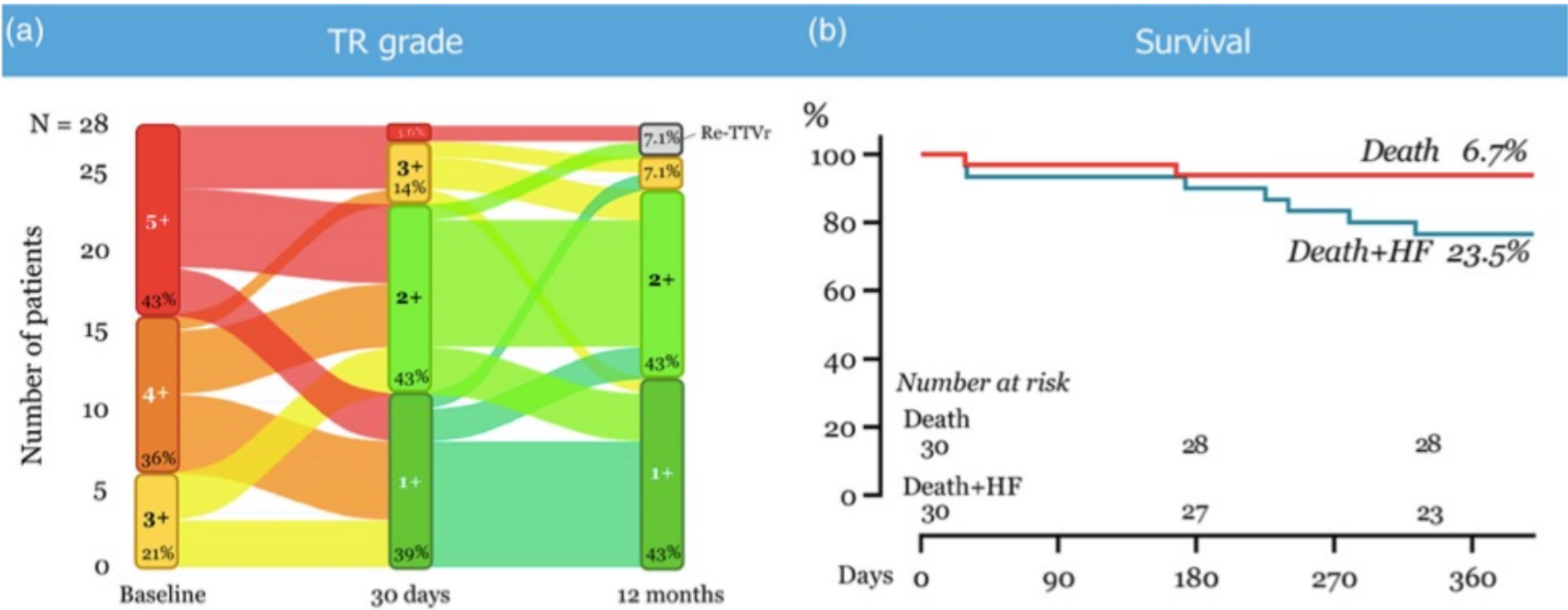
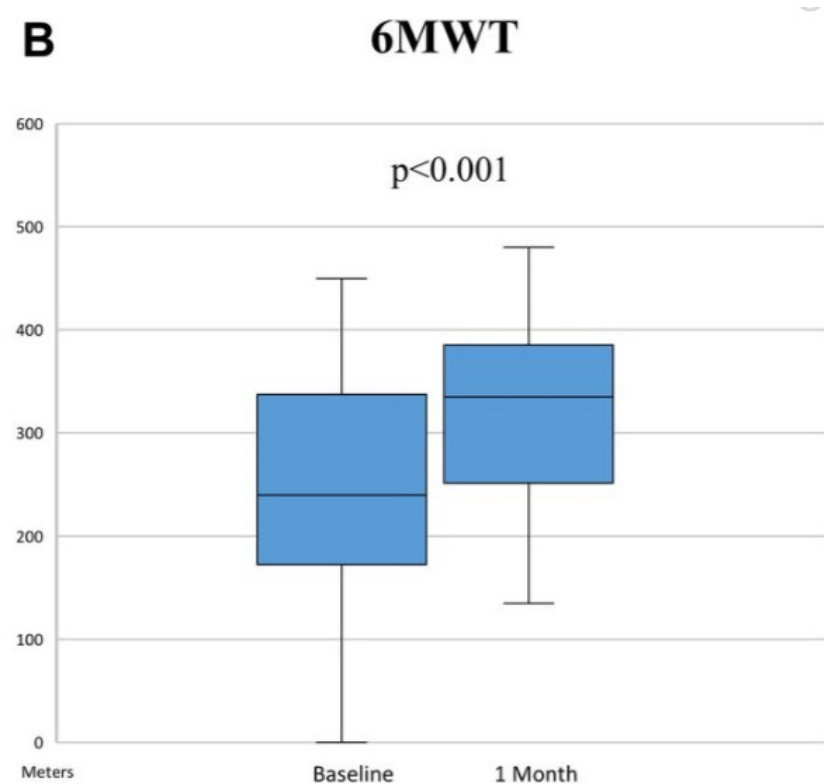
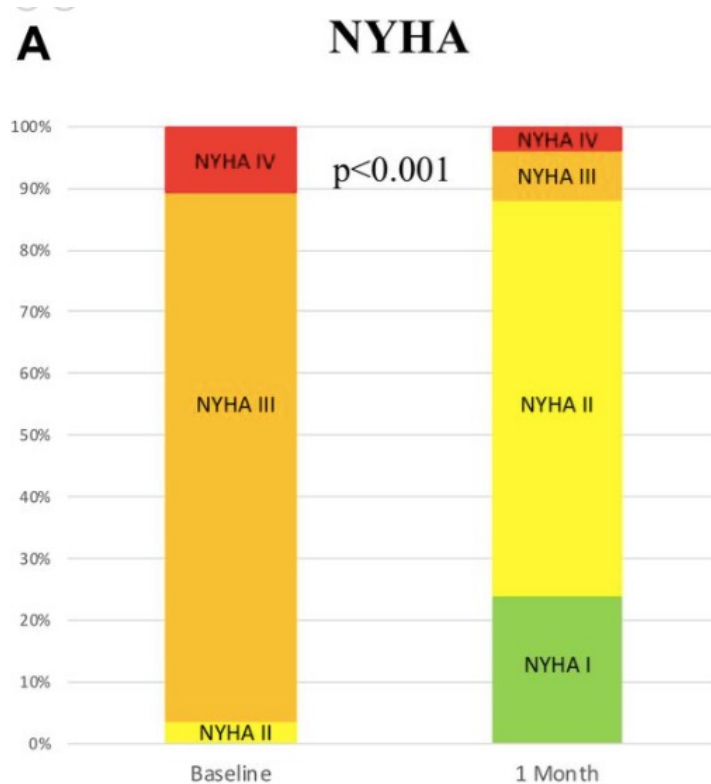


FIGURE 2 (a) TR reduction (b) Kaplan–Meier curves after the index procedure for severe TR. HF, heart failure; TR, tricuspid regurgitation

Compassionate Use of the PASCAL Transcatheter Valve Repair System for Severe Tricuspid Regurgitation

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von 240 m auf 335 m

ORIGINAL STUDIES

12-Month outcomes of transcatheter tricuspid valve repair with the PASCAL system for severe tricuspid regurgitation

Mitsunobu Kitamura MD¹ | Neil P. Fam MD² | Daniel Braun MD³ |
 Tobias Ruf MD⁴ | Atsushi Sugiura MD⁵ | Akhil Narang MD⁶ |
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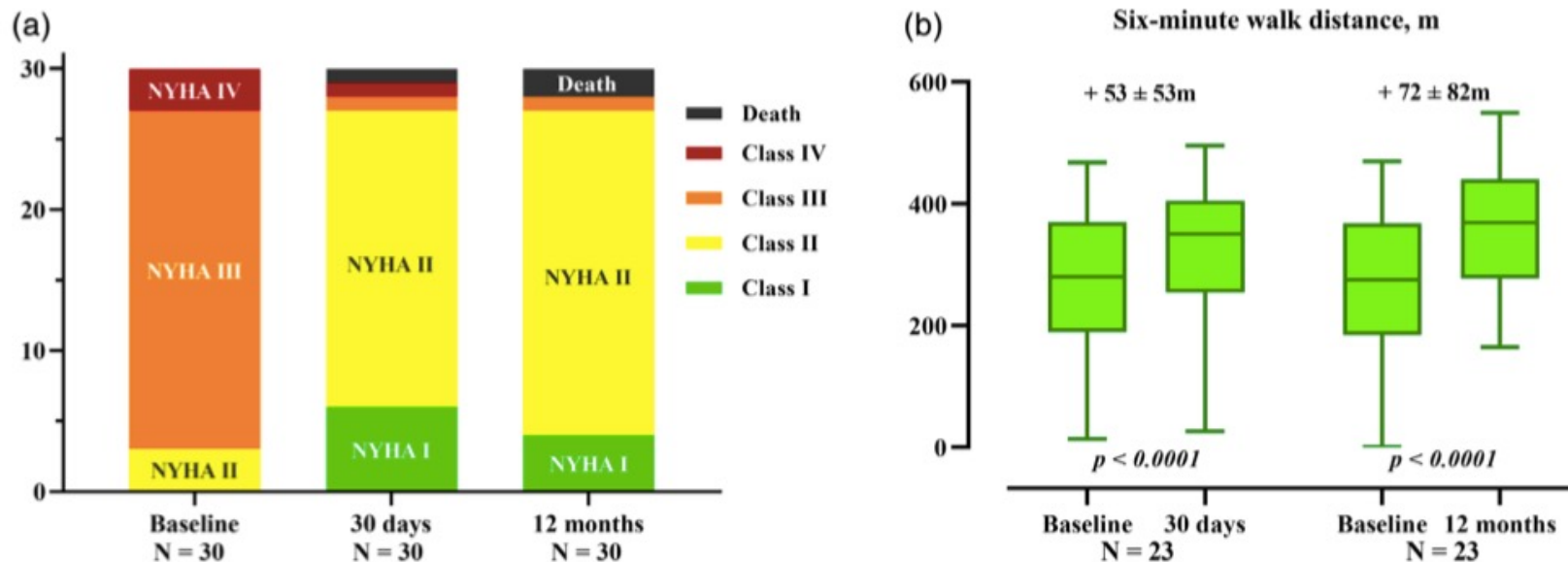
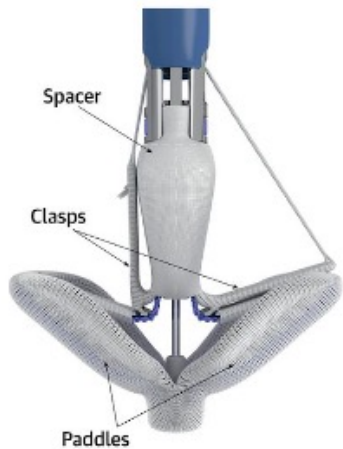


FIGURE 3 Changes in New York Heart Association functional class and 6-minute walk distance. (a) 12-month follow-up of the NYHA functional class. (b) Changes in 6-minute walk distance. Data are presented as box plots (25th centile, median, and 75th centile) and whisker (fifth centile, median, and 95th centile). NYHA; New-York Heart Association [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

Compassionate Use of the PASCAL Transcatheter Valve Repair System for Severe Tricuspid Regurgitation

A Multicenter, Observational, First-in-Human Experience

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- Niedrige 30 Tages-Mortalität 7.1%,
- Reduktion der $TR \leq 2+$ in 85%
- Besserung der Symptomen : 88% Patienten NYHA I-II
- Besserung des 6MGT von 240 m auf 335 m ($p < 0.001$)
- 2 SLD (konservative Therapie)

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NaviGate Cardiac Structures



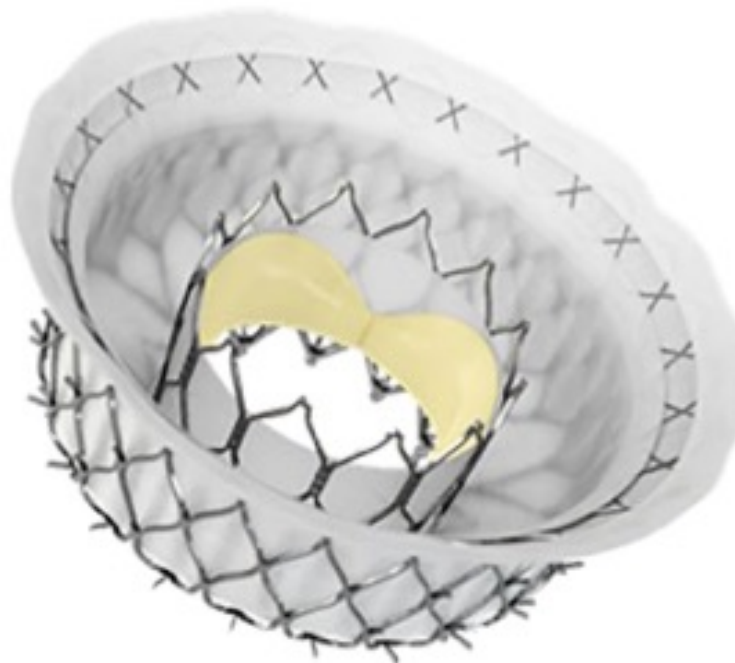
Navigate

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Edwards Lifesciences



EVOQUE

© Mit freundl. Genehmigung von
Medtronic



Intrepid

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Cardiovalve Ltd.



CardioValve

Transfemoraler Trikuspidalklappenersatz:



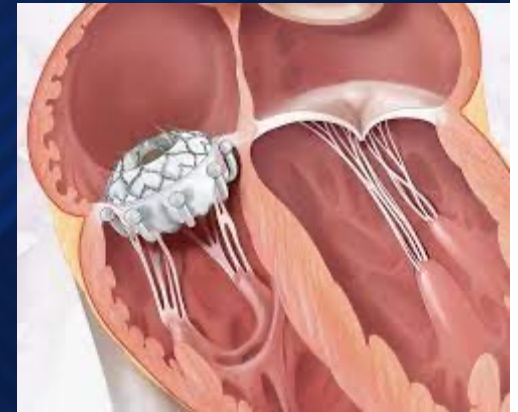
TRISCEND: prospektive, multicetrische, single-arm Studie zu Machbarkeit und Effektivität

Endpunkte: prozeduraler Erfolg, Reduktion der TI, MAEs @ 30d

FU: 30 d, 6 Mo, 12 Mo, jährlich für 5 J

ACC 21: 30-day Results of the TRISCEND Study Transfemoral Tricuspid Valve Replacement in Patients with Tricuspid Regurgitation

Dr Susheel Kodali
Columbia University Medical Center
New York, NY, US



28 F; Gr. 44-48-52mm

Transfemoraler Trikuspidalklappenersatz:



TRISCEND: prospektive, multicentrische, single-arm Studie zu Machbarkeit und Effektivität

Endpunkte: prozeduraler Erfolg, Reduktion der TI, MAEs @ 30d

FU: 30 d, 6 Mo, 12 Mo, jährlich für 5 J

N=56

84% NYHA III-IV

92% => TI III

68% sekundäre TI

11% degenerative TI

21% Gemischt/andere Ätiologie

90% VHF

43% nach Herz-OP





High Device and Procedural Success Rates

Procedural characteristics	% (n/N) or Mean $\pm$ SD (N)
Right femoral vein access	100% (56/56)
Device success ¹	98% (55/56)
Procedural success ²	94% (50/53) ^a
Device time (implant insertion to release), mins	70 $\pm$ 31 (56)

¹Device is deployed and delivery system is retrieved as intended at the time of the patient's exit from the cardiac catheterization laboratory. ²Device success without clinically significant paravalvular leak at the time of discharge. ^aParavalvular leak data not available for 3 patients.

Hospital Outcomes	% (n/N) or Median (Min,Max) (N)
Length of Stay	3.0 (1.0,25.0)
Discharge Location	
Home	89.3% (50/56)
Home with services	5.4% (3/56)
Skilled Nursing Facility	1.8% (1/56)
Other	3.6% (2/56)



Major Adverse Events (MAEs) at 30 Days

CEC Adjudicated Events	N=53 ^a % (n)
Cardiovascular mortality	1.9% (1)
Myocardial infarction	0.0% (0)
Stroke	0.0% (0)
Renal complications requiring unplanned dialysis or renal replacement therapy	0.0% (0)
Severe bleeding ^b	22.6% (12)
Non-elective tricuspid valve re-intervention, percutaneous or surgical	3.8% (2)
Major access site and vascular complications	1.9% (1)
Major cardiac structural complications	0.0% (0)
Device-related pulmonary embolism	0.0% (0)
Composite MAE Rate	22.6% (12)
Other events	
All-cause mortality	3.8% (2) ^c

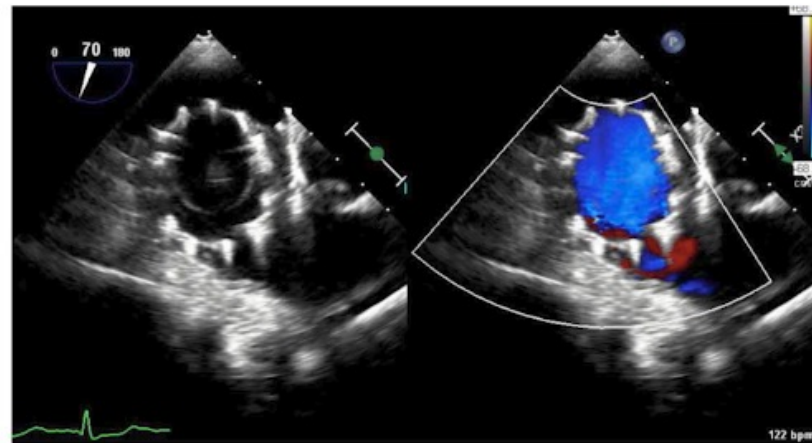
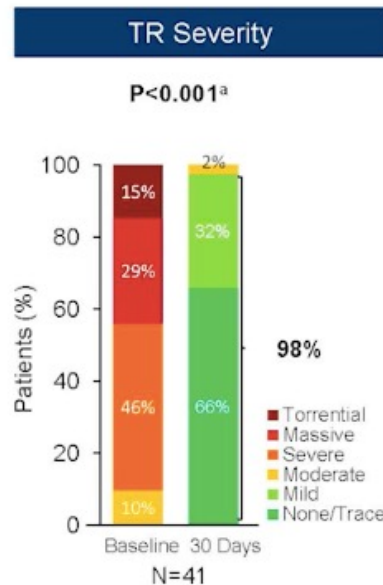
77.4% of patients had no MAEs at 30 days

None of the severe bleeding events were life-threatening or fatal

^aDenominator includes patients who have been in the trial for at least 30 days or have an MAE. ^bSevere bleeding is defined as major, extensive, life-threatening or fatal bleeding per Mitral Valve Academic Research Consortium (MVARC). Severe bleeding events included one access-site, one epistaxis, two GI, one hematuria, one hemolytic anemia, two perioperative blood loss during surgical TV reintervention, and four vascular (non-access site). ^cAll-cause mortality includes one cardiovascular and one non-cardiovascular.



Significant Reduction in TR Severity by Core Lab¹ at 30 Days



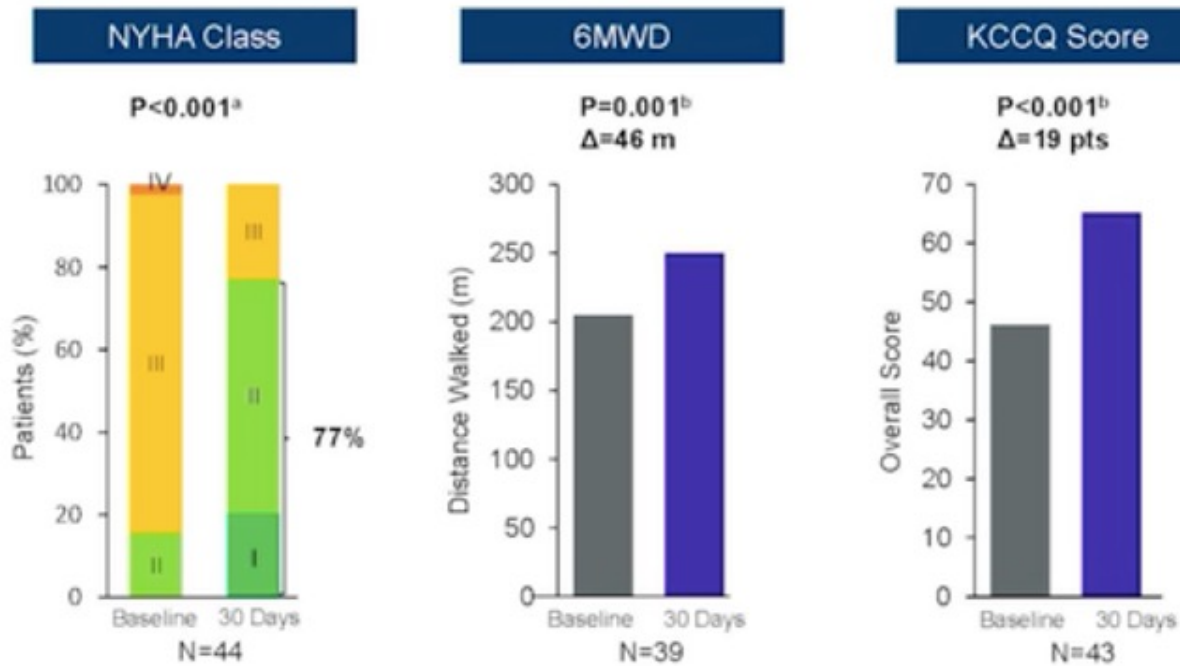
No residual TR post implant with EVOQUE valve

98% achieved reduction in TR severity to none/trace or mild at 30 days
100% achieved ≥ 1 grade reduction, and 95% achieved ≥ 2 grade reduction at 30 days

¹Core lab: Baylor, Scott and White Research Institute; ^aWilcoxon signed-rank test; TR, tricuspid regurgitation



Significantly improved clinical, functional, and quality of life outcomes at 30 days



^aWilcoxon signed-rank test; ^bPaired t-test. NYHA Class, New York Heart Association functional classification; 6MWD, 6-minute walk distance; KCCQ, Kansas City Cardiomyopathy Questionnaire

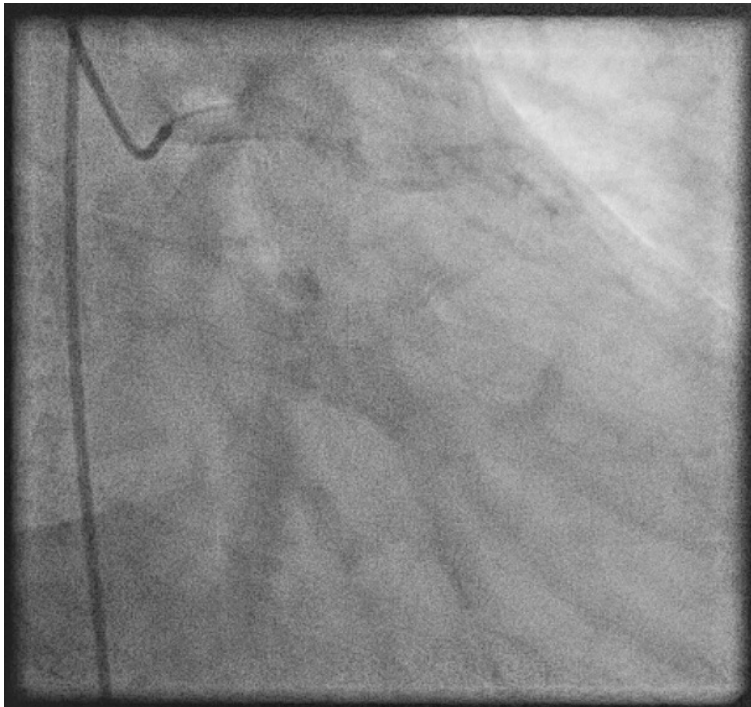


Interventionelle Therapie der ischämischer Kardiomyopathie



Akutes Koronarsyndrom

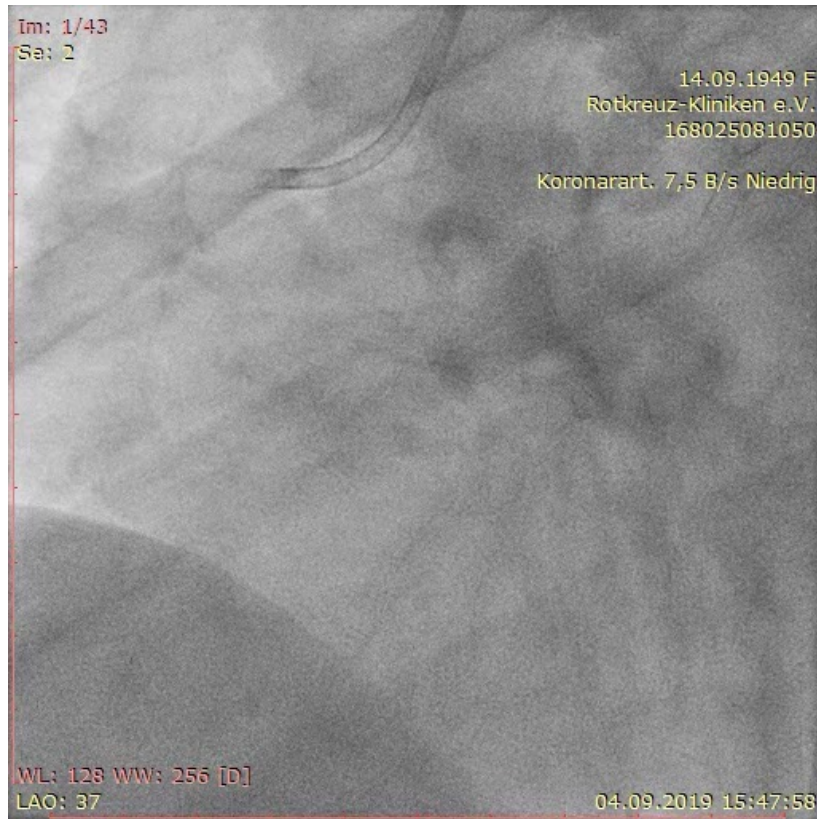
- Ein 48jähriger Pat. mit STEMI
- Interventionelle Behandlung als Rettung der Myokardvitalität



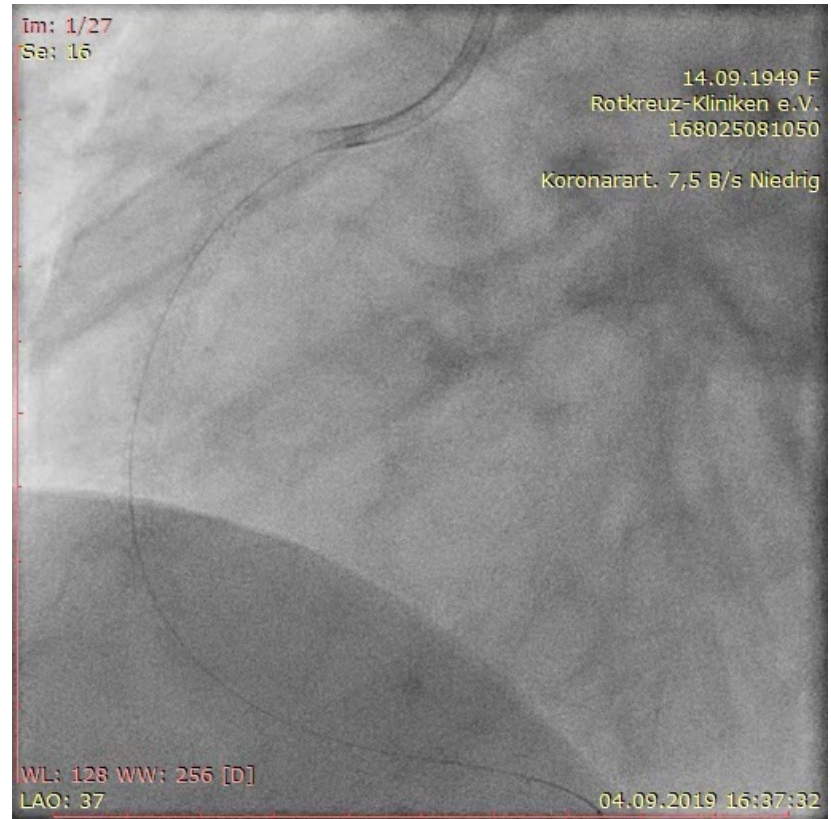
Chronisches Koronarsyndrom



- Eine 70jährige Pat. mit Dyspnoe NYHA II und belastungsinduzierter Ischämie der Hinterwand



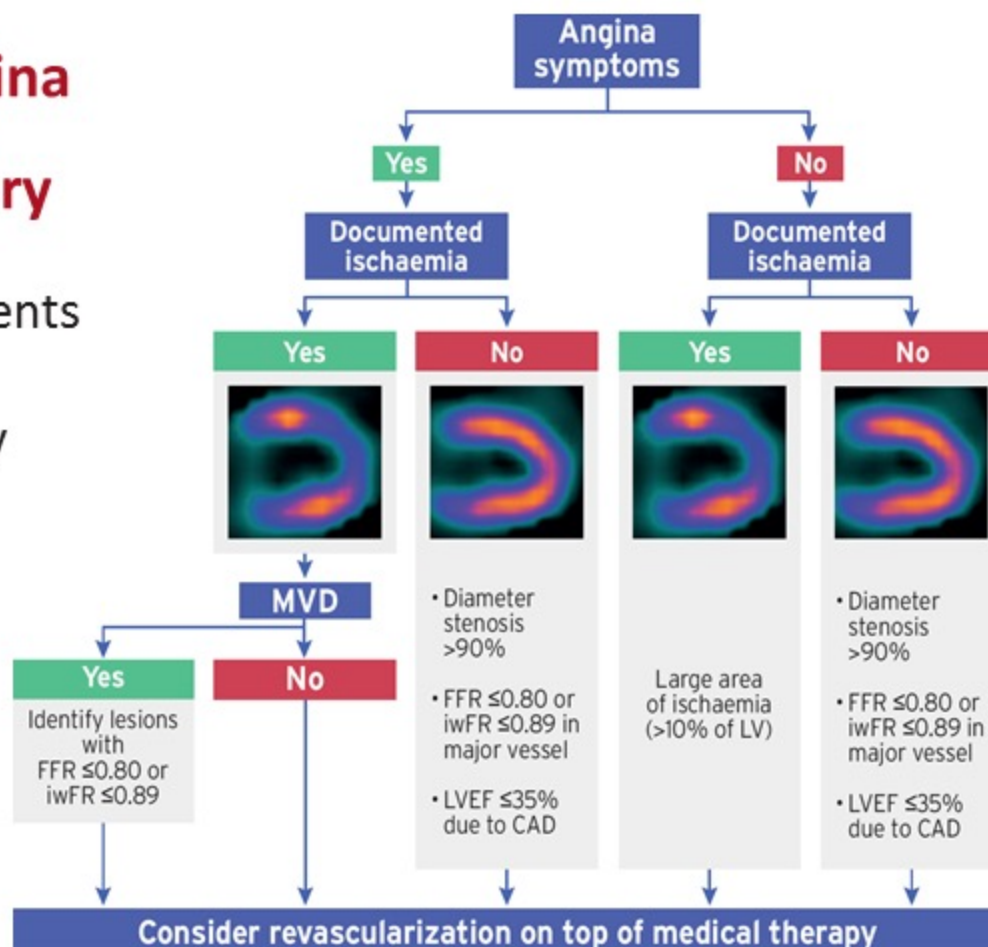
vorher



nachher

Patients with angina and/or dyspnoea and coronary artery disease

Decision tree for patients undergoing invasive coronary angiography



CAD = coronary artery disease;
FFR = fractional flow reserve;
iwFR = instantaneous wave-free ratio;
LV = left ventricle;
LVEF = left ventricular ejection fraction;
MVD = multivessel disease.

Patients with new onset of heart failure or reduced left ventricular function

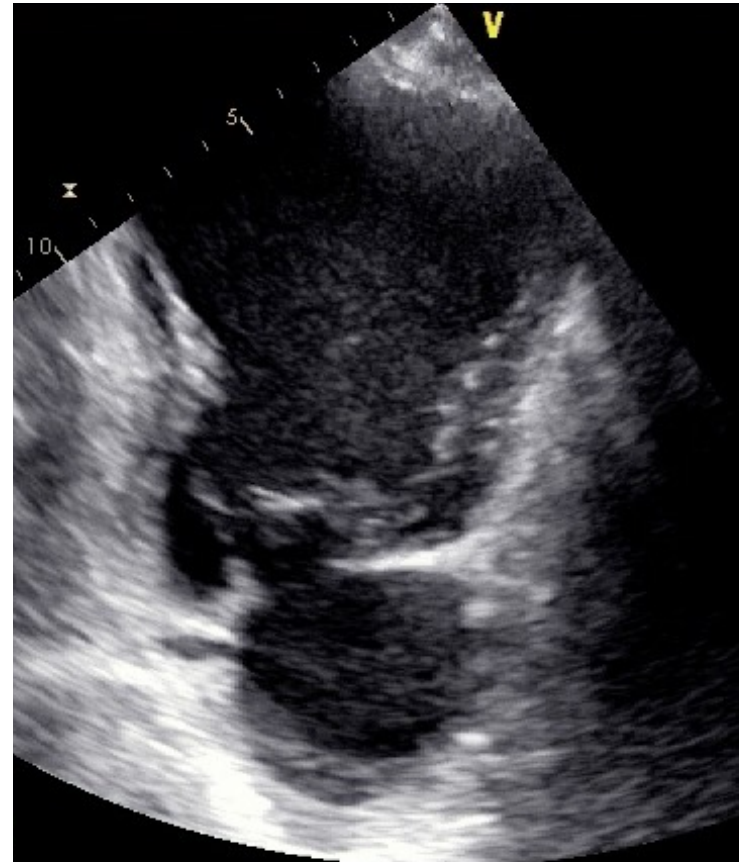
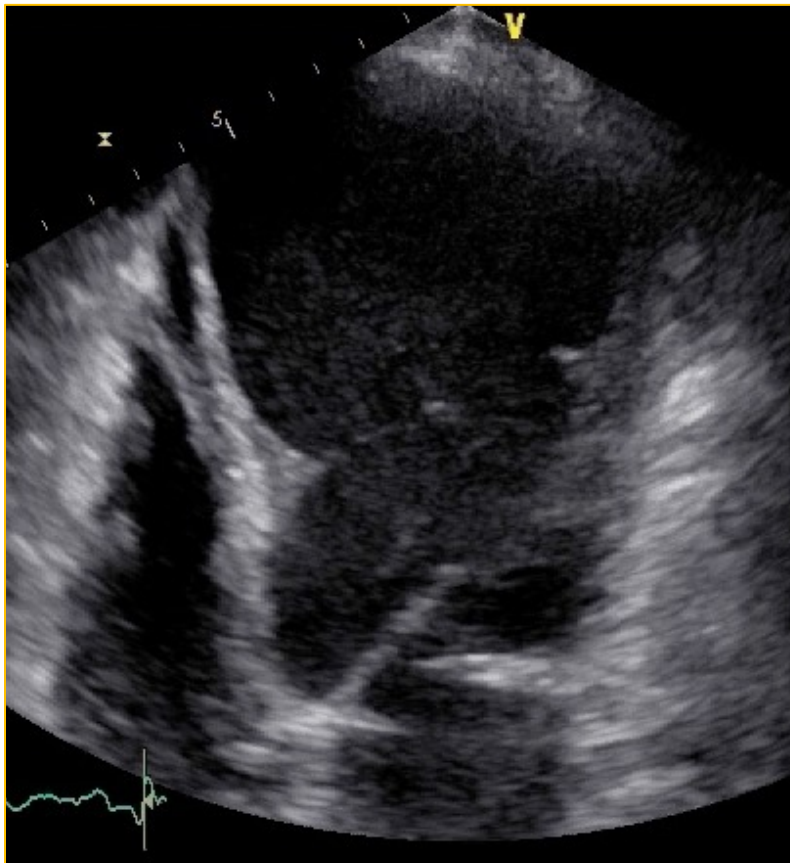
Devices, comorbidities and revascularization (2)

Recommendations	Class	Level
CRT is recommended for symptomatic patients with HF in sinus rhythm with a QRS duration 130-149 ms and LBBB QRS morphology, and with LVEF $\leq 35\%$, despite optimal medical therapy to improve symptoms, and reduce morbidity and mortality.	I	B
Comprehensive risk profiling and multidisciplinary management, including treatment of major comorbidities such as hypertension, hyperlipidaemia, diabetes, anaemia, and obesity, as well as smoking cessation and lifestyle modification, are recommended.	I	A
Myocardial revascularization is recommended when angina persists despite treatment with antianginal drugs.	I	A

.....Endstadium

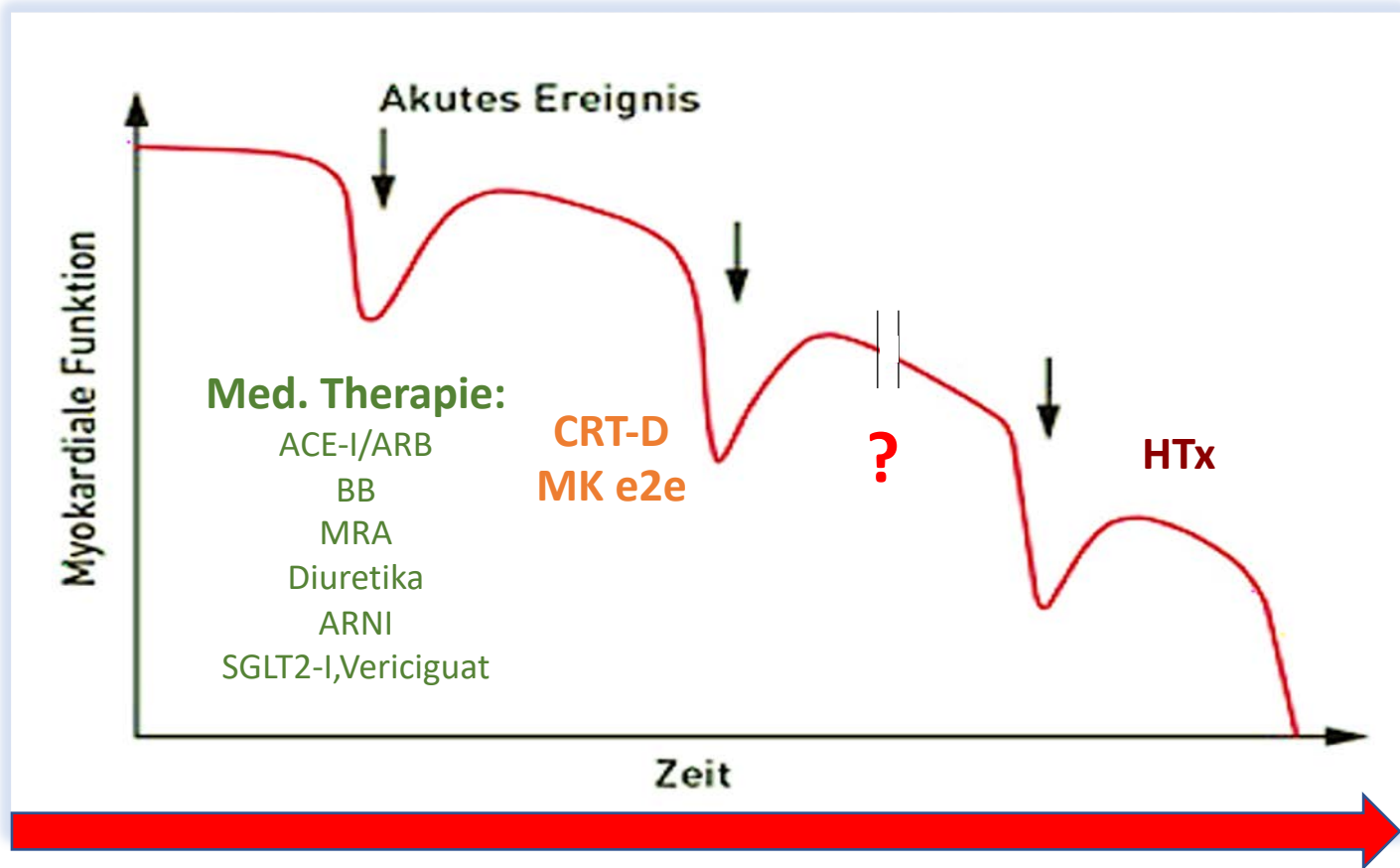
LV-Remodelling nach RIA Verschluss

- Eine 78jährige Pat. nach unbehandeltem Vorderwandinfarkt



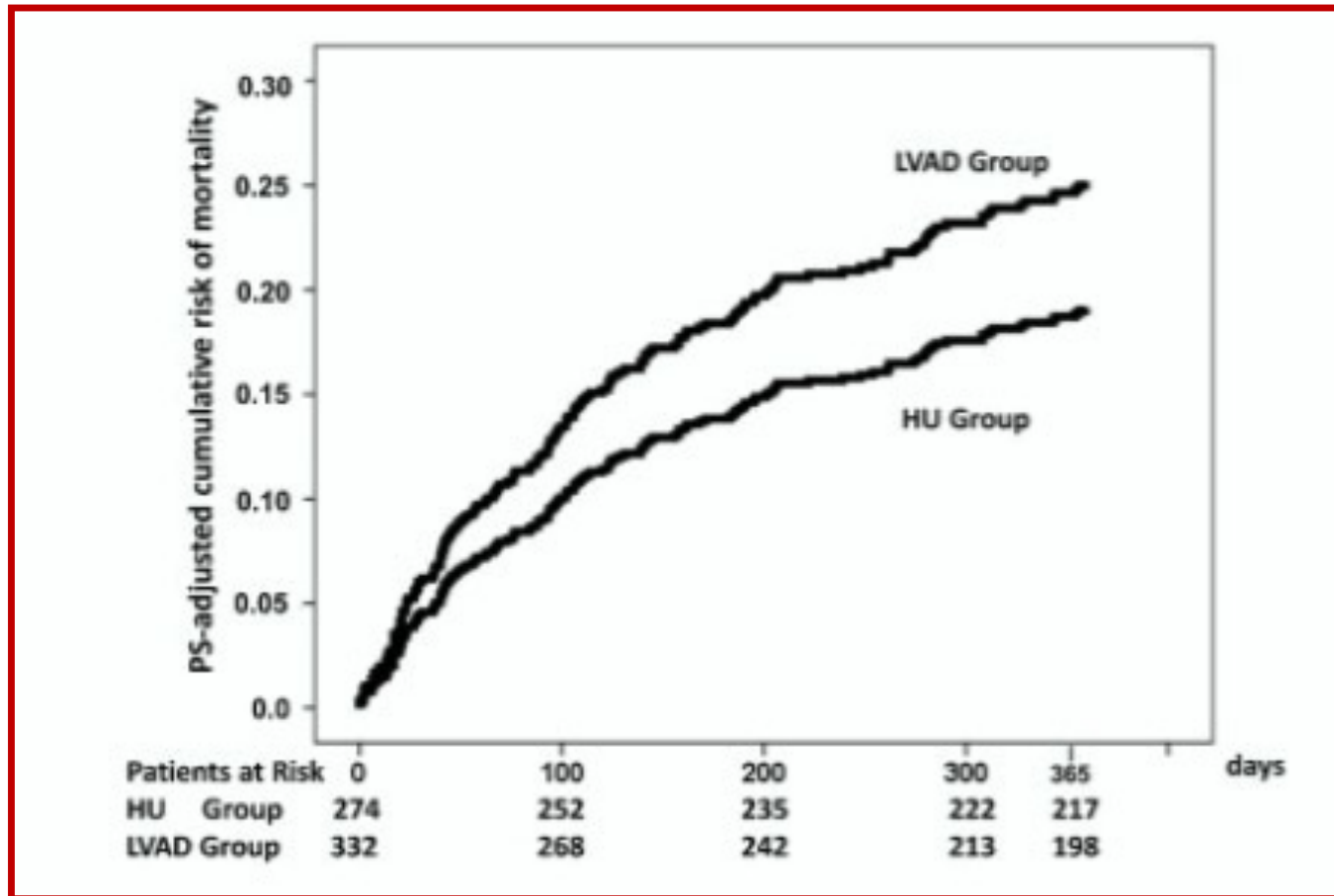


Verlauf der Herzinsuffizienz

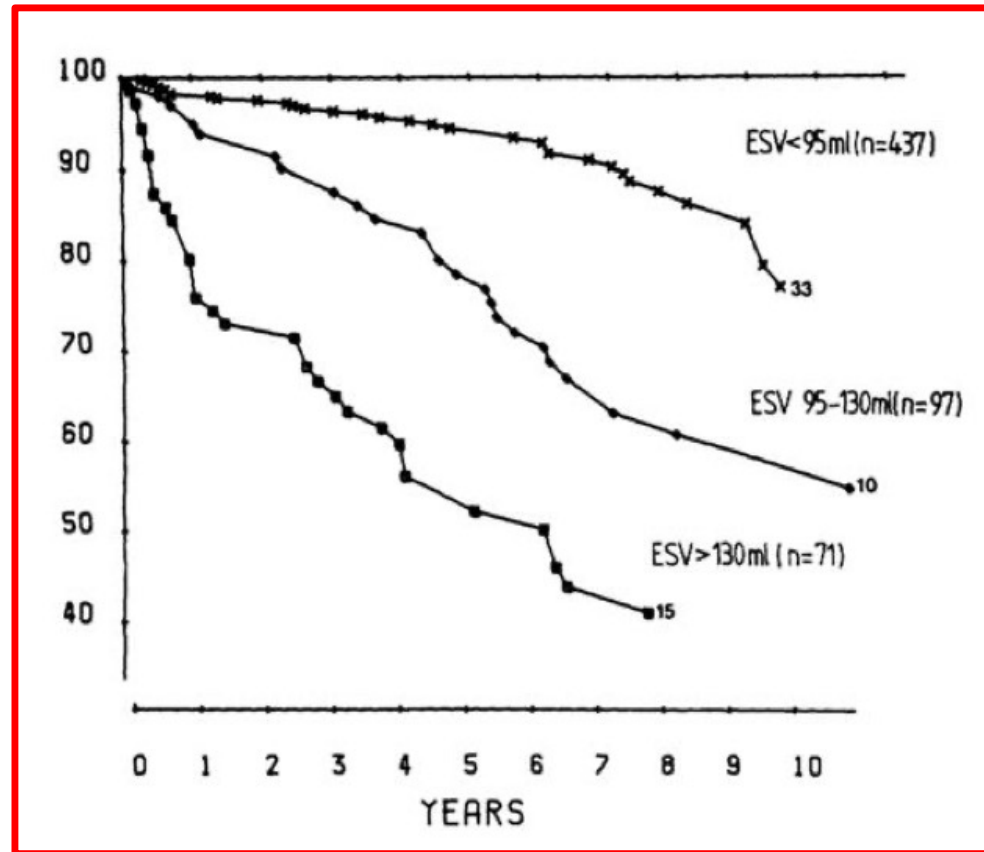




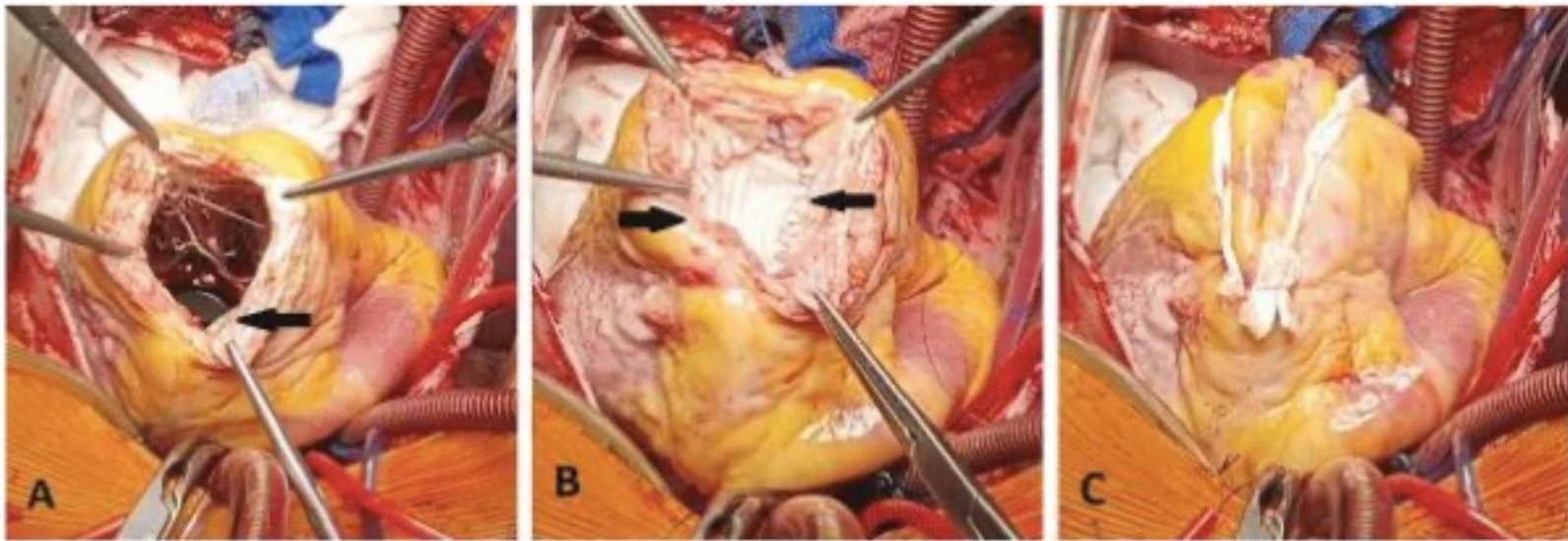
Mortalität auf der Warteliste für HTx



LVESV ist ein unabhängiger Prädiktor der Mortalität nach Herzinfarkt



Dor-Plastik des linken Ventrikels

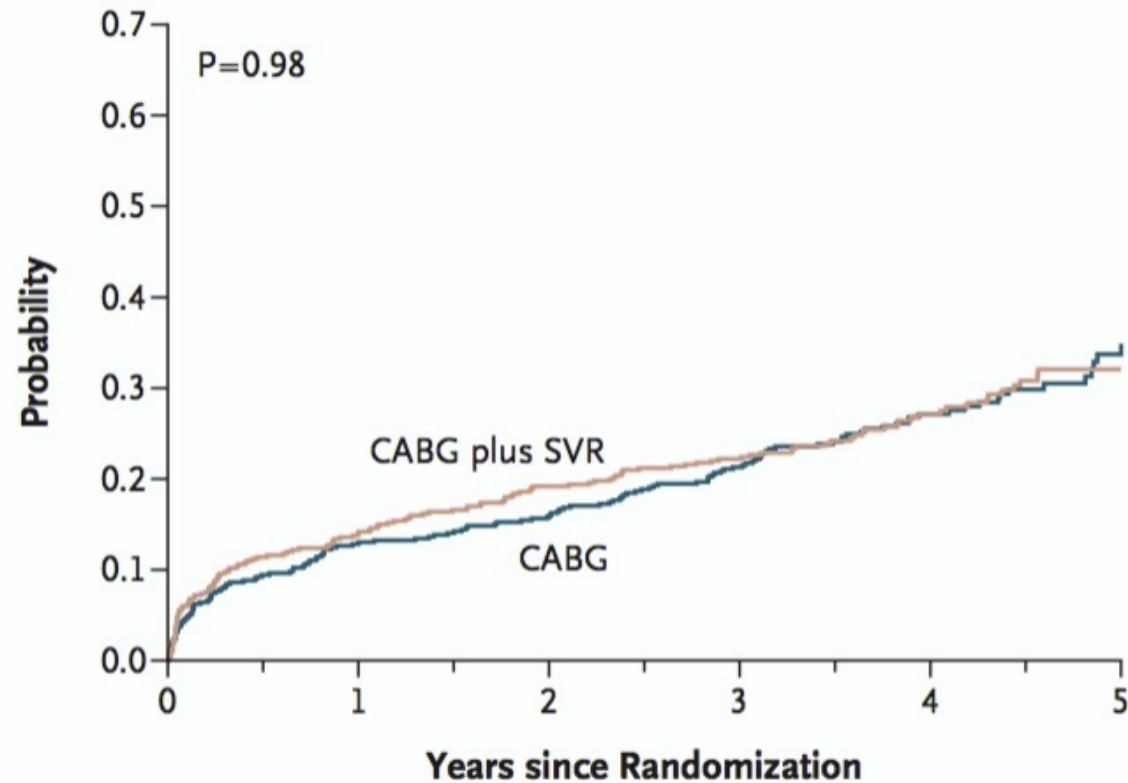


Schreinlechner M et al. Journal für Kardiologie - Austrian Journal of Cardiology 2017; 24 (5-6): 114-116 ©



STICH Studie

B Death from Any Cause



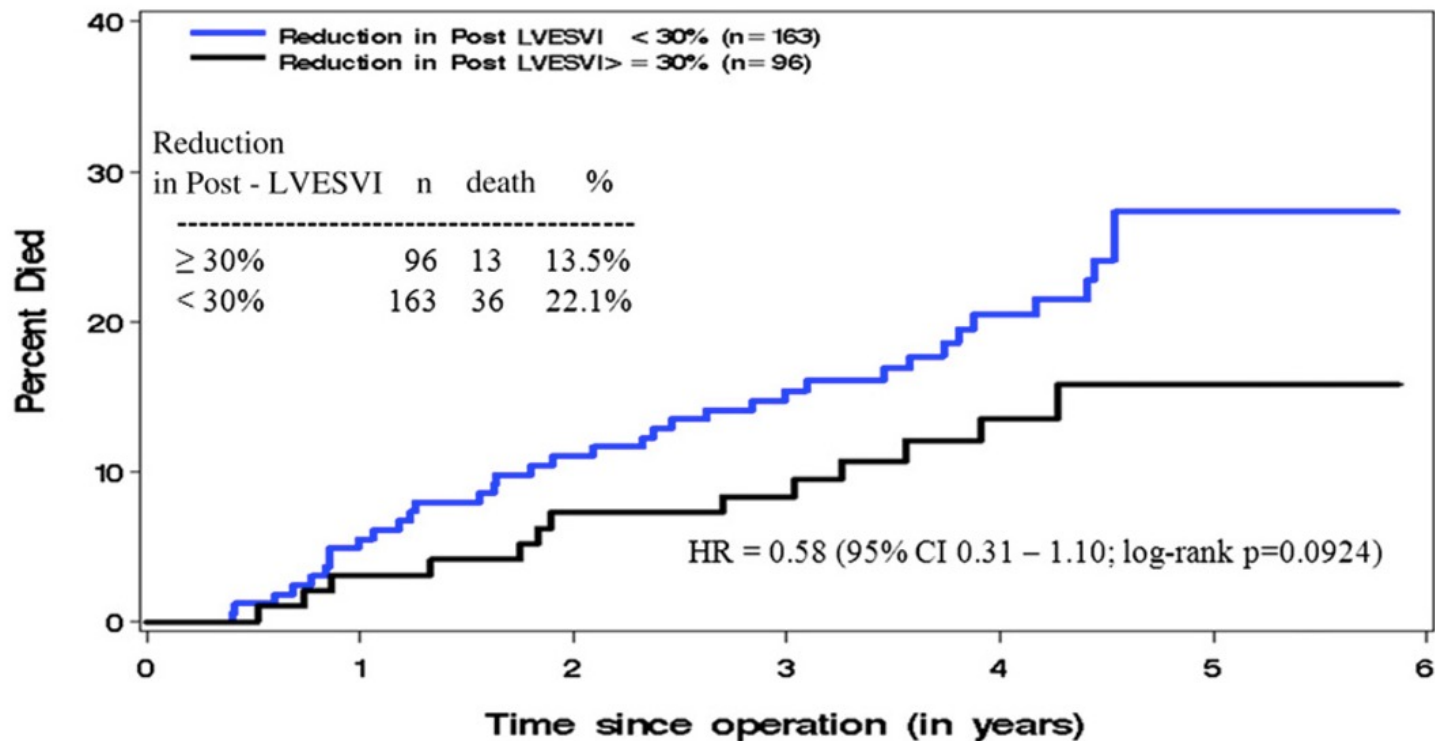
No. at Risk

CABG	499	434	417	363	201	59
CABG plus SVR	501	429	404	352	193	53



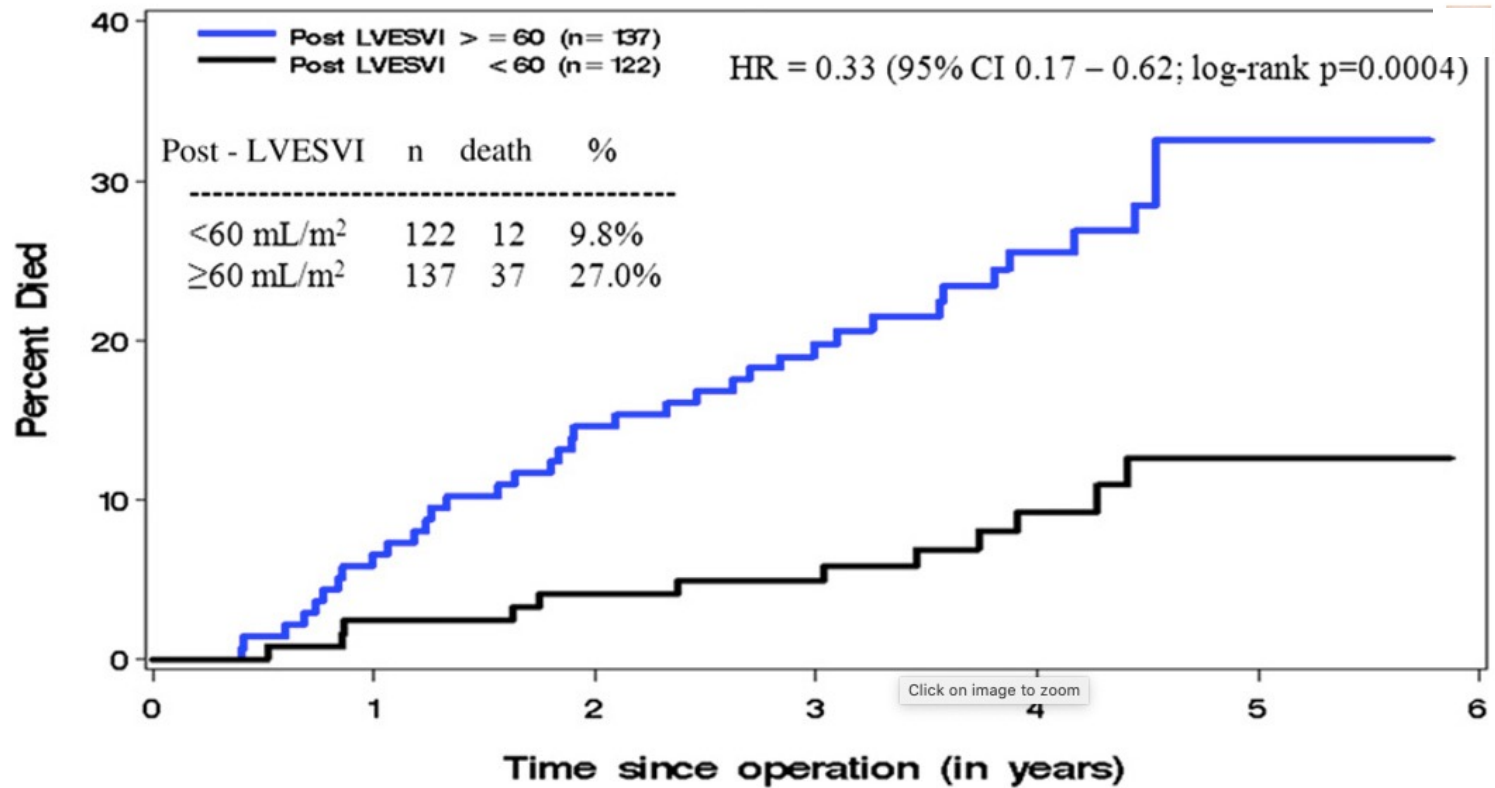
STICH Studie: Subgruppenanalyse

Kaplan-Meier Curves: Cumulative risk of death CABG + SVR patients with same modality (n=259)



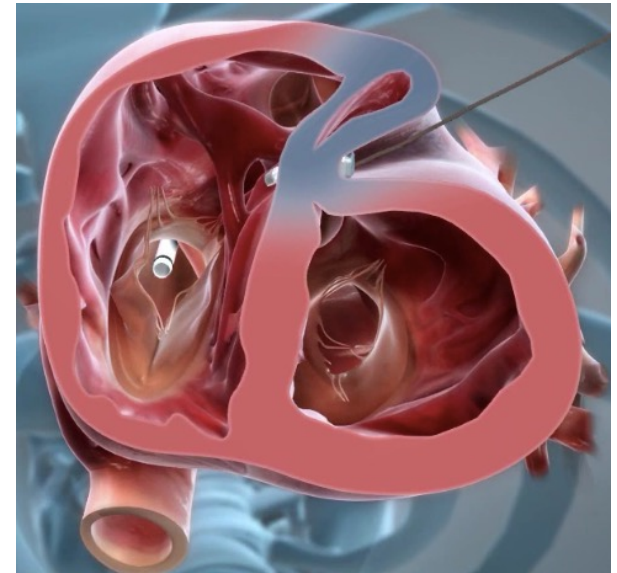
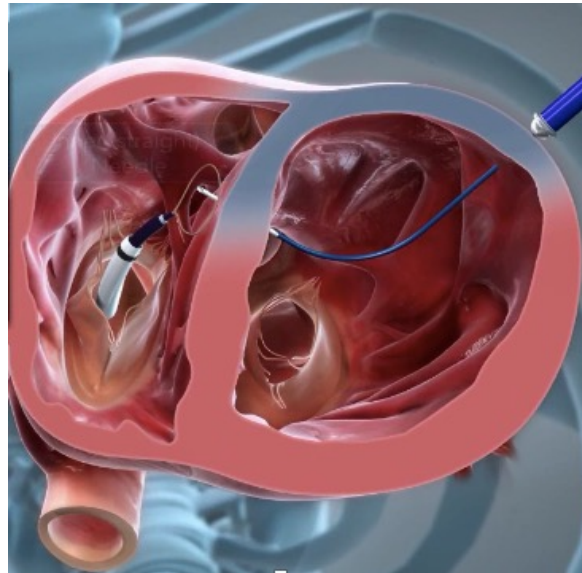


STICH Studie: Subgruppenanalyse





Bioventrix: Revivent-TC

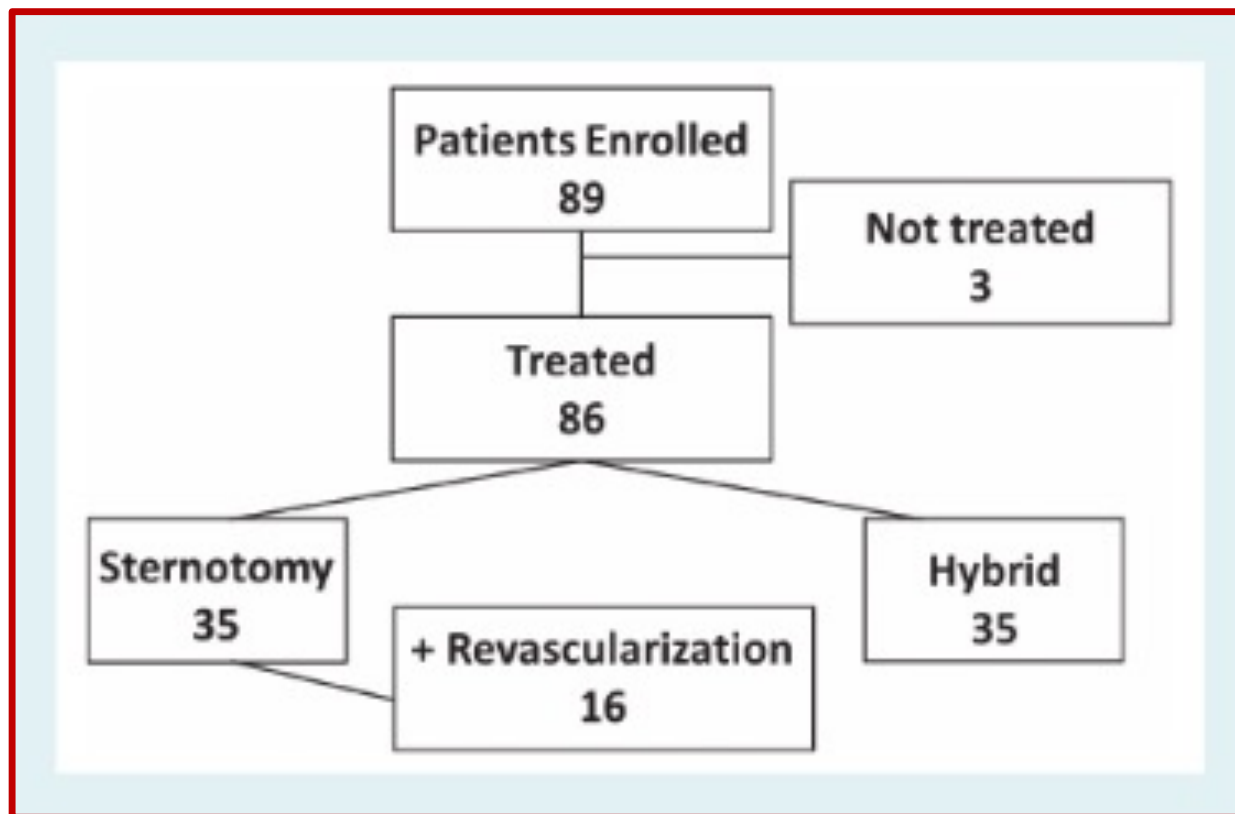




Less invasive ventricular reconstruction for ischaemic heart failure

Patrick Klein^{1*†}, Stefan D. Anker^{2,3,4†}, Andrew Wechsler⁵, Ivo Skalsky⁶, Petr Neuzil⁷, Lon S. Annet⁸, Mauro Bifi⁹, Theresa McDonagh¹⁰, Christian Frerker¹¹, Tobias Schmidt¹¹, Horst Sievert^{12,13}, Anthony N. Demaria¹⁴, and Sebastian Kelle^{4,15,16}

nicht randomisierte, multizentrische Studie





Revivent –TC: Ergebnisse nach 12 Monaten:

Table 3 Haemodynamic data and clinical status at baseline and 12 months for the as treated population with matched data

	Baseline	12 months	% Change	P-value
LVEF (%) (n = 64)	29 ± 8	34 ± 9	16	<0.005
LVESVI (mL/m ²) (n = 67)	74 ± 28	54 ± 23	27	<0.001
LVEDVI (mL/m ²) (n = 67)	106 ± 33	80 ± 26	24	<0.0001
NYHA class (n = 77)	2.6 ± 0.5	1.9 ± 0.8	26	<0.001
6-min walk distance (m) (n = 46)	363 ± 92	416 ± 106	21	<0.001
MLHF score (n = 46)	39 ± 21	26 ± 22	34	<0.001

Values are presented as mean ± standard deviation.

LVEF, left ventricular ejection fraction; LVEDVI, left ventricular end-diastolic volume index; LVESVI, left ventricular end-systolic volume index; MLHF, Minnesota Living with Heart Failure; NYHA, New York Heart Association.



Nach 12 Monaten: Revivent vs. Revivent-TC

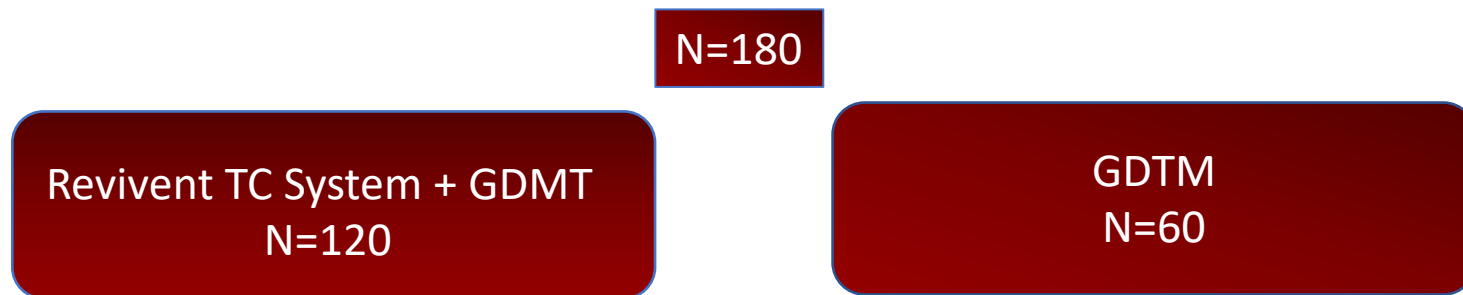
	Revivent	Revivent-TC	
• Besserung der LVEF	29 ± 8% v	34 ± 9%	p<0.005
• Volumenreduktion:			
• LVESI	74 ± 28 ml/m ²	54 ± 23 ml/m ²	p<0.001
• LVEDVI	106 ± 33 ml/m ²	80 ± 26 ml/m ²	p<0.0001
• Überlebensrate		90,6% (4 verstorben im KH)	
• NYHA III nach 12 Monaten	59%	22%	
• QOL	39	26 Punkte	p<0.001
• 6MWT	363m	416m	p<0.001

REVIVE-HF

Randomized Evaluation and Verification of Ventricular Enhancement

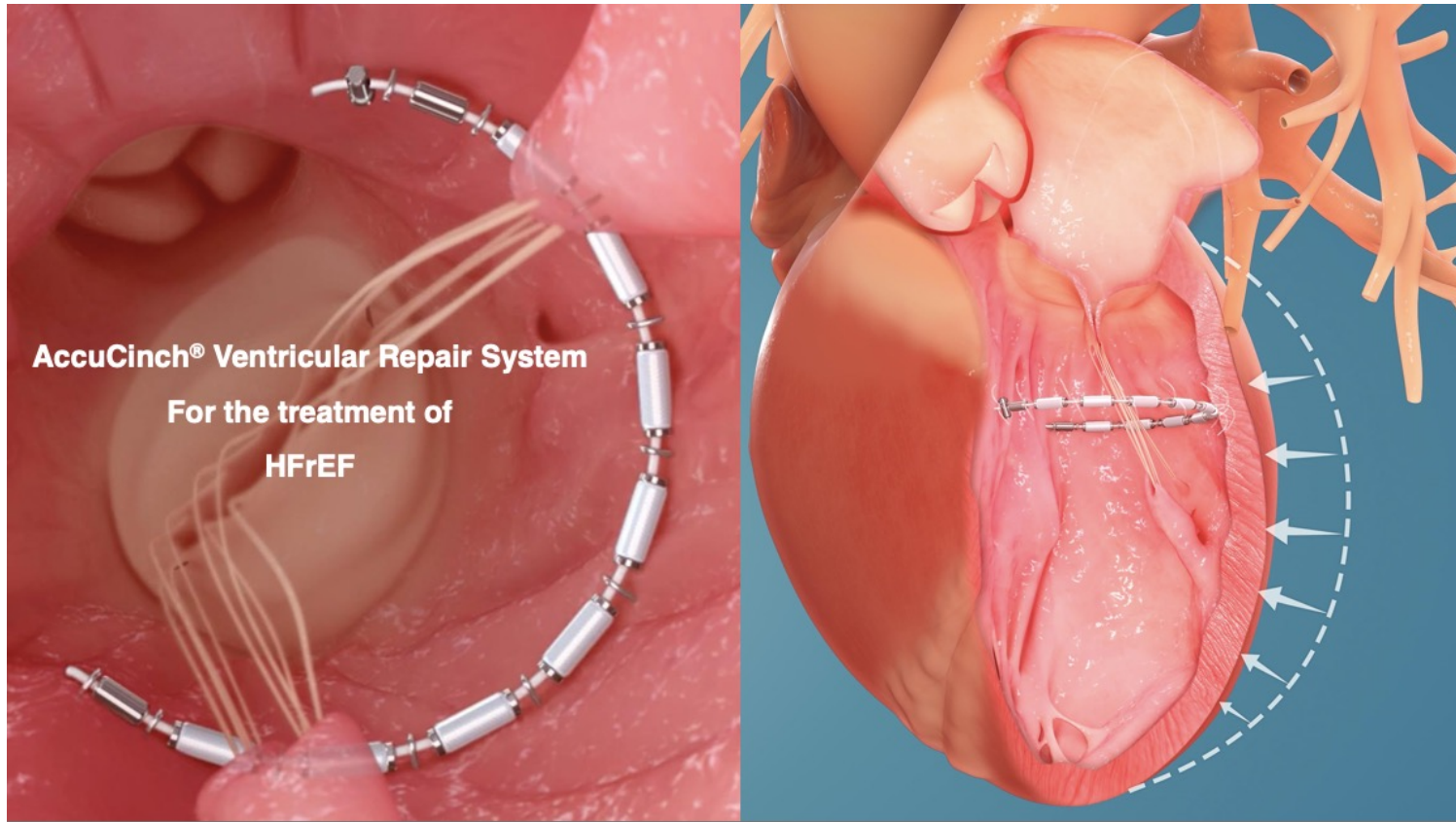


- Prospektive, randomisierte, multizentrische Studie untersucht die Effektivität der Herzinsuffizienztherapie der Ischämischen CMP
- Ziel: nachzuweisen, dass die Behandlung mit BioVentrix-Revivent-TC System ist effektiver als GDMT allein



Studienbeginn	01.01.2020
Zwischenergebnisse	31.12.2021
Studienende	31.12.2022

Subvalvuläre LV-Reduktion: AccuCinch/ANCORA

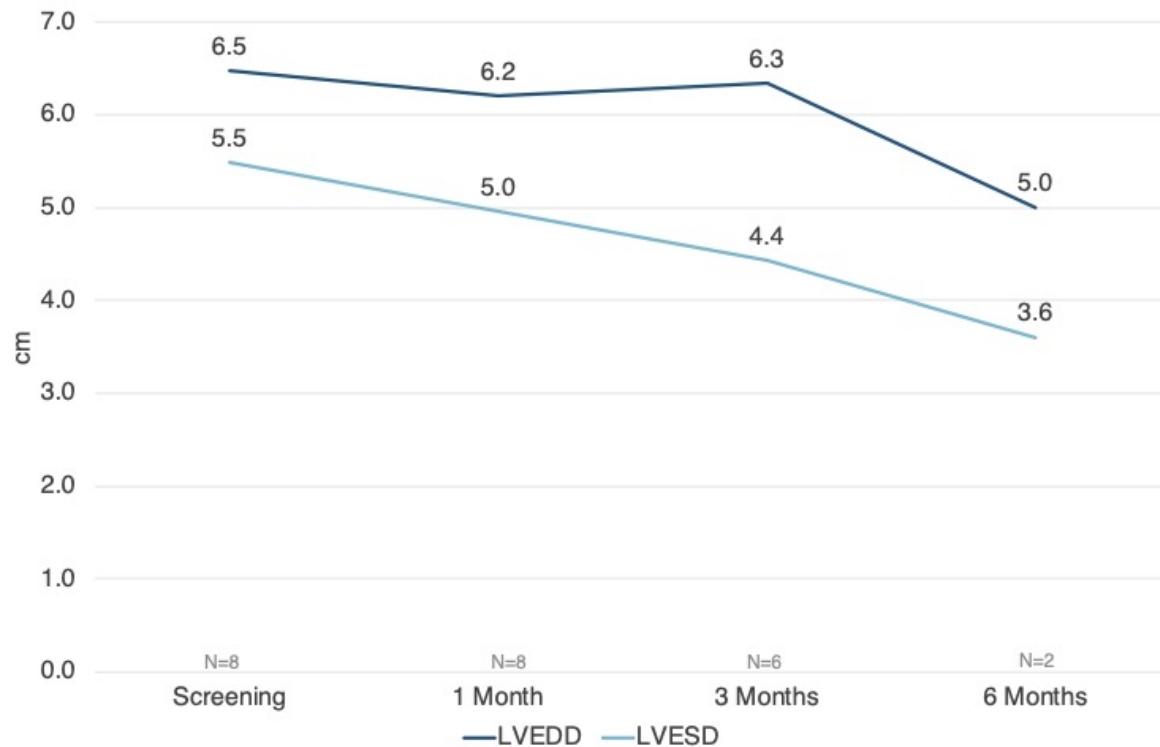


AccuCinch® Ventricular Repair System
For the treatment of
HFrEF

- Reduziert die LV-Dimensionen und Volumina
- Reduziert LV-Wandstress
- Induziert reverses Remodelling

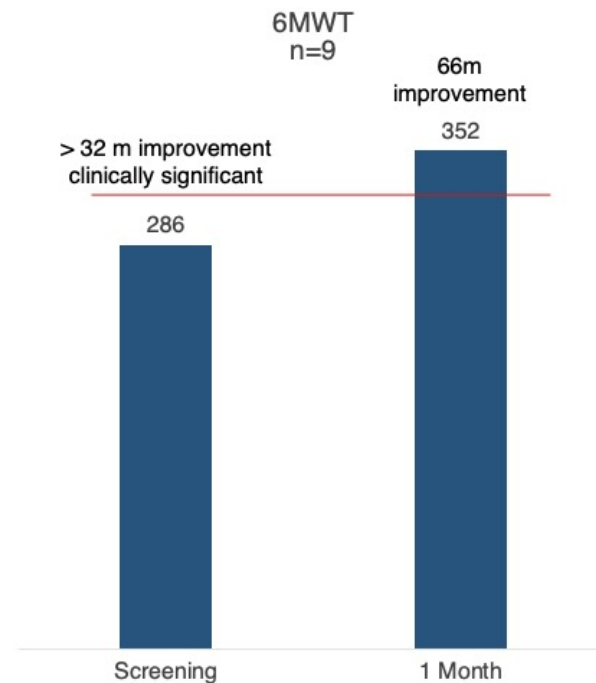
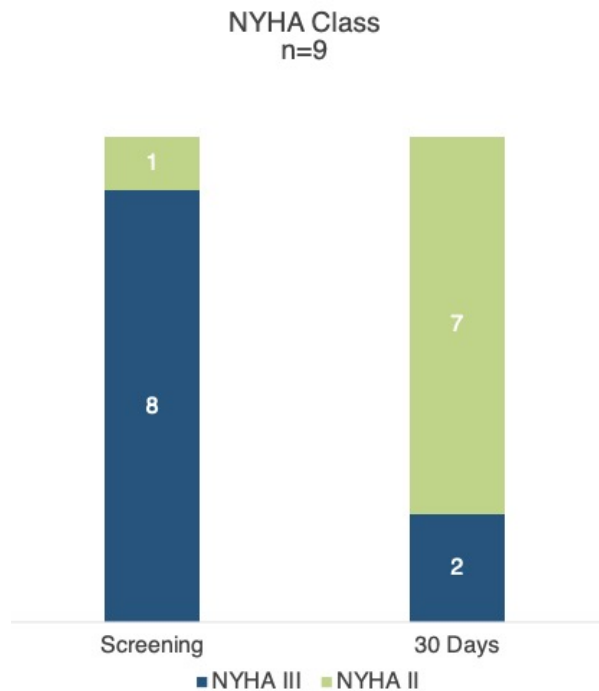


Reduktion der LV- Größe



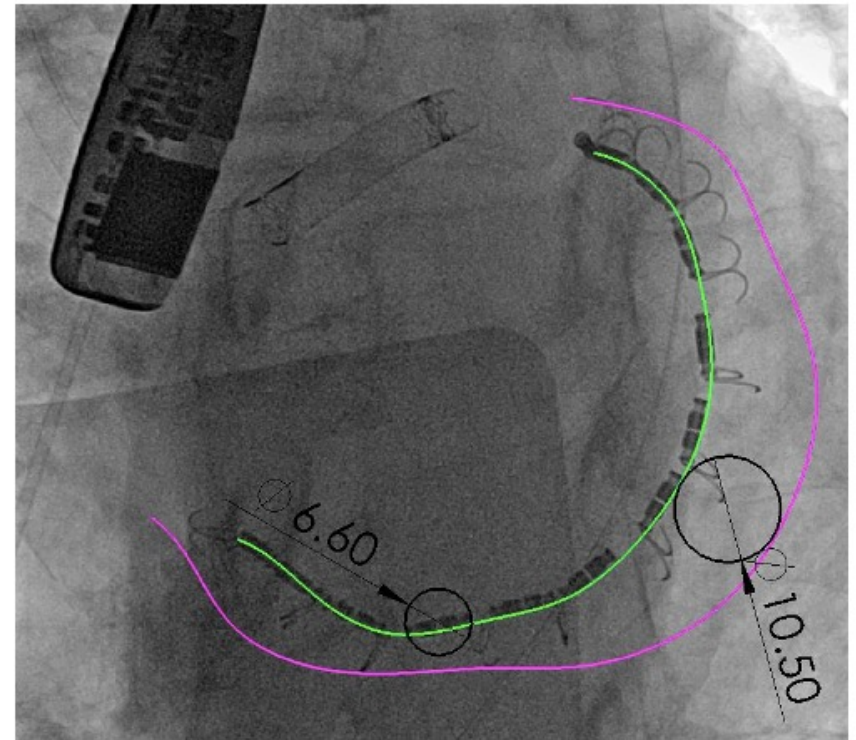
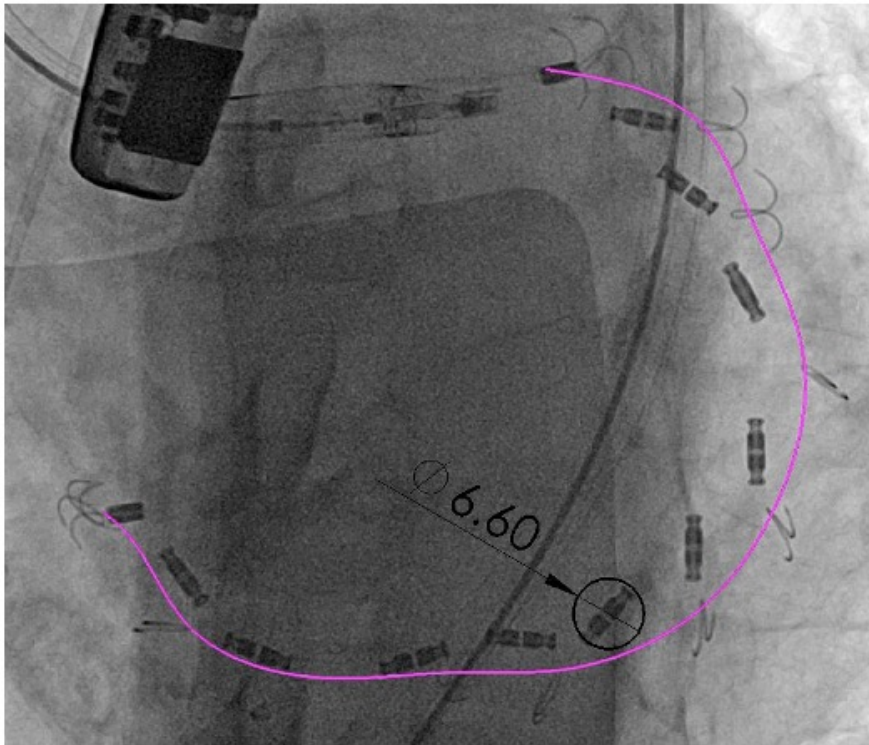


Besserung der Belastbarkeit





Subvalvuläre LV-Reduktion: AccuCinch/ANCORA



pre	129.5	mm
post	89.8	mm
delta	39.7	mm
cinch %	31%	



The CORCINCH-HF Study – IDE Pivotal Trial

OVERVIEW	• Design: Prospective, randomized, open-label, multi-center clinical safety and efficacy investigation • Randomization: 1:1 – Treatment with the AccuCinch System plus guideline-directed medical therapy (GDMT) or GDMT alone • Enrollment: 400 subjects at up to 80 centers • Endpoints: • Safety & efficacy evaluated when 250 subjects reach 6-mo f/u • Safety & efficacy evaluated when 400 subjects reach 12-mo f/u
KEY INCLUSION CRITERIA	• LVEF: 20-40% • NYHA: • II (with HF hospitalization in the past 12 months) • III • IV (ambulatory) • LVEDD: ≥ 55 mm • MR: $\leq 2+$

CORCINCH HF Study Leadership

Chairman:
Marty Leon, MD

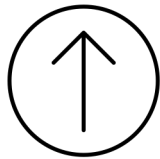
Co-Principal Investigators:
Mark Reisman, MD
Ulrich Jorde, MD



CURRENTLY ENROLLING

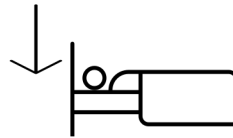


Behandlungsziele:



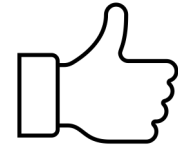
Lebensdauer

- Reduktion von Mortalität, vorzeitigen Todesfällen und zunehmendem Pumpversagen



Reduktion der Hospitalisierungsrate

- Stress für Patienten und Angehörige
- Ungünstiger Prognosefaktor
- Weitere Verschlechterung der Herzfunktion
- Verstärkung der Therapie



Wohlbefinden

- Besserung der Symptome und Lebensqualität
- Bremsen der Progression
- Erhalt der Selbständigkeit mit möglichst wenig Einschränkungen



Kardiocentrum
Frankfurt

Vielen Dank für Ihre Aufmerksamkeit

I.vaskelyte@kardiocentrum.de