UNIVERSITÄTS
KLINIKUM
HEIDELBERG

RV Function in patients with LVAD indication?

PD Dr. Philip WJ Raake, UK Heidelberg

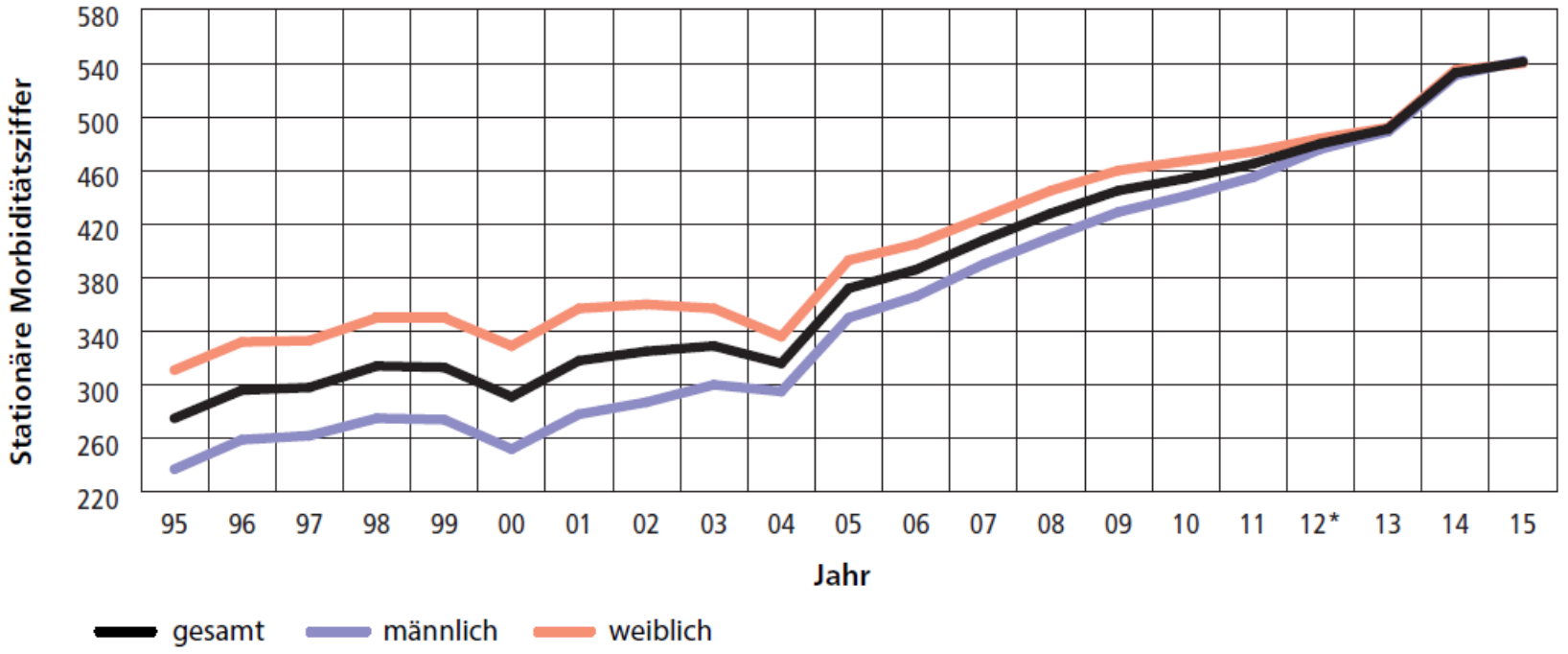
UK HD

Disclosures

- Research grant:
  - Novartis, Servier.

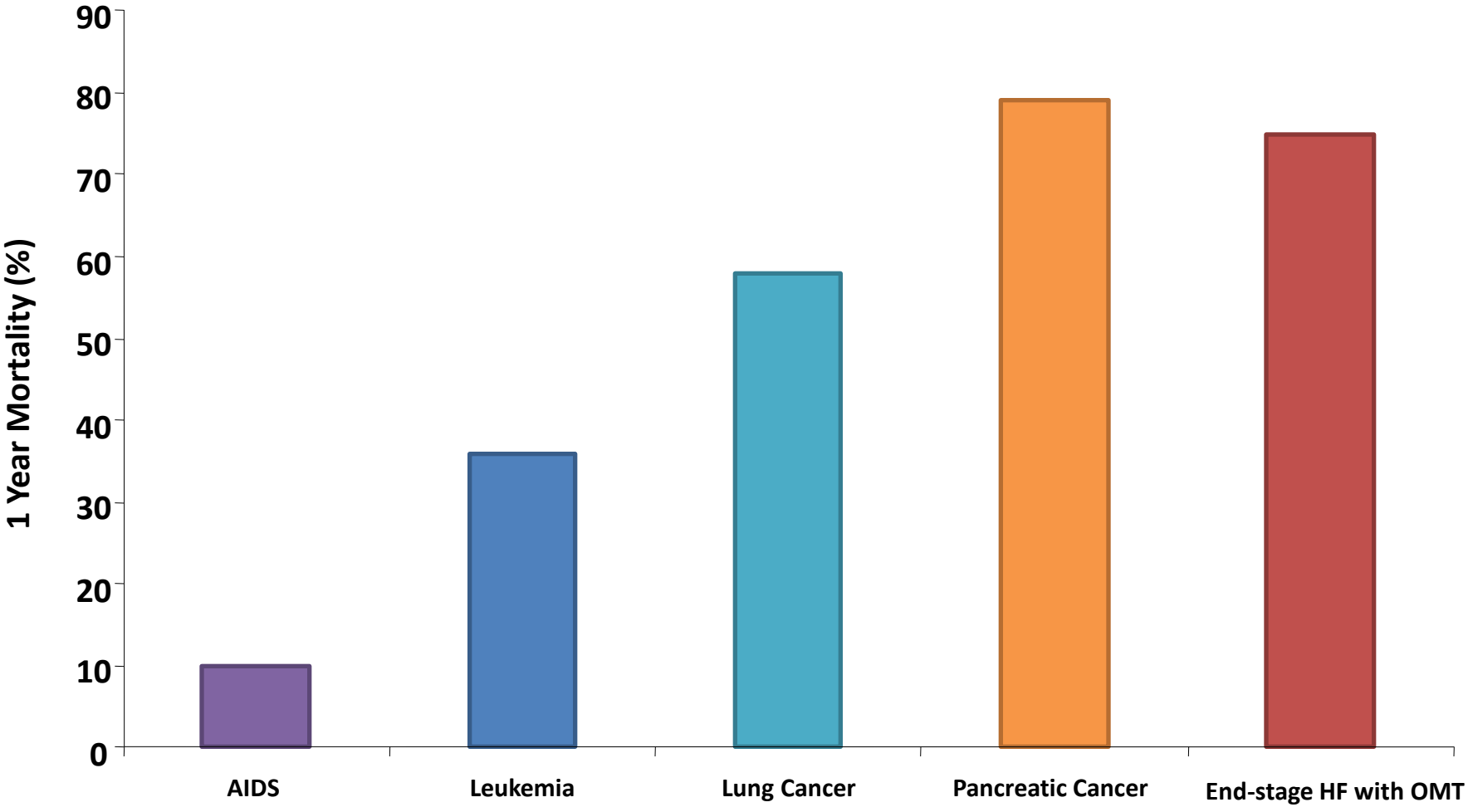
- Speaker honoraria:
  - Novartis, Medtronic, St. Jude Medical, Abbott, Maquet, Heartware.

Pandemie Herzinsuffizienz



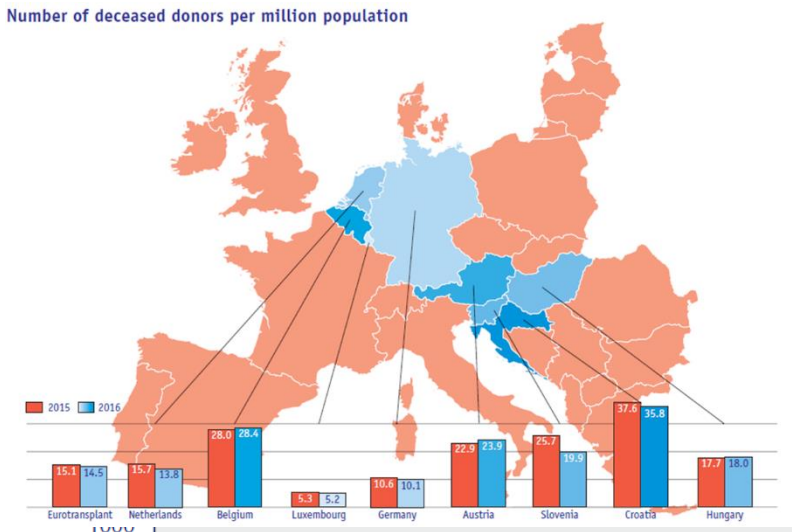
Deutscher Herzbericht, Statistisches Bundesamt

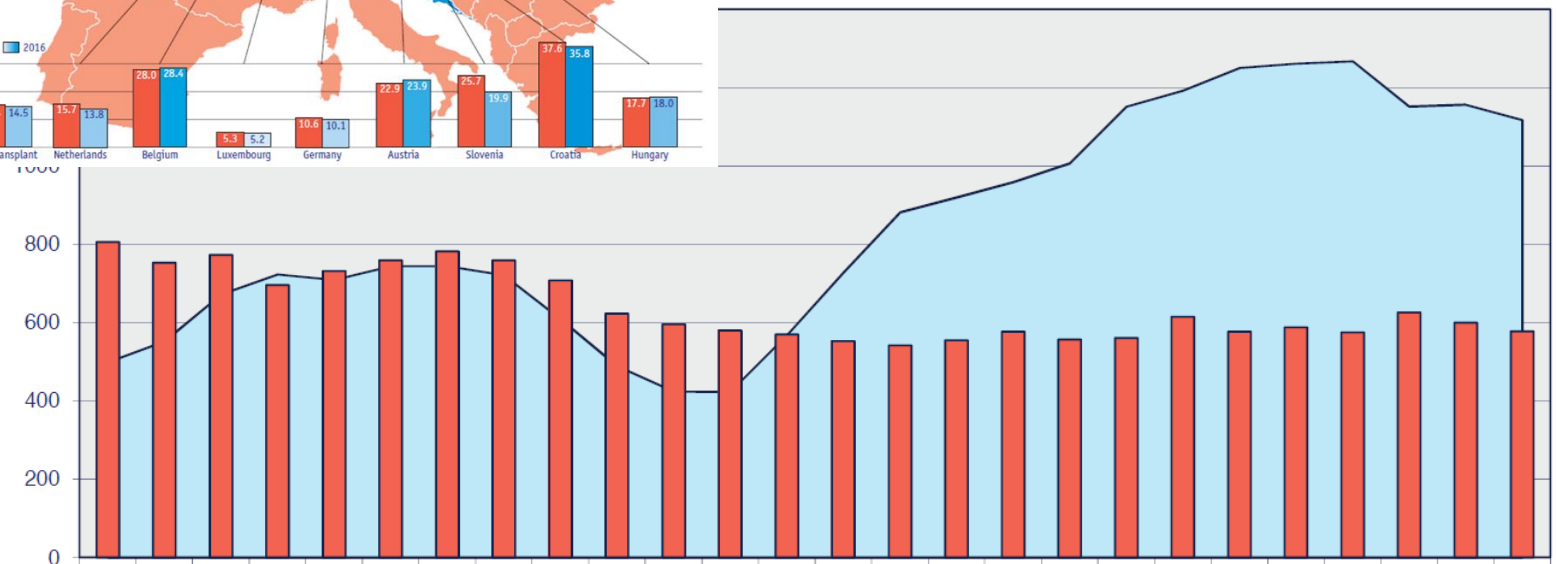
Mortalitätsrisiko bei terminaler Herzinsuffizienz



Rose EA, et al. N Engl J Med. 2001 Nov 15;345(20):1435-43.

ET: Herztransplantationen und Warteliste





	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Active waiting list	499	552	672	723	709	744	744	721	609	489	424	423	568	728	882	920	959	1007	1152	1193	1251	1262	1268	1152	1157	1118
Heart transplants	806	753	773	696	732	759	782	759	708	623	596	580	570	553	542	555	577	557	561	615	577	588	575	626	600	578

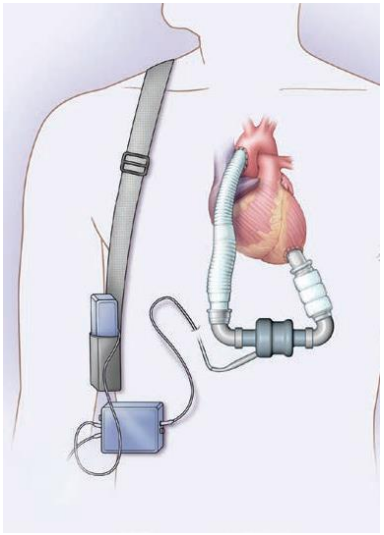
Eurotransplant Annual Report 2016

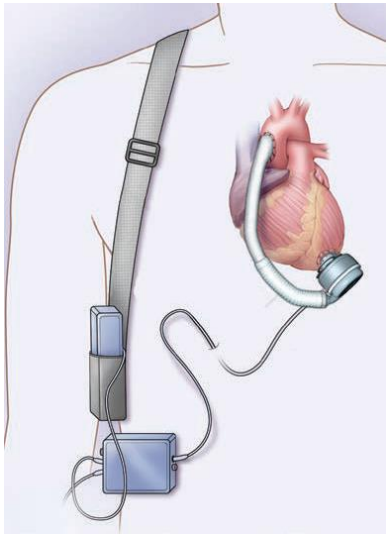
ORIGINAL ARTICLE

Two-Year Outcomes with a Magnetically Levitated Cardiac Pump in Heart Failure

M.R. Mehra, D.J. Goldstein, N. Uriel, J.C. Cleveland, Jr., M. Yuzefpolskaya, C. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, G.A. Ewald, A. Itoh, D. Dean, A. Krishnamoorthy, W.G. Cotts, A.J. Tatooles, U.P. Jorde, B.A. Bruckner, J.D. Estep, V. Jeevanandam, G. Sayer, D. Horstmanshof, J.W. Long, S. Gulati, E.R. Skipper, J.B. O'Connell, G. Heatley, P. Sood, and Y. Naka, for the MOMENTUM 3 Investigators*

2018





HeartMate II™ LVAD

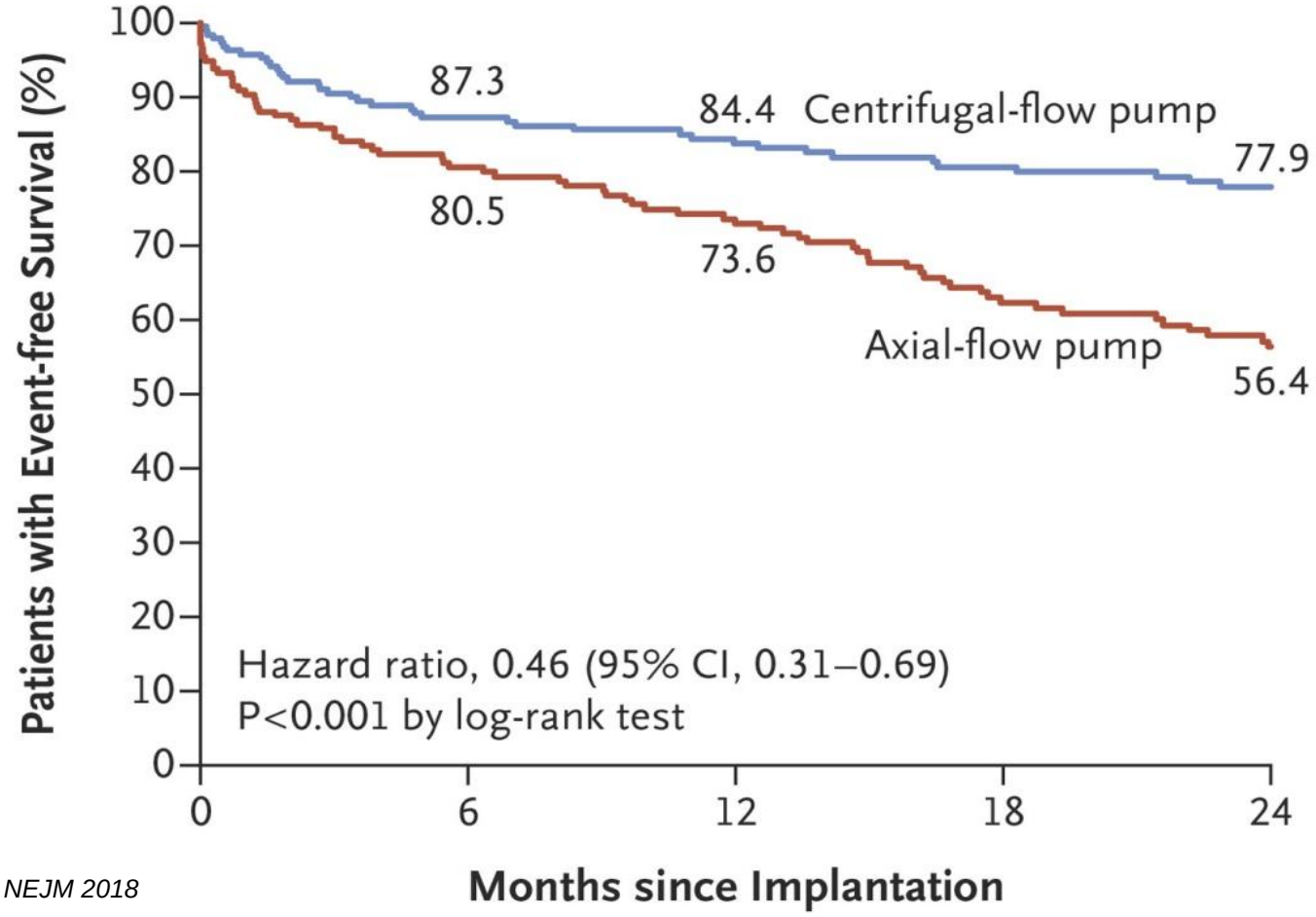
Axial flow-pump

HeartMate 3™ LVAD

Centrifugal flow-pump

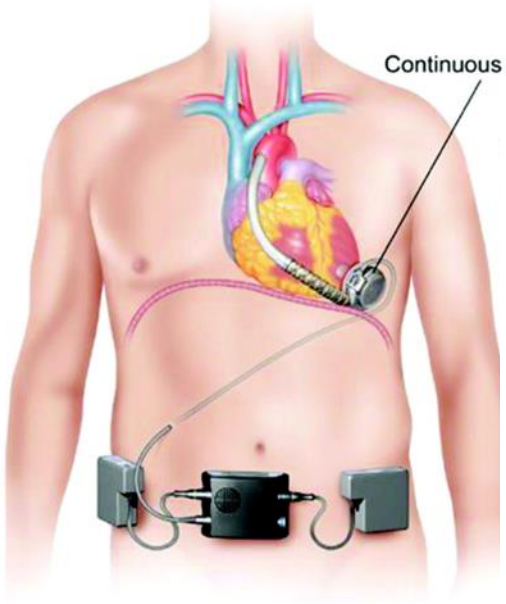
Primärer Endpunkt

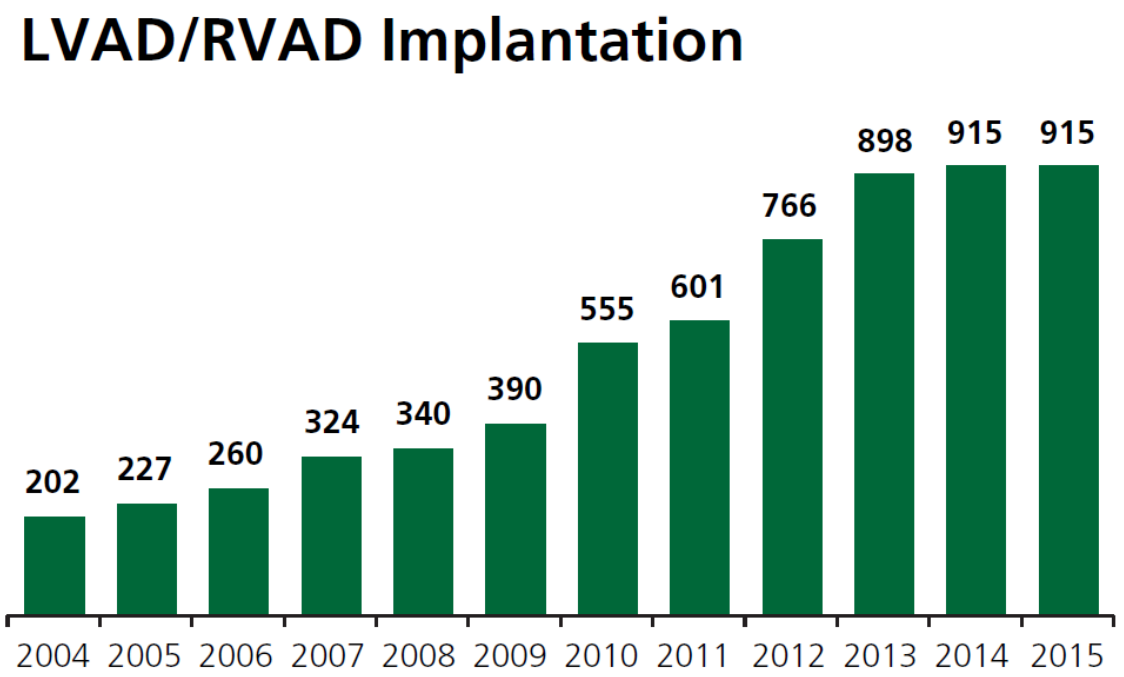
2-Jahres Überleben ohne Reoperationen und/oder Auftreten von Apoplex mit bleibender Beeinträchtigung



Mehra et al. NEJM 2018

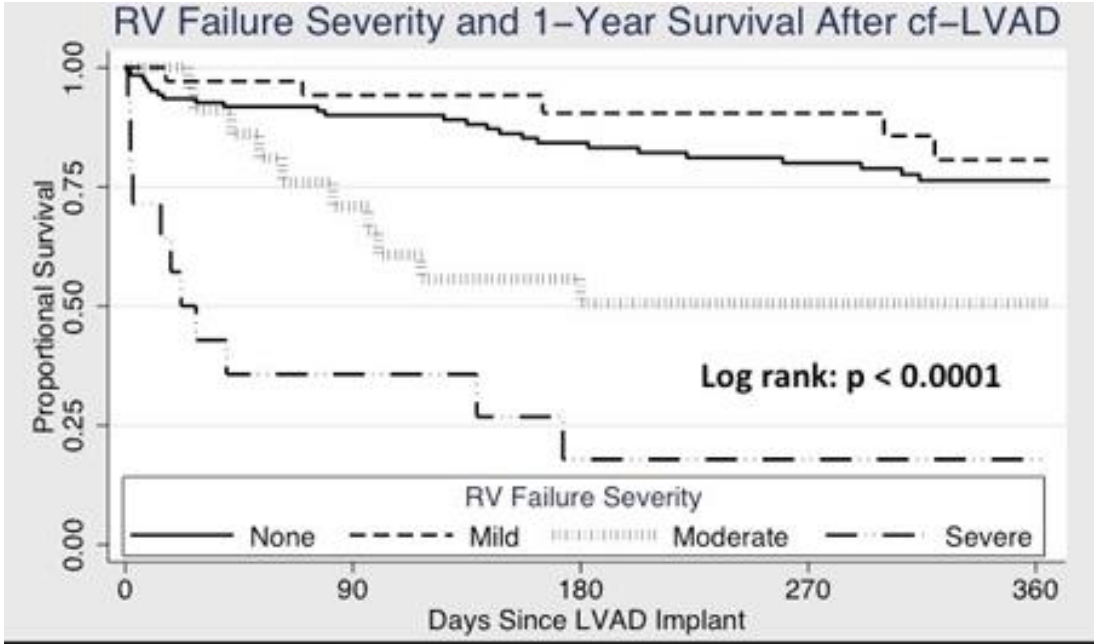
VAD-Implantationen in der BRD





Deutscher Herzbericht 2016, Aaronson Circulation 2012

cf-LVAD: RH-Insuffizienz ist prognostisch relevant



Multivariable Model*		Hazard Ratio (95% CI)	p value
RV Failure Severity	None	Referent	----
	Mild	0.71 (0.27 – 1.91)	0.50
	Moderate	2.59 (1.15 – 5.81)	0.02
	Severe	9.10 (4.22 – 19.66)	< 0.0001

* Adjusted for age, sex, BMI, GFR, CVP, and INTERMACS Class

Wilson et al. Circulation 2015

RV-Failure in LVAD patients

Pre-Market Approval Results for the HeartMate II

19% of patients developed right heart failure during the pre-market approval of the HeartMate II.
Source: HeartMate II FDA Summary of Safety and Effectiveness.
http://www.accessdata.fda.gov/cdrh_docs/pdf6/P060040b.pdf

ADVANCE Clinical Study Results for the HeartWare HVAD

22% of patients developed right heart failure requiring either a right ventricular assist device (RVAD) or inotropic support.
Source: Evaluation of the HeartWare HVAD Left Ventricular Assist System for the Treatment of Advanced Heart Failure: Results of the ADVANCE Bridge to Transplant Trial; Keith Aaronson, Mark Slaughter, Edwin McGee, et al. for the HeartWare ADVANCE Investigators; American Heart Association Scientific Sessions November 2010

Professional Papers

33% Tricuspid annular motion as a predictor of severe right ventricular failure after left ventricular assist device implantation.
Puwanant S, Hamilton KK, et al. J Heart Lung Transplant. 2008 Oct;27(10):1102-7.

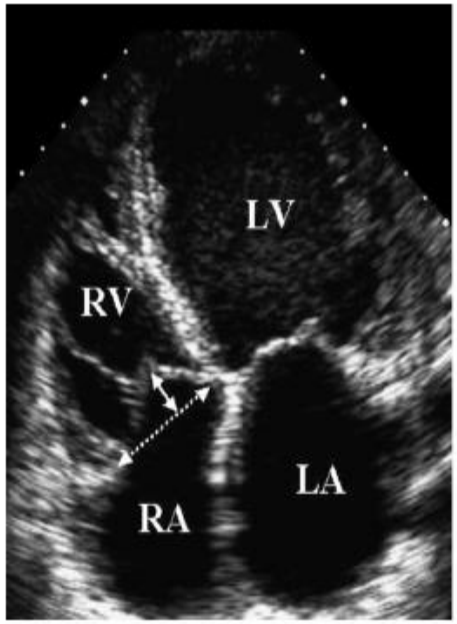
25% The right ventricular failure risk score a pre-operative tool for assessing the risk of right ventricular failure in left ventricular assist device candidates.
Matthews JC, Koelling TM, et al. J Am Coll Cardiol. 2008 Jun 3;51(22):2163-72.

39% Right heart failure after left ventricular assist device implantation in patients with chronic congestive heart failure.
Dang NC, Topkara VK, et al. J Heart Lung Transplant. 2006 Jan;25(1):1-6. Epub 2005 Dec 9.

Modified from Syncardia

19-39% RV-Failure post LVAD-Implant

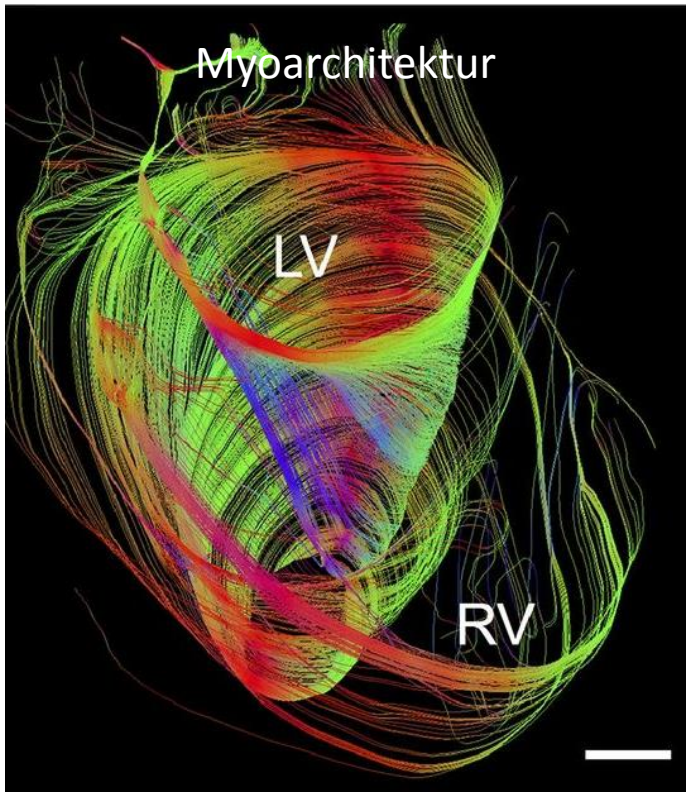
Einflussgrößen bei RH-Insuffizienz und sekundärer TI

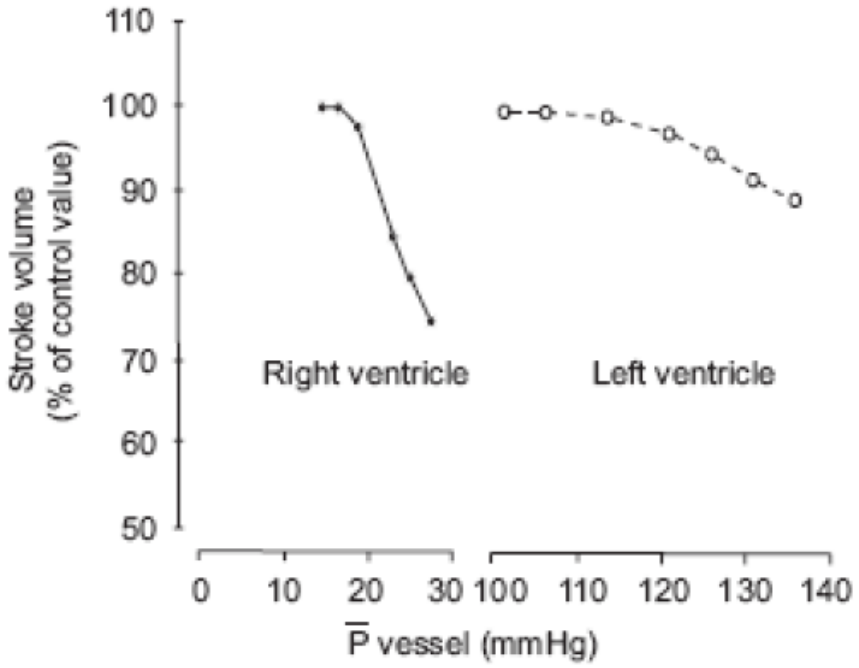


- Vorlast
- Nachlast
- Kontraktilität

Fukuda et al. Am Heart J 2006

Der RV ist sensibel für Änderungen der Vor-/Nachlast





Braunwald 1984, Schulman et al. Cardiol Clinics 1992, Taylor et al. JAHA 2016

Pathophysiologie

Herzinsuffizienz:

- Cardiac Output↓
- PCWP, PVR, PAP ↑
- RV-Funktion ↓

LVAD:

- Cardiac Output ↑
- PCWP, PVR, PAP ↓
- RV-Funktion (↑)

Ideale Konstellation

Linksherzentlastung
(PCWP, PAP & PVR↓)

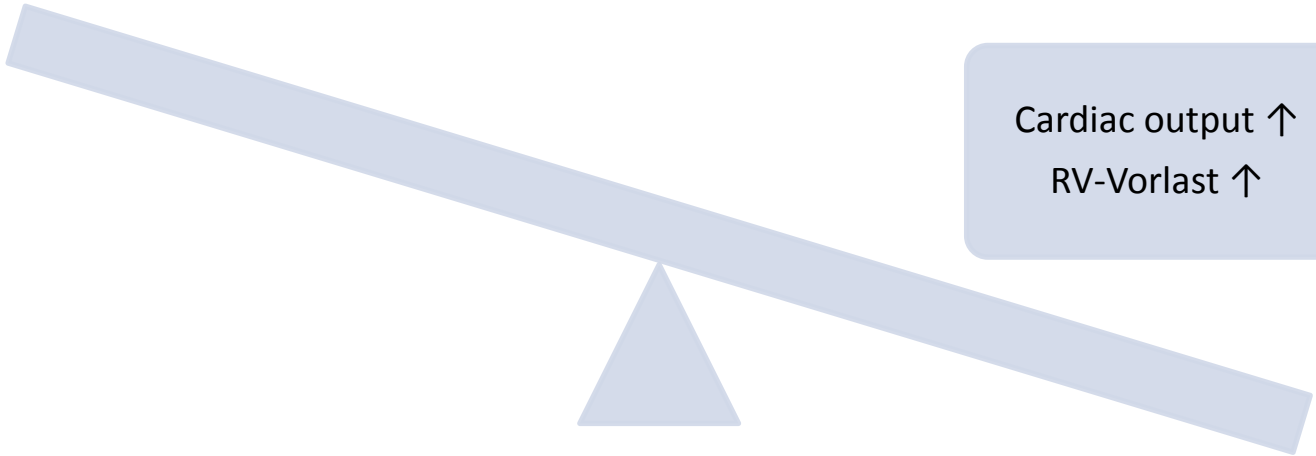
LVAD:
- Cardiac Output ↑
- PCWP, PVR, PAP ↓
- RV-Funktion ↑

Cardiac output ↑

Warum Rechtsherzversagen?

Gefahr eines akuten Rechtsherzversagens

Linksherzentlastung
(PCWP, PAP & PVR↓)



Cardiac output ↑
RV-Vorlast ↑

Beurteilung / Einschätzung der Rechtsherzfunktion vor LVAD-Implantation

- Klinik
  - Aszites, periphere Ödeme, Stauungsdermatitiden, Leberfunktion (Syntheseparameter, Cirrhose cardiaque…)
- Echokardiographie
  - RV-Funktionsparameter, RV Diameter (RVEDD), TAPSE, Trikuspidalinsuffizienz…
- Hämodynamik
  - $mVSO_2$, Cardiac Index, PAP, PVR, TPG, PCWP, RVSWI

Folgen eines Rechtsherzversagen nach LVAD

- **RV-Versagen (RHF) ist nicht selten**
  - Inzidenz der RHF in ca. **20%** (9-44%) der LVAD-Fälle*

- **RV-Versagen verlängert perioperativen (Intensiv-) und Klinikaufenthalt**
  - verantwortlich für hoch komplikative Verläufe mit großer Morbidität und Mortalität

Frühes Rechstherzversagen verdoppelt beinahe die Sterbewahrscheinlichkeit innerhalb eines Jahres nach LVAD (86% increase) *

* Kormos RL et al. J Thor CV Surg 2010; 139:1316-24.
From the HeartMate II BTT trial (n=484 patients)

RV-Failure

Journal of the American College of Cardiology
© 2008 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 51, No. 22, 2008
ISSN 0735-1097/08/$34.00
doi:10.1016/j.jacc.2008.03.009

The Right Ventricular Failure Risk Score

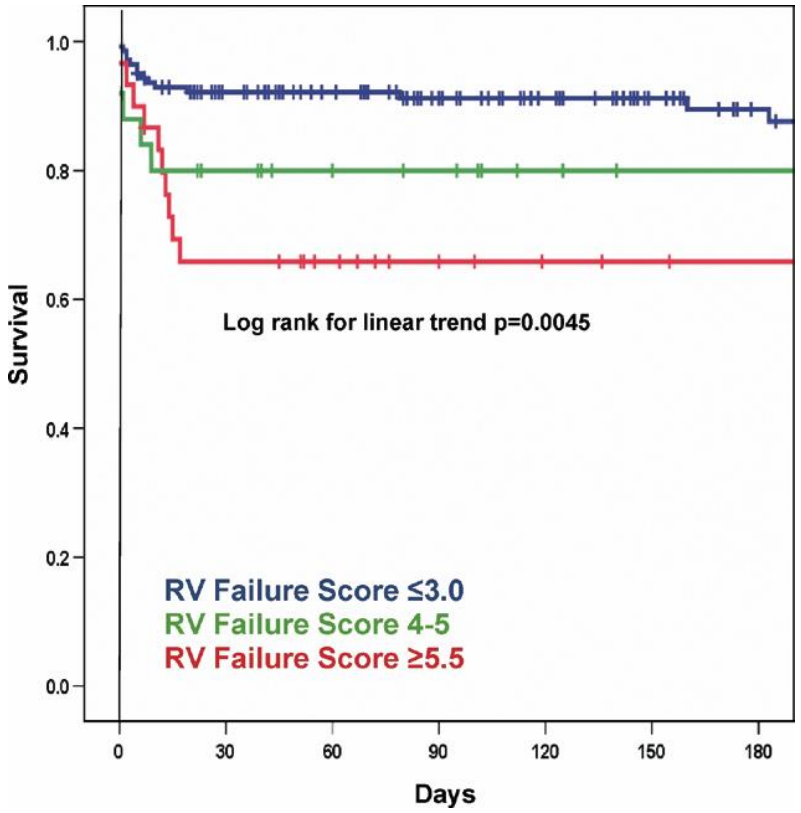
A Pre-Operative Tool for Assessing the Risk of Right Ventricular Failure in Left Ventricular Assist Device Candidates

Jennifer Cowger Matthews, MD,* Todd M. Koelling, MD,* Francis D. Pagani, MD, PHD,†
Keith D. Aaronson, MD, MS*
Ann Arbor, Michigan

Table 6 Right Ventricular Failure Risk Score and Likelihood of RV Failure by Score Strata

Risk Score	n	RV Failure (n)	No RV Failure (n)	Likelihood Ratio (95% CI)
≤3.0	142	29	113	0.49 (0.37–0.64)
4.0–5.0	25	15	10	2.8 (1.4–5.9)
≥5.5	30	24	6	7.6 (3.4–17.1)

Risk Score is derived by summing points awarded for the presence of a vasopressor requirement (4 points), AST ≥80 IU/l (2 points), bilirubin ≥2.0 mg/dl (2.5 points), and creatinine ≥2.3 mg/dl (3 points).



Rechtsherzversagen - Risk evaluation scores

ELSEVIER

The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

Validation of clinical scores for right ventricular failure prediction after implantation of continuous-flow left ventricular assist devices

Andreas P. Kalogeropoulos, MD, MPH, PhD,[a] Anita Kelkar, MD,[a]
Jeremy F. Weinberger, MD,[a] Alanna A. Morris, MD,[a]
Vasiliki V. Georgiopoulou, MD, MPH,[a] David W. Markham, MD, MSc,[a]
Javed Butler, MD, MPH,[b] J. David Vega, MD,[c] and Andrew L. Smith, MD[a]

The Journal of Heart and Lung Transplantation, Vol 34, No 12, December 2015

Table 4 Performance Characteristics of Clinical Risk Prediction Scores for RVF in the Study Population

	C (95% CI)	*p*	Sensitivity	Specificity	PPV	NPV
RVF Definition 1[a]						
Michigan	0.62 (0.52 to 0.72)	0.021	40.5%	87.3%	60.0%	75.8%
Penn	0.56 (0.44 to 0.68)	0.328	54.1%	60.8%	39.2%	73.8%
Utah	0.59 (0.47 to 0.70)	0.137	62.2%	59.5%	41.8%	77.0%
Kormos et al	0.59 (0.48 to 0.69)	0.096	46.0%	68.4%	40.5%	73.0%
Pittsburgh	0.54 (0.47 to 0.60)	0.289	16.2%	91.1%	46.2%	69.9%
CRITT	0.60 (0.50 to 0.71)	0.059	40.5%	72.2%	40.5%	72.2%
RVF Definition 2[b]						
Utah	0.50 (0.39 to 0.60)	0.947	43.9%	59.3%	51.0%	52.2%
Kormos et al	0.62 (0.54 to 0.71)	0.005	47.4%	74.6%	64.3%	59.5%
Pittsburgh	0.51 (0.45 to 0.57)	0.720	12.3%	89.8%	53.8%	51.5%
CRITT	0.60 (0.50 to 0.70)	0.045	75.4%	39.0%	54.4%	62.2%

NPV, negative predictive value; PPV, positive predictive value; RVF, right ventricular failure.

[a]Defined as need for a right ventricular assist device (RVAD); use of pulmonary vasodilators ≥48 hours; multi-organ failure due to right ventricular failure (RVF); inotrope use for ≥14 days after implantation; or re-institution of inotropes after 14 days.

[b]Defined as need for a right ventricular assist device (RVAD); use of pulmonary vasodilators ≥48 hours; multi-organ failure due to right ventricular failure (RVF); inotrope use for ≥7 days after implantation; or re-institution of inotropes after 7 days, with concomitant evidence of hemodynamic compromise (central venous pressure >18 mm Hg with a cardiac index <2.0 liters/min/m^2 in the absence of pulmonary capillary wedge >18 mm Hg) or renal or hepatic dysfunction (INTERMACS Protocol 3.0 definition).

CONCLUSION: Current schemes for post-LVAD RVF risk prediction perform only modestly when applied to external populations.

The Journal of Heart and Lung Transplantation, Vol 34, No 12, December 2015

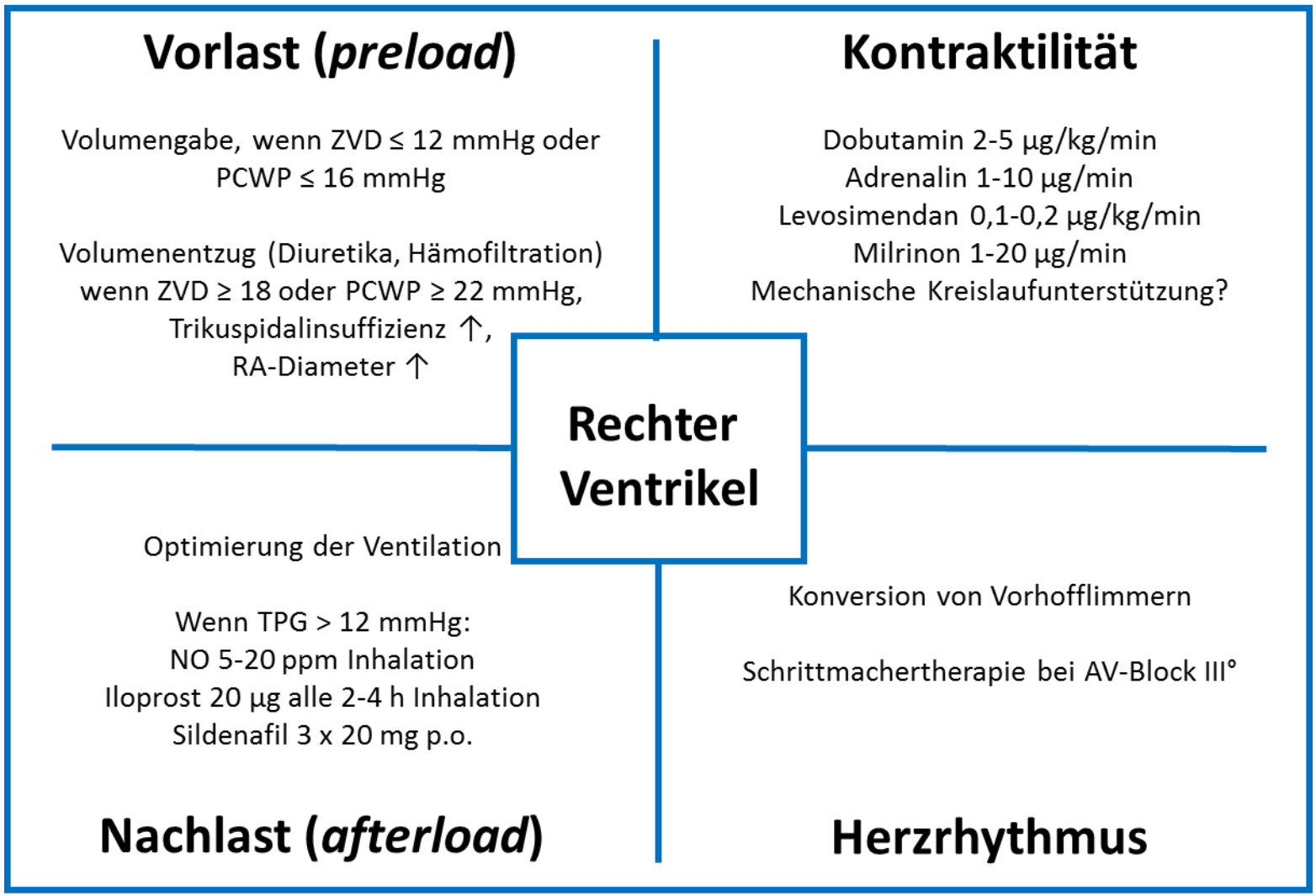
Evaluating RV-Function pre VAD

Table 6 Evaluating Right-Heart Function

Parameter	Desirable value[a]
RVSWI	>300 mm Hg × ml/m²
Central venous pressure	<15 mm Hg
Tricuspid regurgitation	Minimal to moderate
Pulmonary vascular resistance	<4 Woods units
Transpulmonary gradient	<15 mm Hg
RV size	
RVEDV	<200 ml
RVESV	<177 ml
Need for pre-op ventilator support	None

TAPSE > 15mm.

Slaughter JHLT 2010


Vorlast (*preload*)
Volumengabe, wenn ZVD ≤ 12 mmHg oder PCWP ≤ 16 mmHg
Volumenentzug (Diuretika, Hämofiltration) wenn ZVD ≥ 18 oder PCWP ≥ 22 mmHg, Trikuspidalinsuffizienz ↑, RA-Diameter ↑
Kontraktilität
Dobutamin 2-5 µg/kg/min
Adrenalin 1-10 µg/min
Levosimendan 0,1-0,2 µg/kg/min
Milrinon 1-20 µg/min
Mechanische Kreislaufunterstützung?
Rechter Ventrikel
Optimierung der Ventilation
Wenn TPG > 12 mmHg:
NO 5-20 ppm Inhalation
Iloprost 20 µg alle 2-4 h Inhalation
Sildenafil 3 x 20 mg p.o.
Konversion von Vorhofflimmern
Schrittmachertherapie bei AV-Block III°
Nachlast (*afterload*)
Herzrhythmus

Alternativen zur LVAD-Therapie

Clinical Research in Cardiology (2018) 107:413–420
https://doi.org/10.1007/s00392-017-1200-4

ORIGINAL PAPER

Successful support of biventricular heart failure patients by new EXCOR® Adult pumps with bileaflet valves: a prospective study

Bastian Schmack[1] · Alexander Weymann[1] · Frank Ruschitzka[2] · Rüdiger Autschbach[3] · Philip W. Raake[4] · Nadine Jurrmann[5] · Ares K. Menon[5] · Matthias Karck[1] · Markus J. Wilhelm[6] · Arjang Ruhparwar[1]

Clinical Research in Cardiology (2018) 107:413–420
https://doi.org/10.1007/s00392-017-1200-4

ORIGINAL PAPER

Successful support [illegible] new EXCOR® Adult pump [illegible] study

Table 1 Demographic and pre-operative profile of EXCOR® Adult BiVAD patients

Variable	$n = 12$
Gender (n), male	10
Age, mean (range), years	45 (21–58)
BMI, mean (range), kg/m^2	23.9 (19.8–30.2)
BSA, mean (range), m^2	1.9 (1.6–2.5)
Etiology (n)	
Idiopathic CMP	6
Ischemic CMP / AMI	4
Myocarditis	1
Cardiogenic shock (aortic dissection)	1
INTERMACS Level (n)	
1	6
2	5
4	1
Pre-operative	
CPR (n)	1
Dialysis (n)	2
Cardiac surgery (n)	4
Ventilator (n)	5
ECMO (n)	8

Clinical Research in Cardiology (2018) 107:413–420
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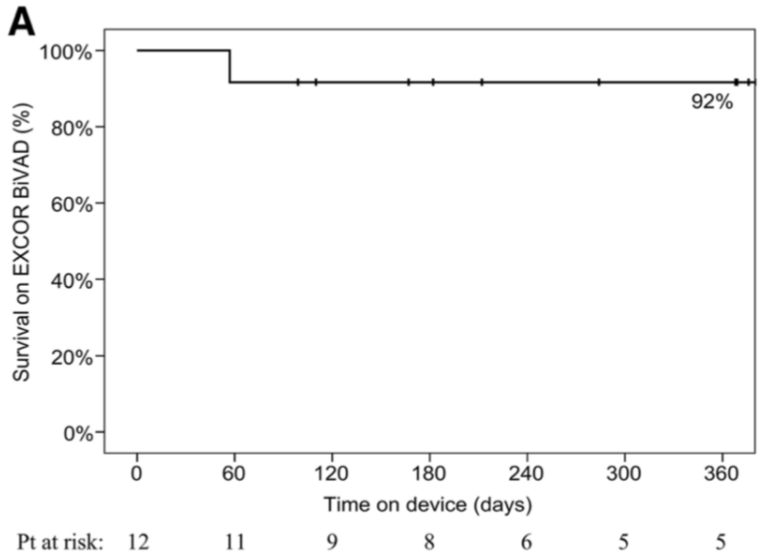

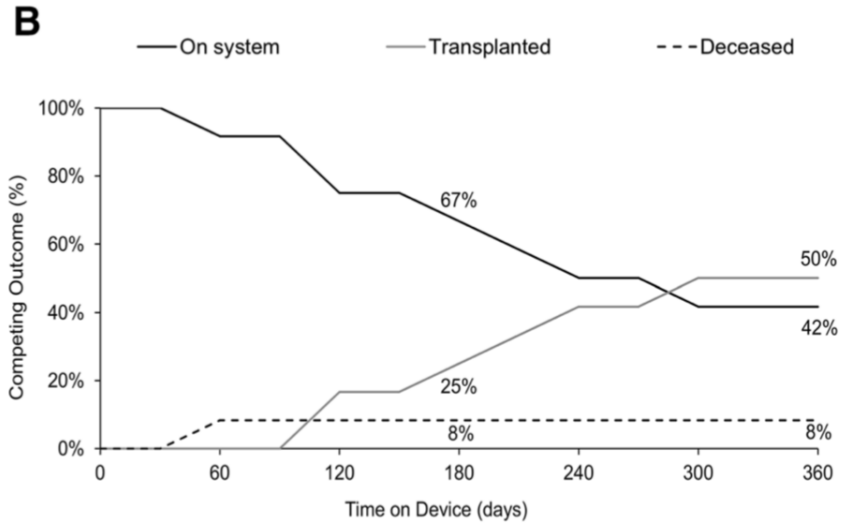

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The Journal of Heart and Lung Transplantation
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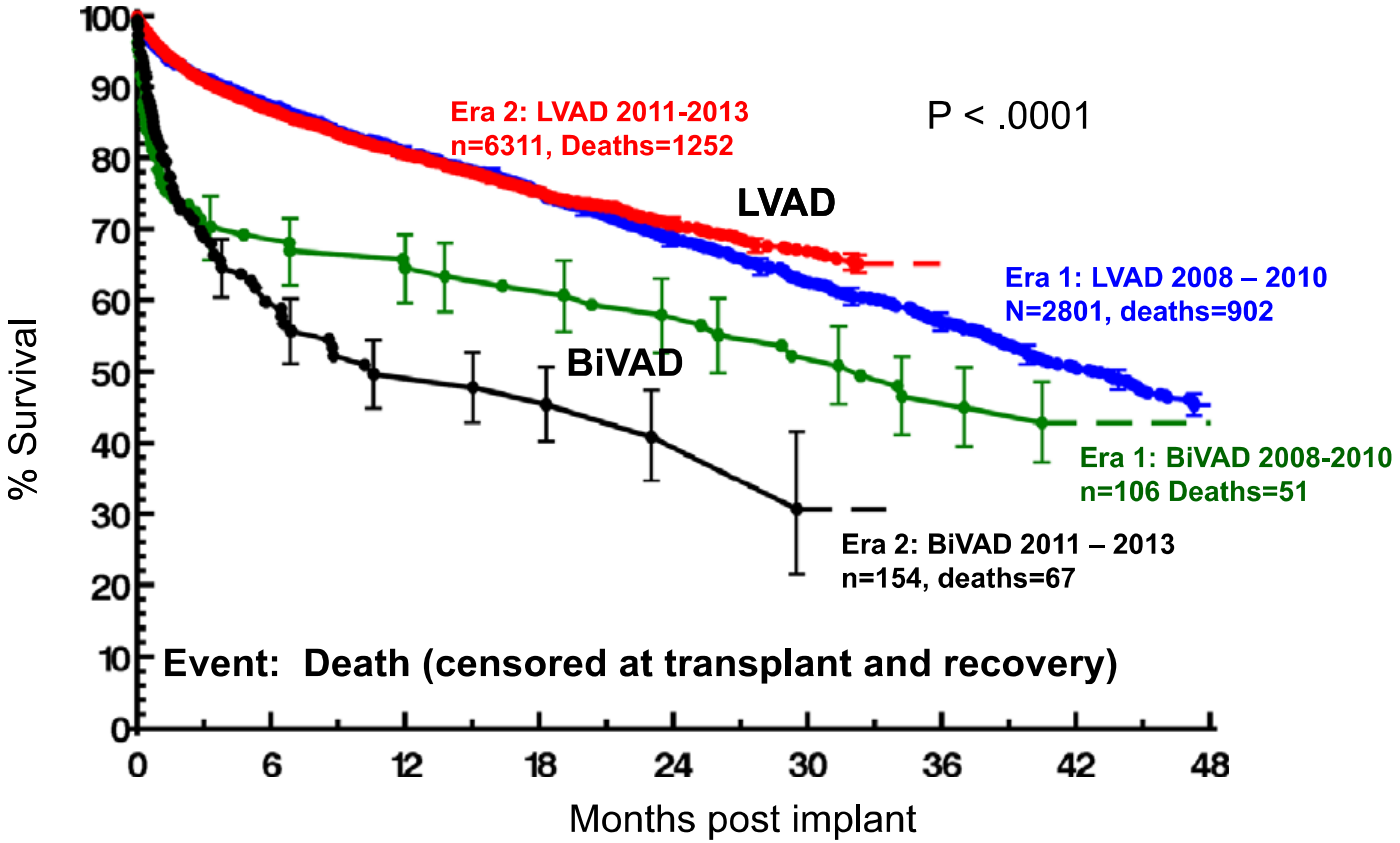
SPECIAL FEATURE

Fifth INTERMACS annual report: Risk factor analysis from more than 6,000 mechanical circulatory support patients

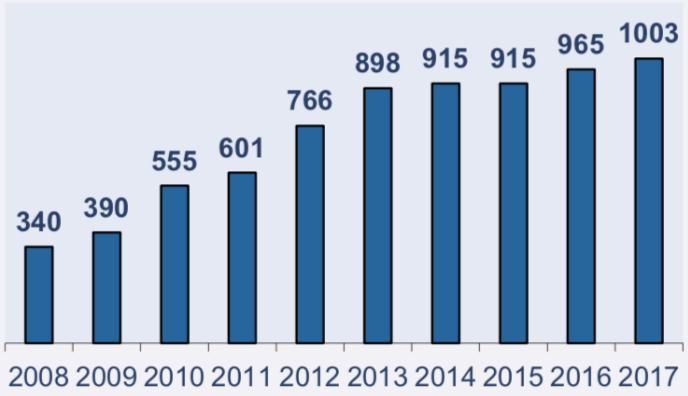
James K. Kirklin, MD,[a] David C. Naftel, PhD,[a] Robert L. Kormos, MD,[b]
Lynne W. Stevenson, MD,[c] Francis D. Pagani, MD, PhD,[d] Marissa A. Miller, DVM, MPH,[e]
J. Timothy Baldwin, PhD,[e] and James B. Young, MD[f]



Mechanical circulatory support

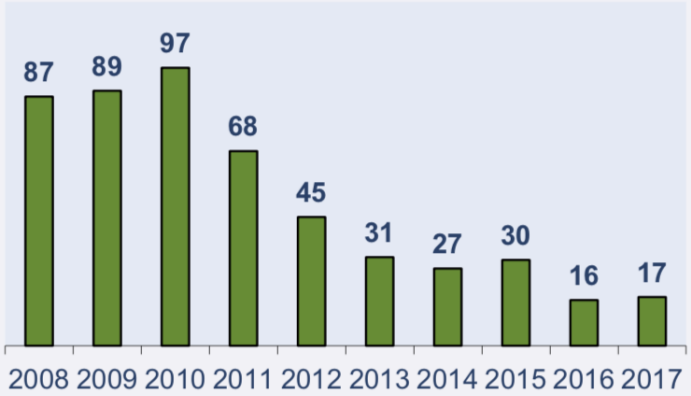
Selected assist devices 2008 - 2017

LVAD Implantation

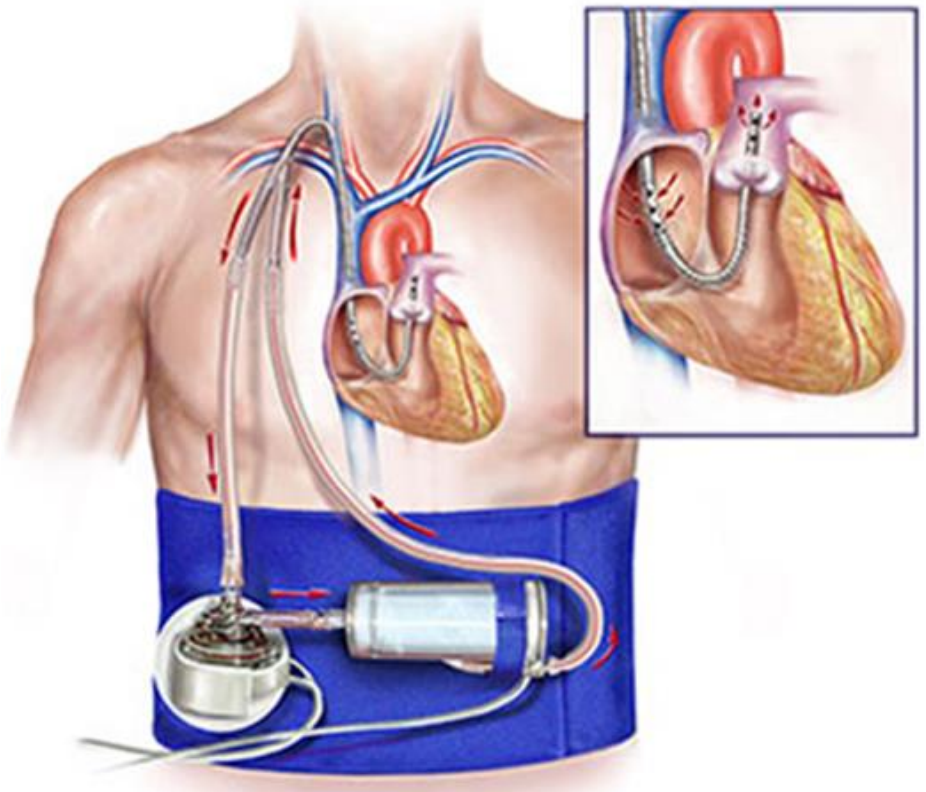


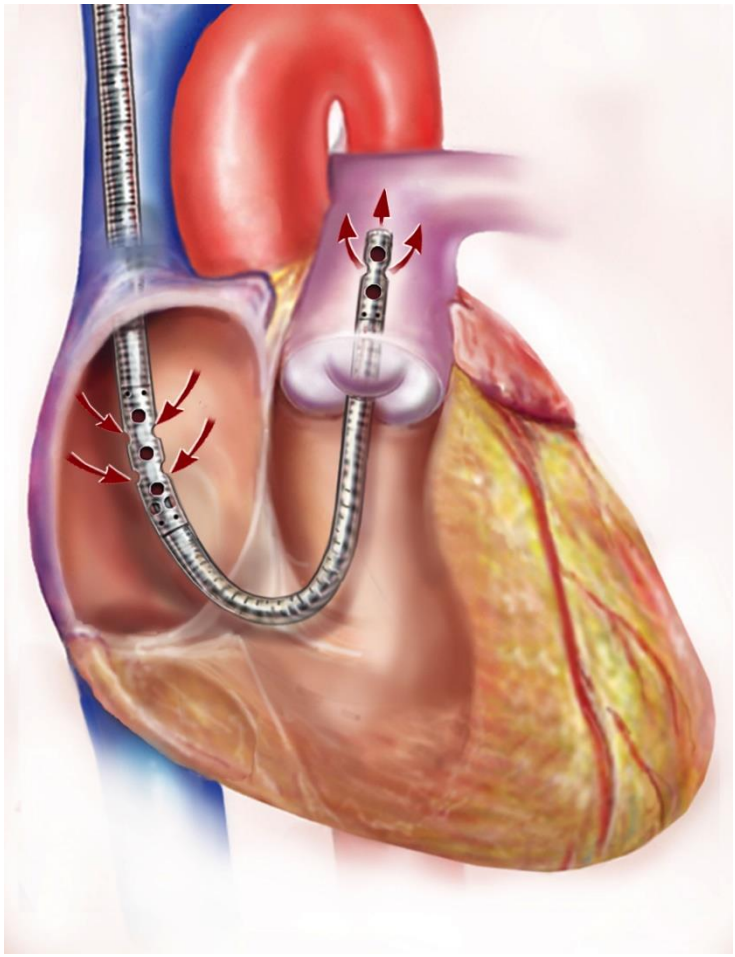
TAH

BVAD



Results of concomitant groin-free percutaneous temporary RVAD support using a centrifugal pump with a double-lumen jugular venous cannula in LVAD patients





Schmack B,…, Kreusser M, Raake P, Ruhparwar A; Under review, Cardiac Assist

Results of concomitant groin-free percutaneous temporary RVAD support using a centrifugal pump with a double-lumen jugular venous cannula in LVAD patients

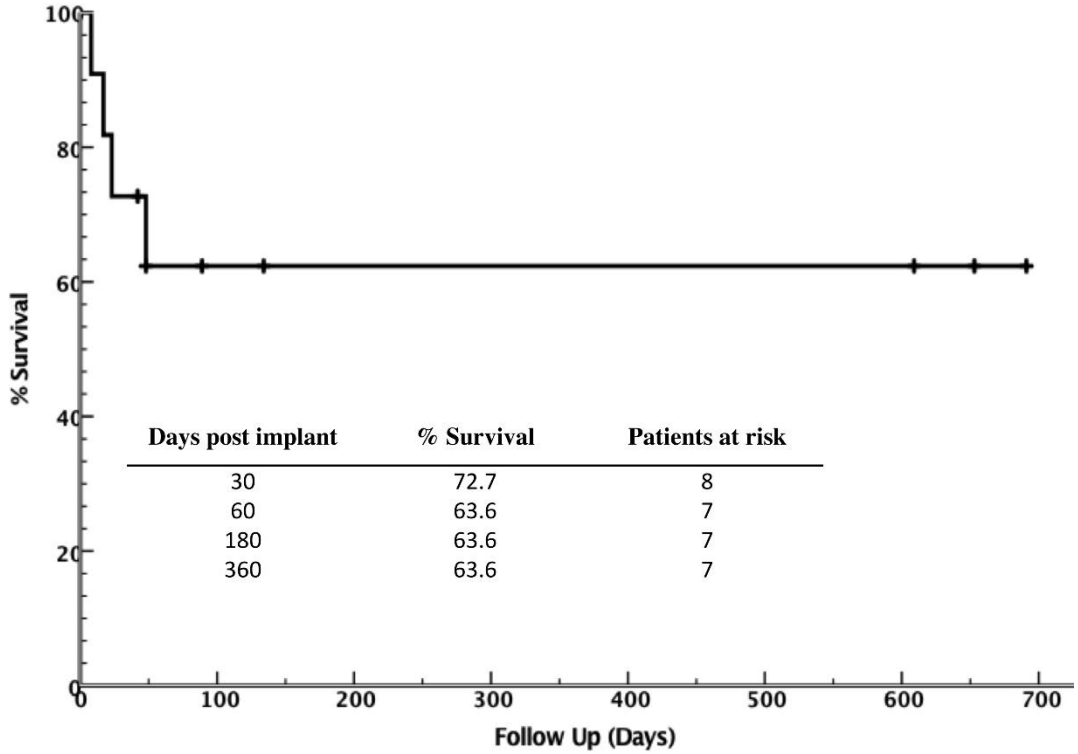
Male	10 (90.9%)
Age (years)	51.6 ± 13.1
Height (cm)	177 ± 6.1
Weight (kg)	84.7 ± 11.1
Body surface area (BSA, m^2)	2 ± 0.11
Diagnosis	
ICMP	6 (54.5%)
DCMP	5 (45.5%)
NYHA class	3.8 ± .75
INTERMACS class	3.5 ± 1.5
Pre-Implant inotropic support	4 (36.4%)
Pre-Implant MCS	4 (36.4%)
Bridge-to-transplantation	10 (90.9%)
Destination therapy	1 (9.1%)

LV Dysfunction	
Severe	11 (100%)
LVEF (%)	23.4 ± 7.4
Cardiac Index (l/m^2)	1.99 ± .34
CVS (%)	47.2 ± 9.4
PCWP (mmHg)	25.7 ± 5.7
RV Dysfunction (n, %)	
Severe	7 (63.6%)
Moderate	4 (36.4%)
TAPSE (mm)	10.4 ± 2.8
Tricuspid Regurgitation (n, %)	
Moderate	3 (27.2%)
Severe	3 (27.2%)
Creatinine (mg/dl)	1.59 ± 0.95
Urea (BUN, mg/dl)	78.2 ± 43.5
Creatinine-Clearance (ml/min)	55.5 ± 33.5
Albumin (mg/dl)	36.5 ± 6.4
Bilirubin (conjugated, mg/dl)	1.6 ± 1.35
Alanine transaminase (ALT, IU/l)	79.7 ± 164
Aspartate transaminase (AST, IU/l)	43 ± 45.2

RVAD support (n, %)	11 (100%)
RVAD plus Oxygenator (n, %)	1 (9.1%)
RVAD duration (days)	16.8 ± 9.5
Successful RVAD Weaning (n, %)	10 (90.9%)
ICU stay (days)	23.8 ± 16.5
Mechanical ventilation (h)	265 ± 381
Inhalative Nitric Oxide (n, %)	11 (100%)
Nitric Oxide (h)	117 ± 123
30d Survival (n, %)	8 (72.3%)
Overall Cause of Death (n, %)	
MOF	3 (75%)
ICB	1 (25%)

Schmack B; Under review

Results of concomitant groin-free percutaneous temporary RVAD support using a centrifugal pump with a double-lumen jugular venous cannula in LVAD patients

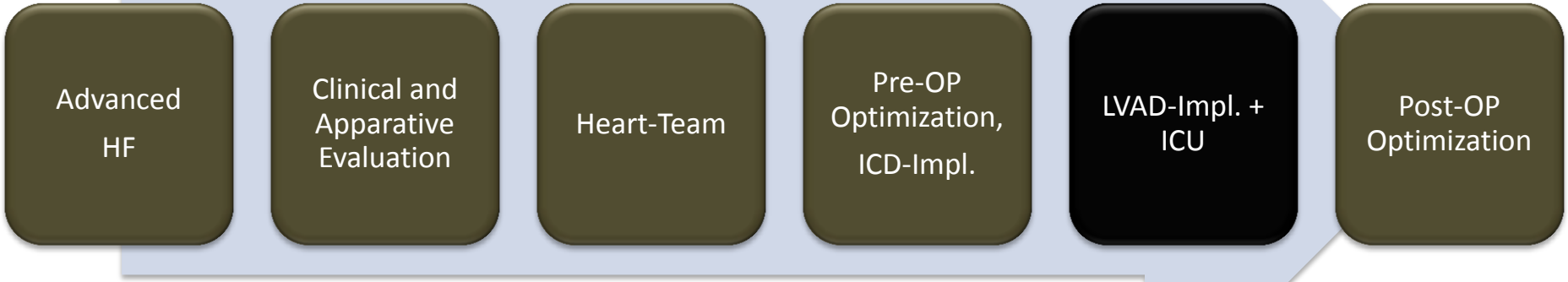


Days post implant	% Survival	Patients at risk
30	72.7	8
60	63.6	7
180	63.6	7
360	63.6	7

Schmack B et al.; Under review

Uneingeschränkte und sichere Mobilisation durch Vermeidung einer femoralen Kanülierung

HeartCenter Heidelberg: Prevention RV-Failure



Patients at Risk
-Prognostic models, rare cases permanent BiVAD

Pre-OP Care
-Prevention: pre-OP optimization of RV function (ZVD < 15mmHg, Volume withdrawel, CVVH, inotropes)

Peri-/Post-OP Care
-Inotropes, reduction RV-afterload (NO / Iloprost), pRVAD

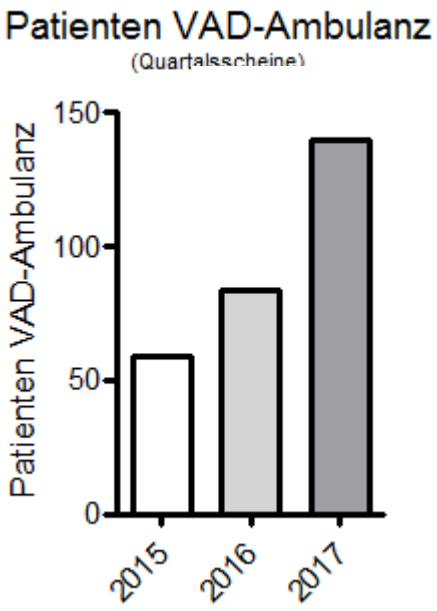
VAD-Outpatient Service
-LV optimization, optimized medical HF therapy

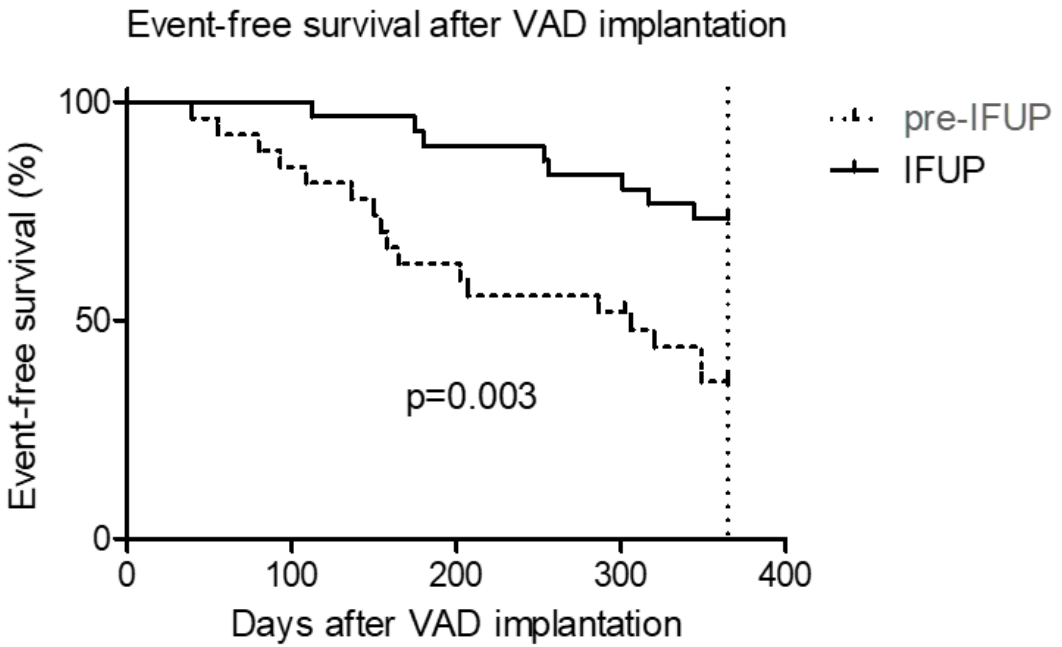
AHFU

HCH/
AHFU

Matthews 2008, Fitzpatrick 2009, Drakos 2010, Meieneri 2012

Optimierung der Versorgung in der VAD-Ambulanz





Kreusser et al. (submitted)


Universitätsklinikum Heidelberg
Medizinische Klinik Krehl Klinik

Herausforderungen in der modernen LVAD-Medizin

- Infektionen
- Blutungskomplikationen, erworbene Blutungskomplikationen (acquired van Willebrand Syndrom…..)
- AV-Malformationen (Schleimhaut, Magen-Darm-Trakt…)
- Aortenklappeninsuffizienz
- **Rechstherzversagen**

Strategien zur Vermeidung eines RV-Versagens bei permanenter LVAD-Implantation - **Wege aus dem Dilemma**

- **Präoperativ**
  - Enge interdisziplinäre und überregionale Kooperation
  - Bestmögliche RV-Evaluation (TEE, RH-Katheter…)
  - Patientenselektion, Identifikation von Risikopatienten
  - Patientenoptimierung (AHFU, Inotropikatherapie)
  - Volumenmanagement (Negativbilanz, ggf. CVVH)
  - Planung / Timing der Operation….

Strategien zur Vermeidung eines RV-Versagens bei permanenter LVAD-Implantation - **Wege aus dem Dilemma**

- **Intra/Perioperativ**
  - Operative Strategien zur Vermeidung eines RV-Versagens
  - Ideale Implantation, optimale LV-Entlastung
  - (Präemptive) Minimalinvasive pRVAD-Optionen bereithalten
  - Volumenrestiktive OP und Intensivtherapie
  - Balancierte Katecholamintherapie
  - Inhalative NO-Beatmung
  - Zeitnahe Extubation und Mobilisation

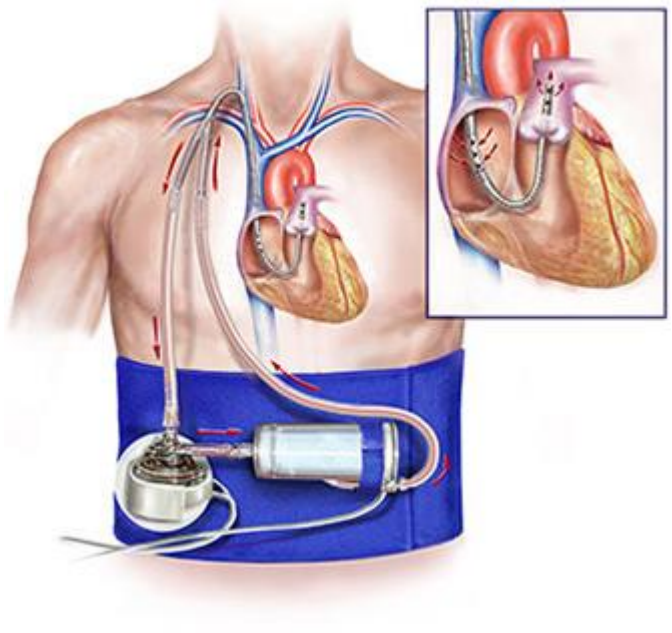
Strategien zur Vermeidung eines RV-Versagens bei permanenter LVAD-Implantation - **Wege aus dem Dilemma**

- **Postoperativ**
  - Enge, interdisziplinäre und interprofessionelle VAD-Nachsorge in einer spezialisierten Ambulanzumgebung…….

Temporäre perkutane RV-Unterstützung

Impella

Tandem Heart



Schmack et al. Med Sci Monit Basic Res, 2016
Abiomed

Percutanous RVAD + LVAD-Implantation: Tandem Heart® + ProtekDuo

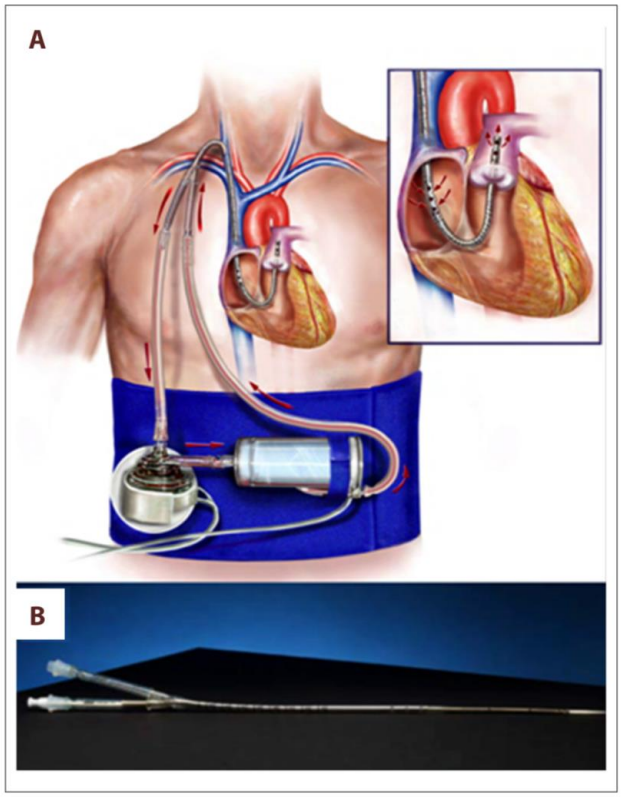


Figure 1. (**A**) Schematic illustration of the ProtekDuo® cannula *in-situ* with pump attached to the body vest. An oxygenator can be interposed to maintain full lung support; (**B**) Picture of the coaxial dual-lumen wire-reinforced 29 Fr. ProtekDuo® cannula. (Both pictures reproduced with kind permission of CardiacAssist Inc., Pittsburgh, PA).

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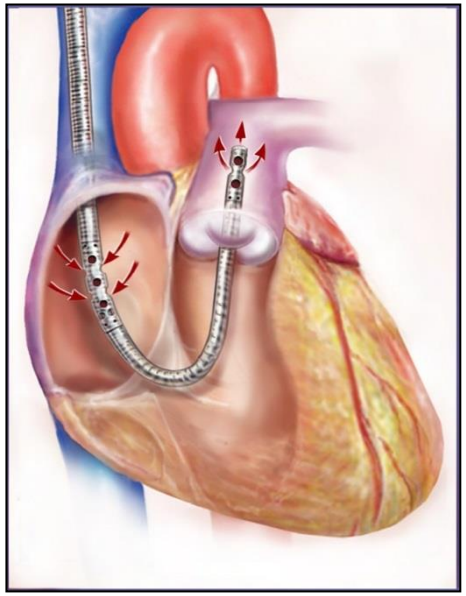
Published: 2016.05.05

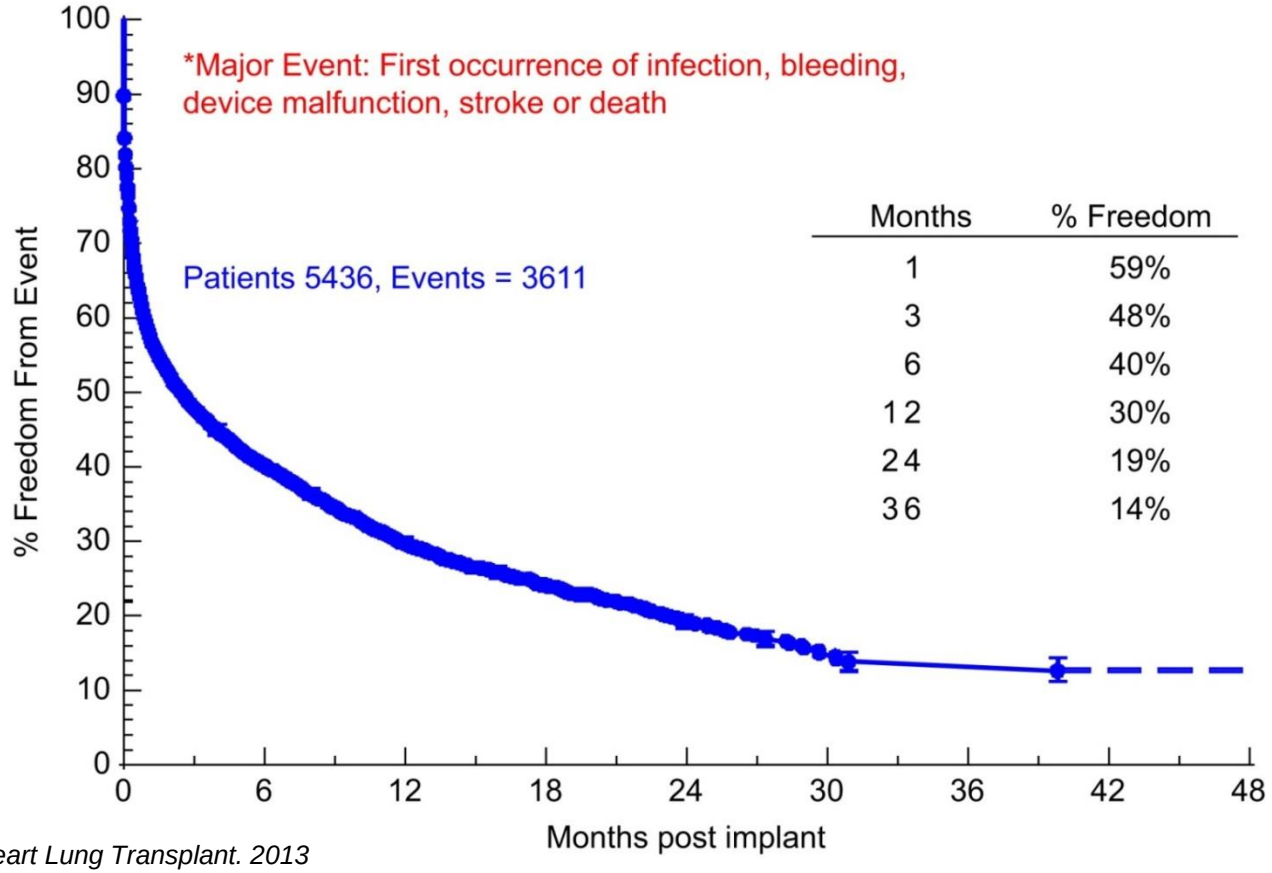
Concurrent Left Ventricular Assist Device (LVAD) Implantation and Percutaneous Temporary RVAD Support via CardiacAssist Protek-Duo TandemHeart to Preempt Right Heart Failure



Schmack B..., Ruhparwar A
Concurrent ventricular assist device (LVAD) implantation and percutaneous temporary RVAD support via Cardiac Assist Protek Duo TandemHeart to preempt right heart failure. Med Sci Monit Basic Res 2016;

Real World: INTERMACS-Report

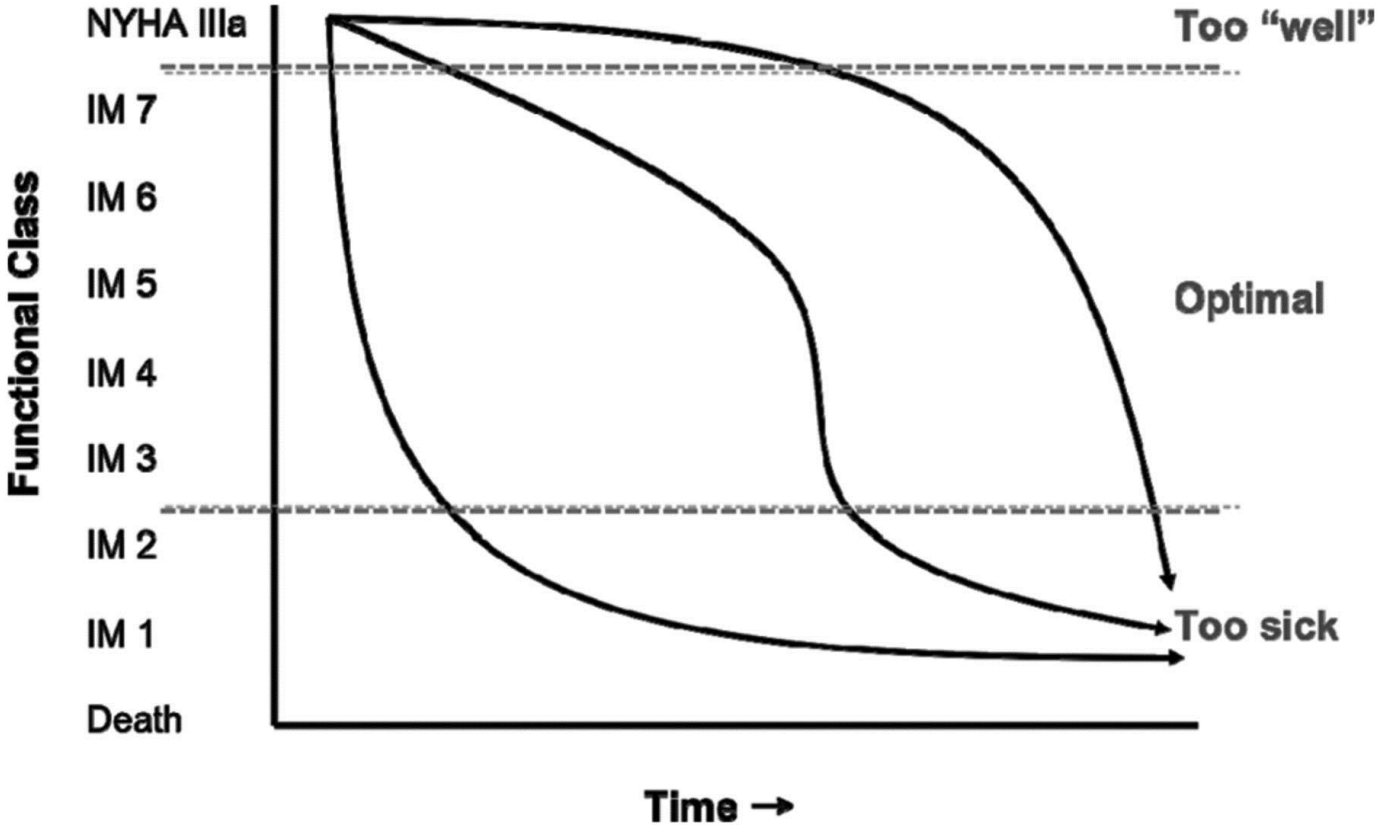
Adult Primary Continuous Flow LVADs & BIVADs, DT and BTT, n = 5436
Implants: June 2006 – June 2012
Time to First Major Event*



Months	% Freedom
1	59%
3	48%
6	40%
12	30%
24	19%
36	14%

Kirklin JK et al J Heart Lung Transplant. 2013

Optimale VAD-Patienten Selektion



Peura J et al. AHA Scientific Statement Circulation 2012

Ursachen der Rechtsherzinsuffizienz

- Dekompensation bei chronischer Herzinsuffizienz
- Akuter RV-Myokardinfarkt
- Fulminante Myokarditis
- Lungenarterienembolie
- Dekompensierte pulmonale Hypertonie
- Post-Kardiochirurgie (0,1%)
- Nach Herztransplantation (2-3%)
- Nach Left Ventricular Assist Device (LVAD)-Implantation (30-40%)

Thoennes & Garan JACC, 2017

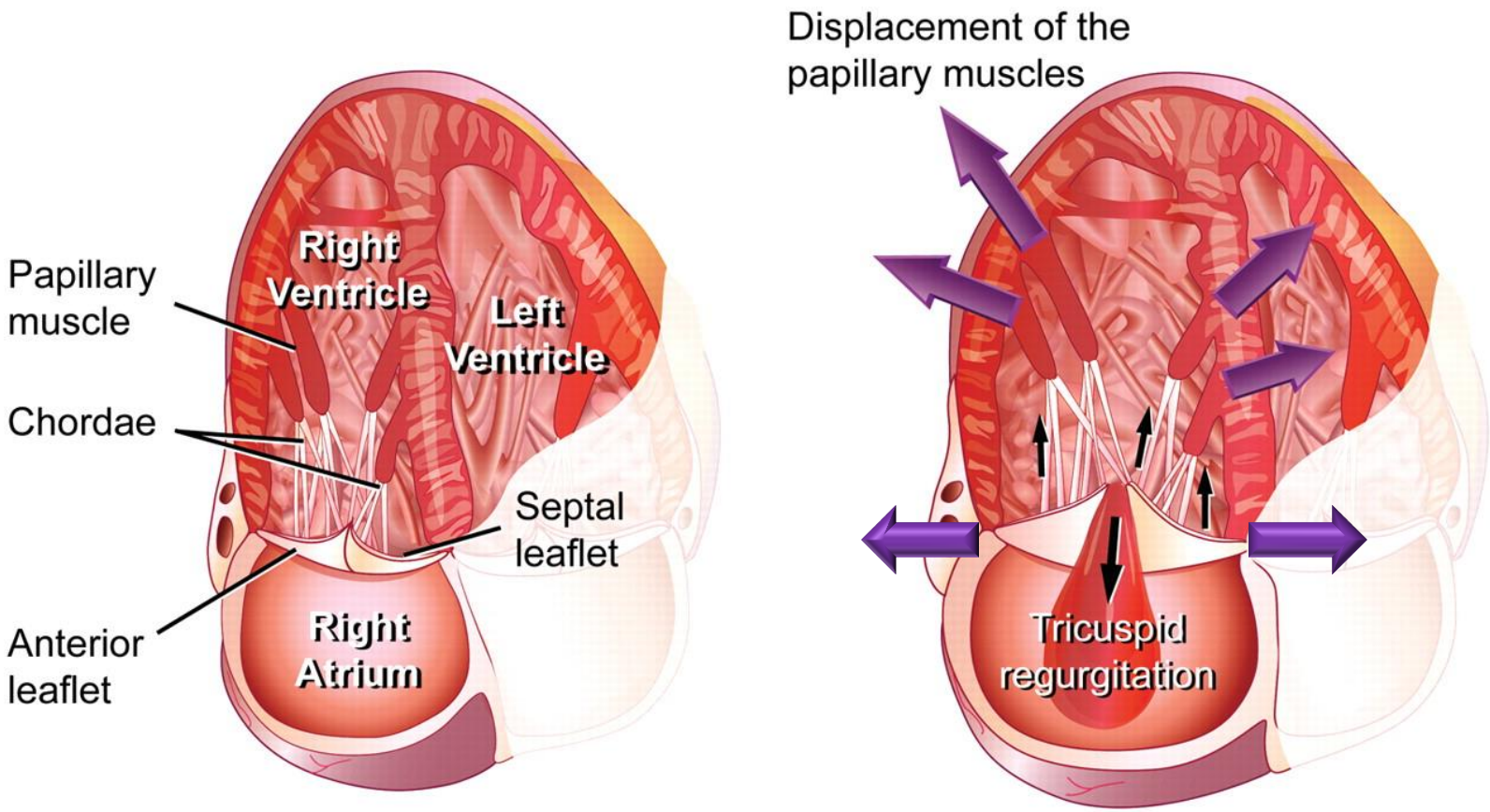
Zusammenfassung

- **Rechtsherzinsuffizienz** resultiert häufig in einer **sekundären TK-Insuffizienz**. Die sekundäre TI ist **prognostisch relevant**.

- Die **konservative Behandlung** umfasst die Optimierung von Vor- (Volumen) und Nachlast (PA-Druckverhältnisse). Eine **operative Korrektur** der TI ist im Rahmen linksseitiger Herzoperationen angeraten (hochgradige TI, TVAD >40mm, oder TVAD >21mm/m²).

- **Neue Interventionelle Verfahren** für transvaskuläre TK-Eingriffe sind in der Entwicklung.

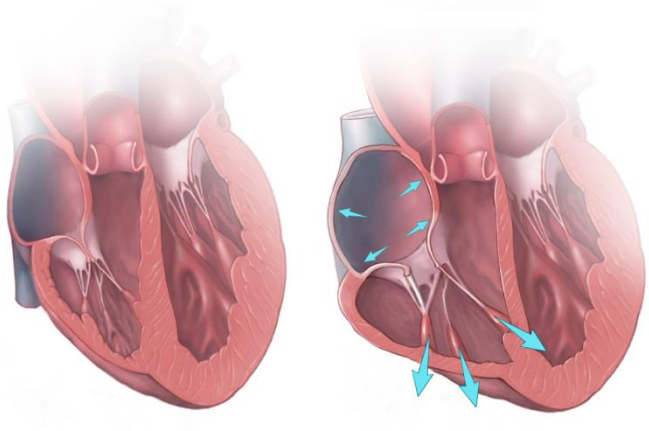
Mechanismen der sekundären TI

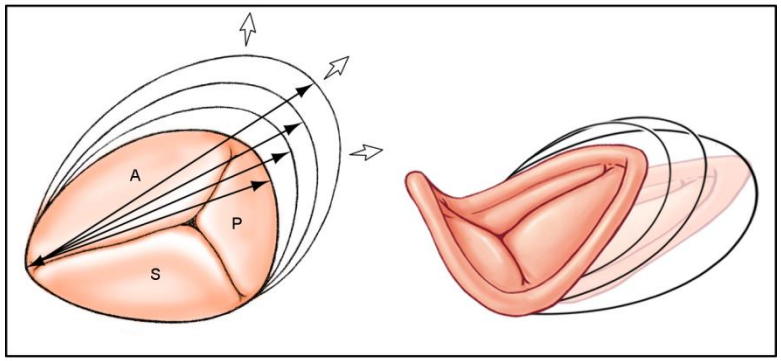


Mascherbauer & Maurer Eur. Heart Journal 2010

Dilatation des Trikuspidalklappenannulus

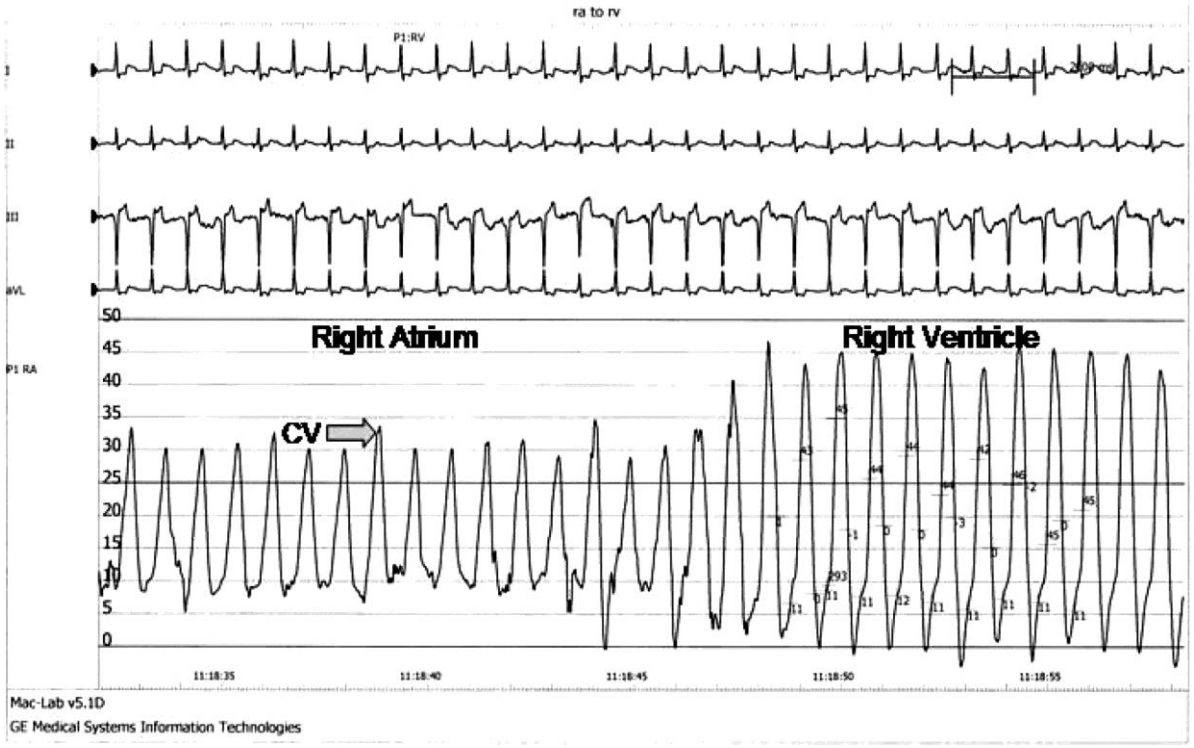
Anteroseptal nach anteroposterior
in Richtung freie RV-Wand





Fender et al. Heart 2017

Invasive Messung bei Trikuspidalinsuffizienz



Verstärkt bei Inspiration → Kußmaul-Zeichen

Rosenberg et al. Circulation 2007

Chirurgisch implantierte RVAD-Systeme?

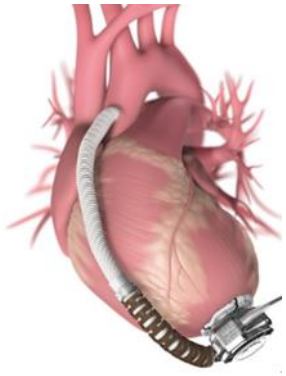


Table 3: Outcomes of 8 patients of the EUROMACS registry with isolated RVAD implantation

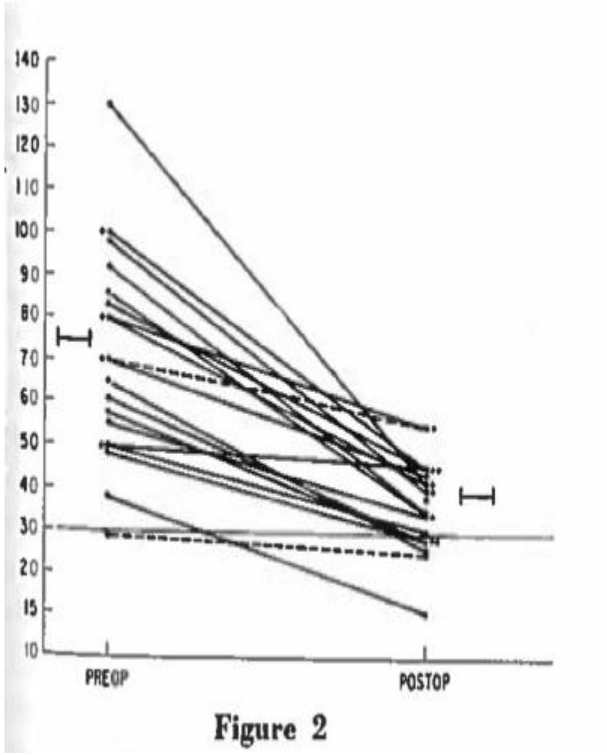
Patient	Time on device	Event	Outcome	Cause of death
1	16	Subileus, laparotomy and caecal fistula	Died	Infection
2	20		Died	Multiorgan failure
3	44		Died	Multiorgan failure
4	419	Driveline infection	Transplanted	
5	40	Pump thrombosis	Explanted	
6	5	Reoperation after three days for bleeding	Died	Multiorgan failure
7	29		Transplanted	
8	14	Pump thrombosis	Died	Pump thrombosis

RVAD: right ventricular assist device.

Bernhardt et al. Eur J of Cardioth Surg, 2015
Thoratec, Heartware

Conservative management of tricuspid regurgitation in patients undergoing mitral valve replacement.

Braunwald NS, Ross J Jr, Morrow AG.

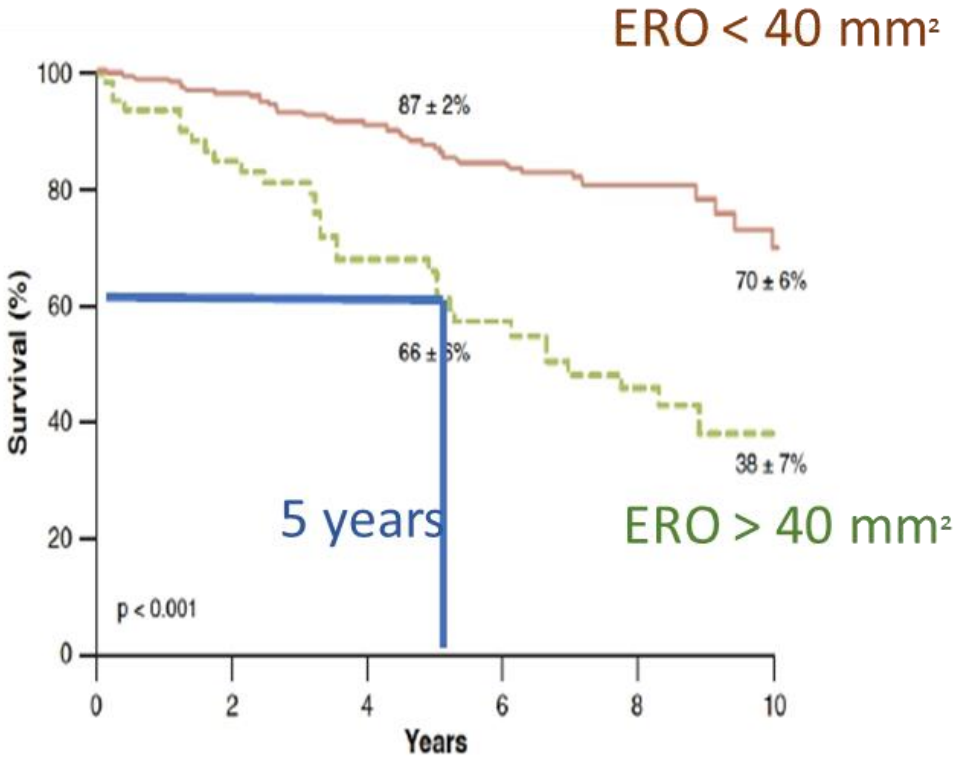


"The present results indicate that in such patients tricuspid regurgitation will improve or disappear after mitral replacement and that tricuspid valve replacement is seldom necessary"

Braunwald et al. Circulation 1967

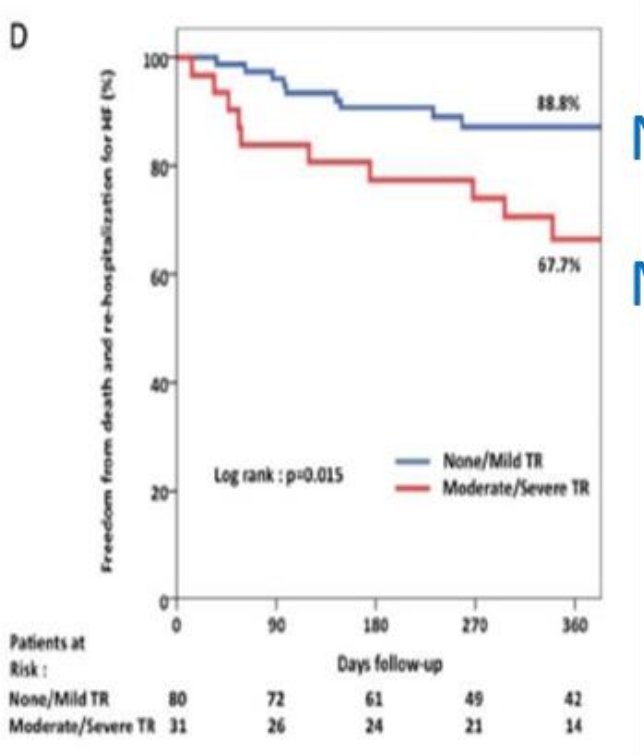
Systolic RV or PA pressures before and after MVR in 20 patients with severe TR

Prognostische Bedeutung der isolierten TI



Topilsky et al. J Am Coll Cardiol Img 2014

MC MK: Prognostische Bedeutung der TI

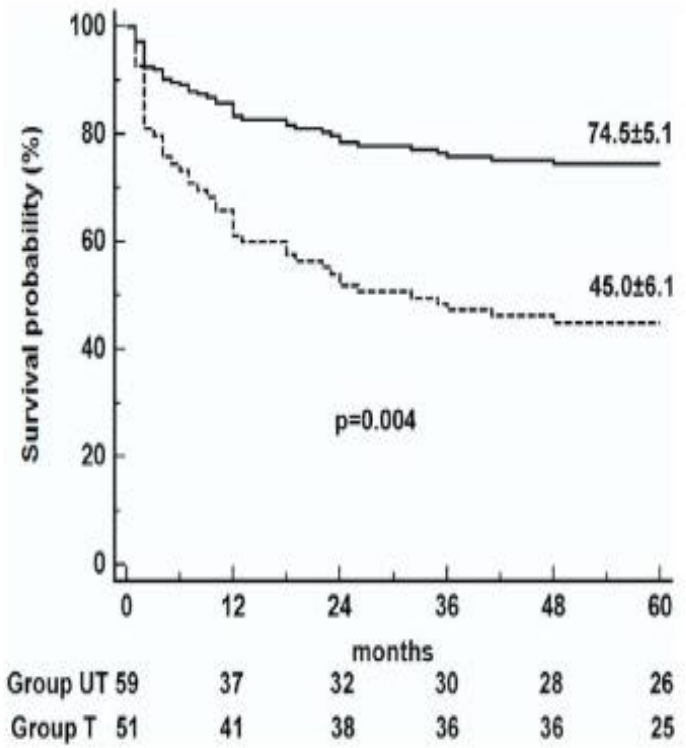


None-mild TR

Mod-severe TR

Ohno et al. Eur Heart J Cardiovasc Img 2014

110 patients for MV surgery (20 MR) had 3+/4+ TR

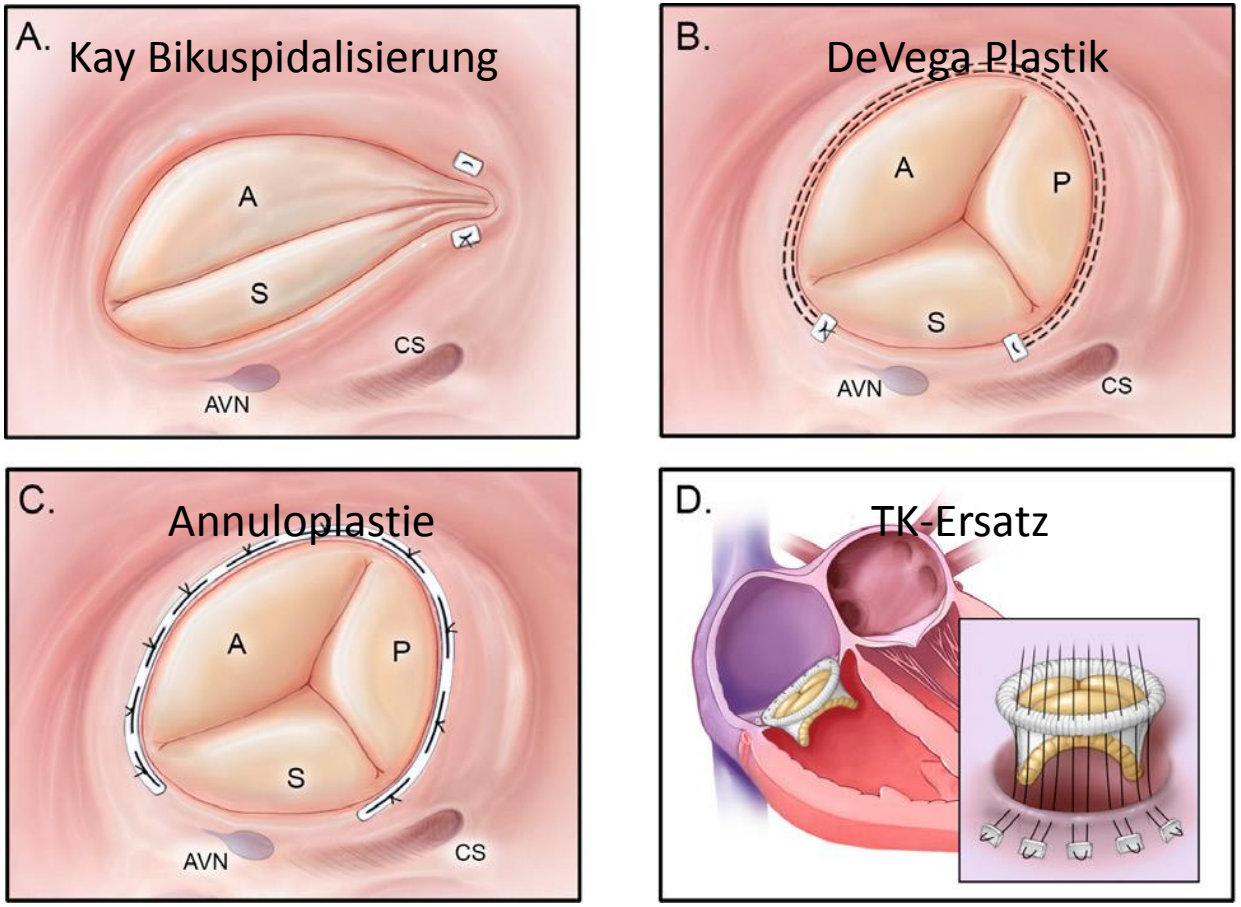


MV + TV surgery

MV surgery alone

Calafiore et al. Ann Thorac Surg 2009

Operative Therapie



Fender et al. Heart 2017

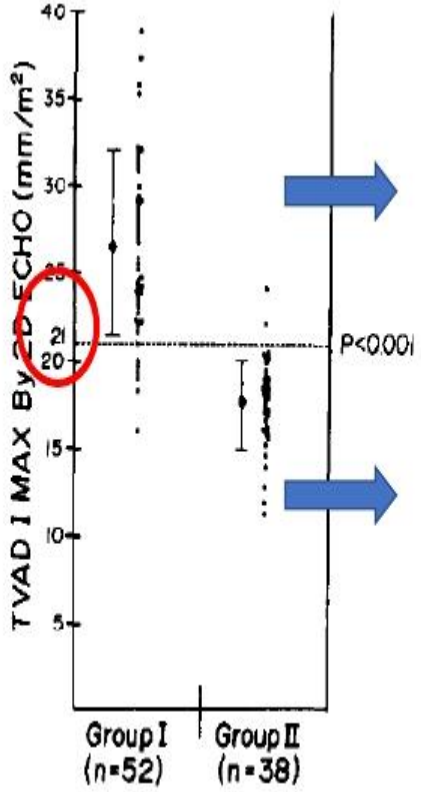
TI – Wann operieren?

In those undergoing left-sided surgery TV repair is indicated if

- **Severe secondary TR (Class I)**
- **Mild or moderate secondary TR with annular diameter > 40 mm or 21 mm/m2 (Class IIa)**

ESC Valvular Heart Disease Guideline Recommendations. Eur Heart J 2012/2017

Cut-off chosen by the “magic finger” for TV surgery



Underwent TV repair

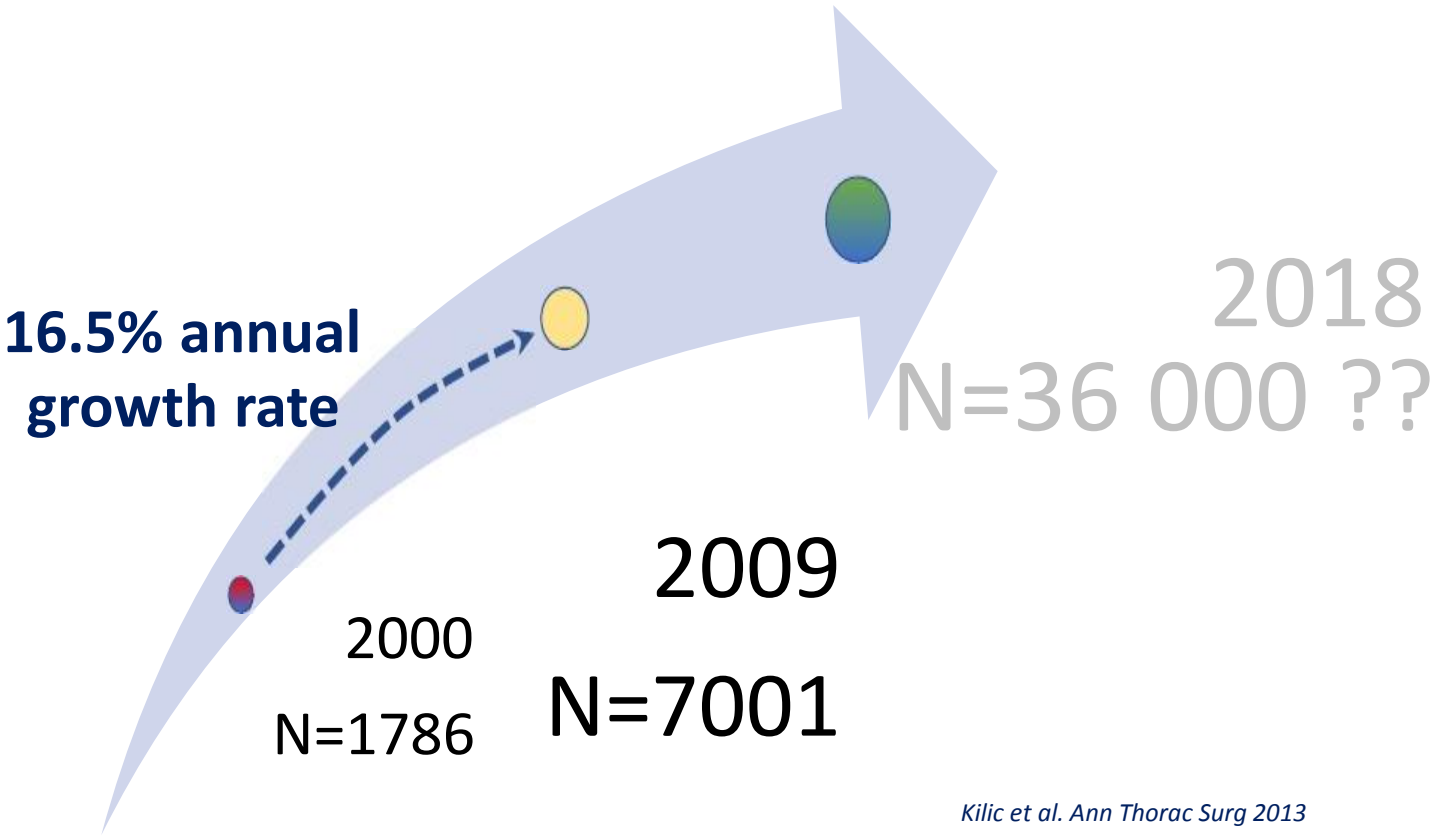
21 mm/m²

No TV repair

Chopra et al. J Am Coll Cardiol 1989

STS Datenbank 2000-2009

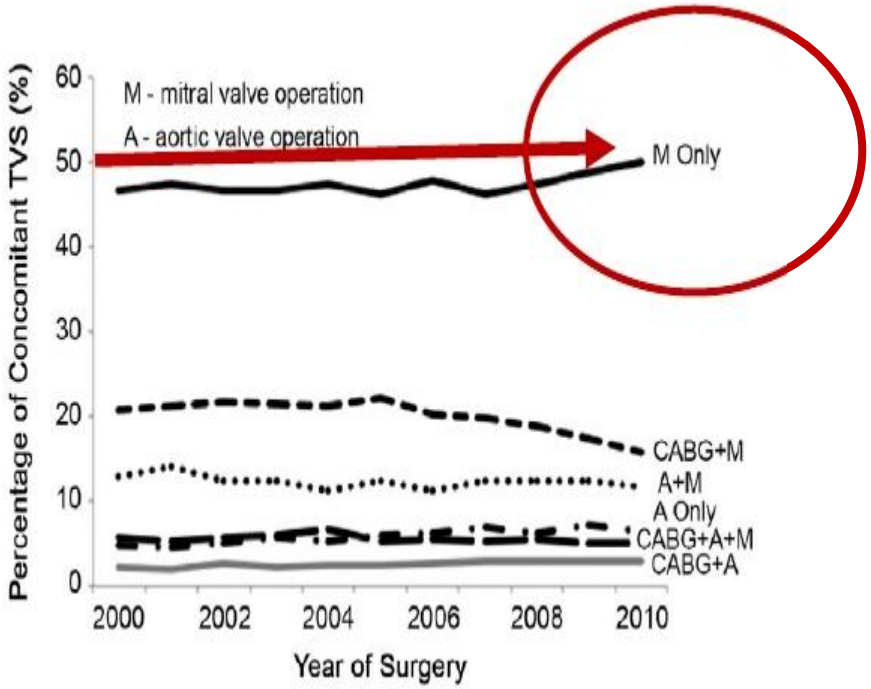
(A study of 50 004 TV surgeries)



Kilic et al. Ann Thorac Surg 2013

STS Datenbank für chirurgische TK-Eingriffe

2000-2009

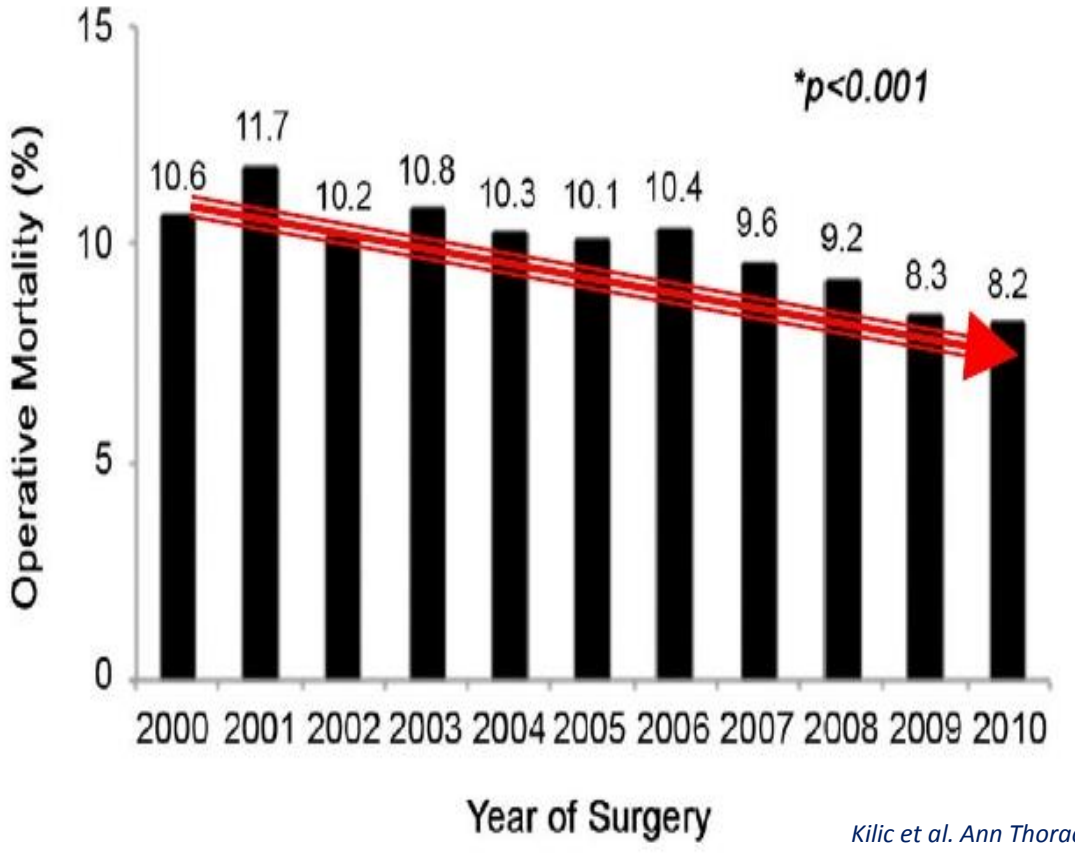


85% der TK-OPs in Kombination mit MK-OP.

Kilic et al. Ann Thorac Surg 2013

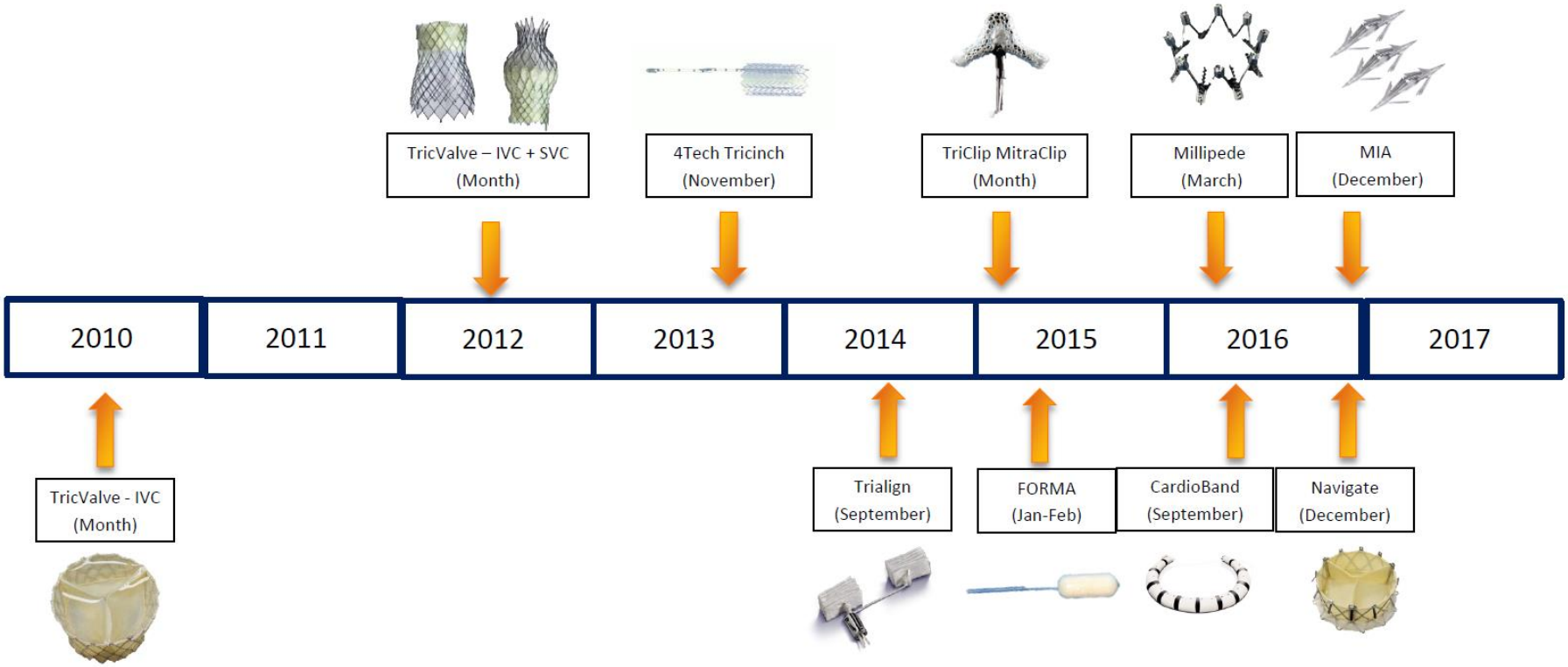
STS Datenbank für chirurgische TK-Eingriffe:

Mortalität



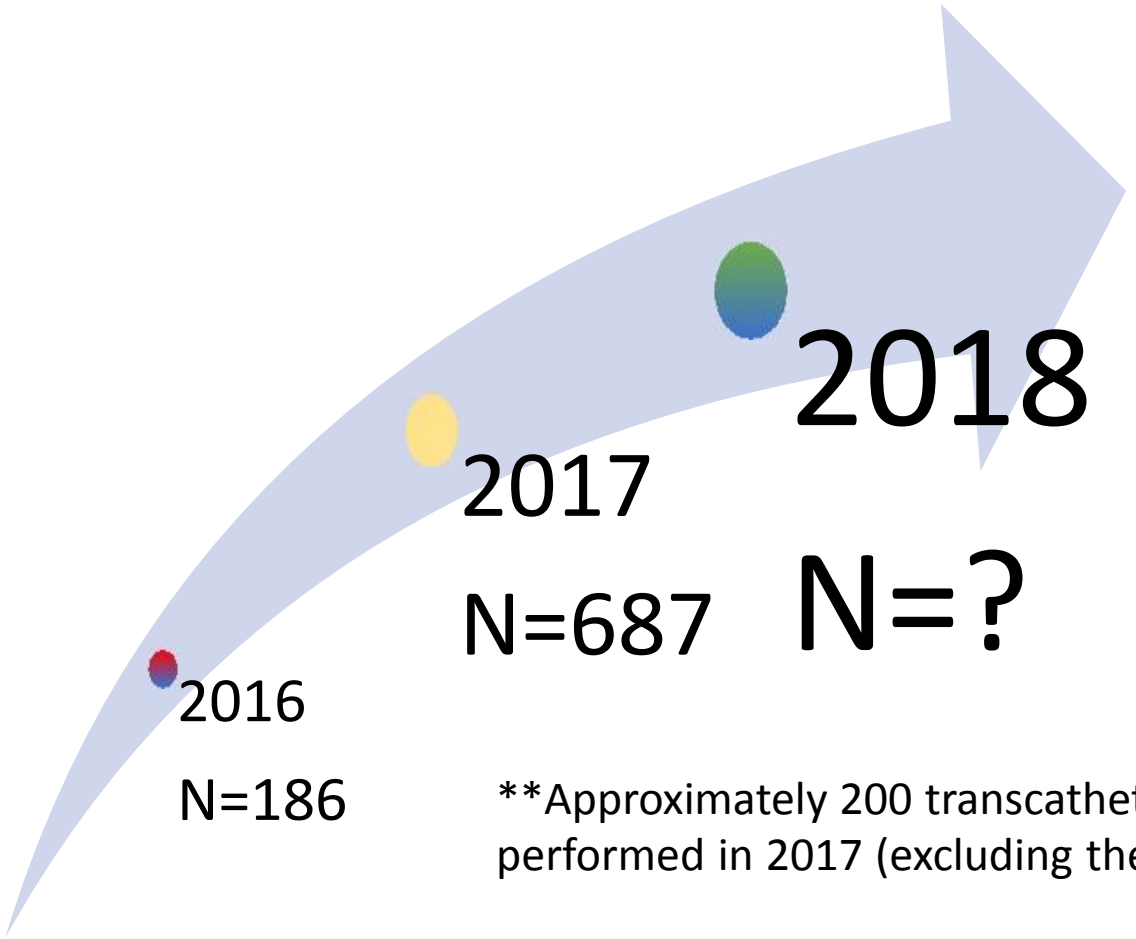
Kilic et al. Ann Thorac Surg 2013

Entwicklung: Transvaskuläre Therapie der TI



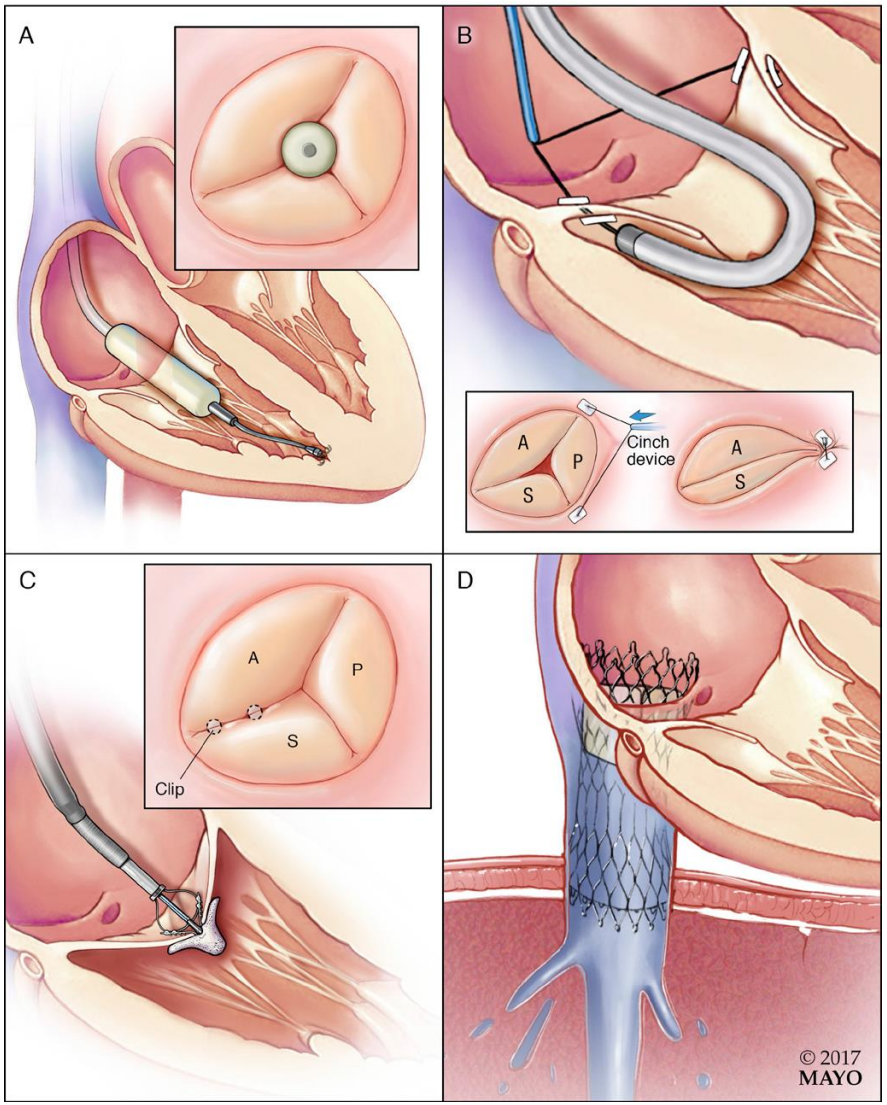
Piazza, EuroPCR 2017

Transvaskuläre TK-Interventionen



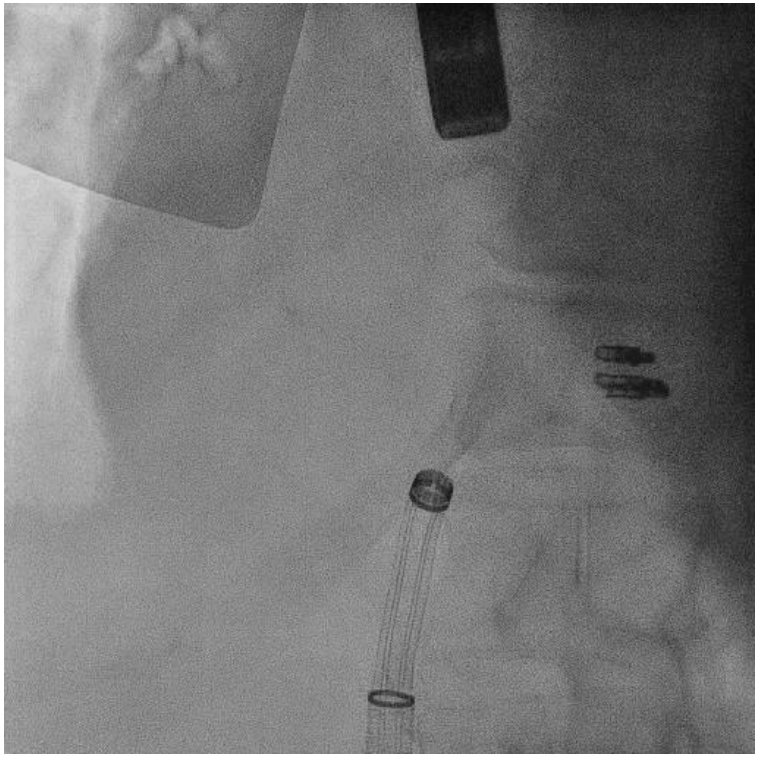
**Approximately 200 transcatheter TV interventions performed in 2017 (excluding the MitraClip for TR)

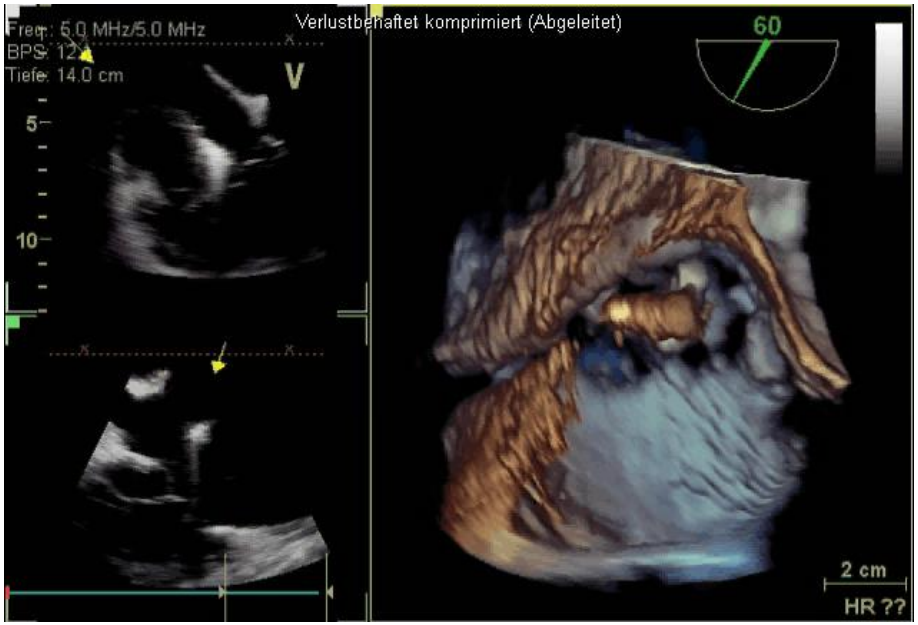
Pipeline: Interventionelle Therapie



Fender et al. Heart 2017

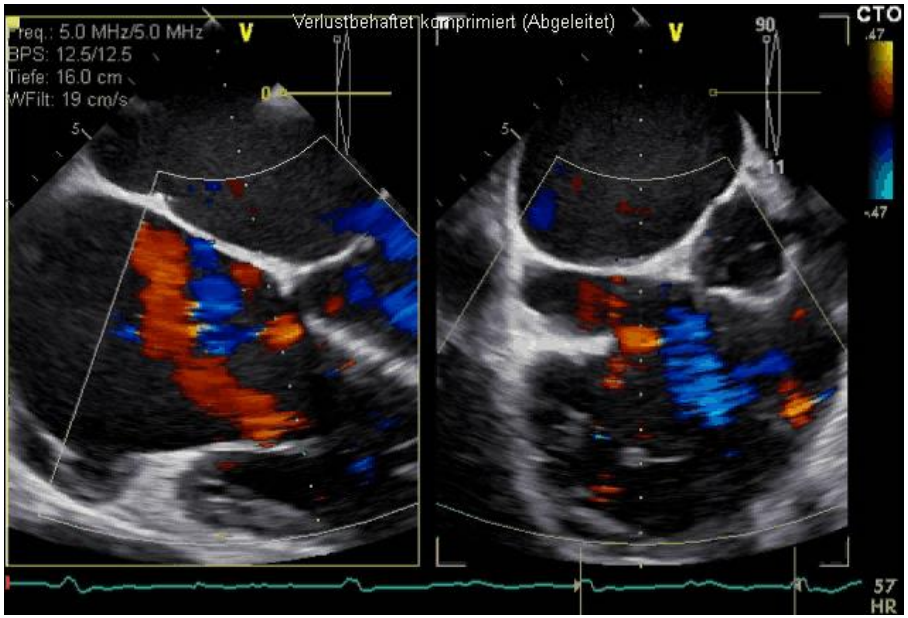
MitraClip Trikuspidalklappeninsuffizienz (Off-Label)



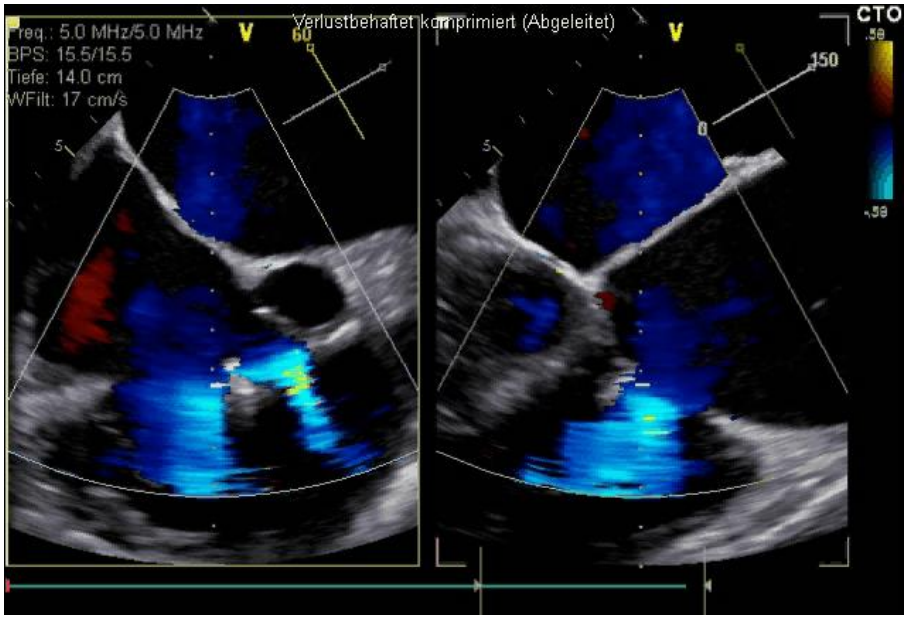


MitraClip Trikuspidalklappeninsuffizienz (Off-Label)

Ausgangsbefund

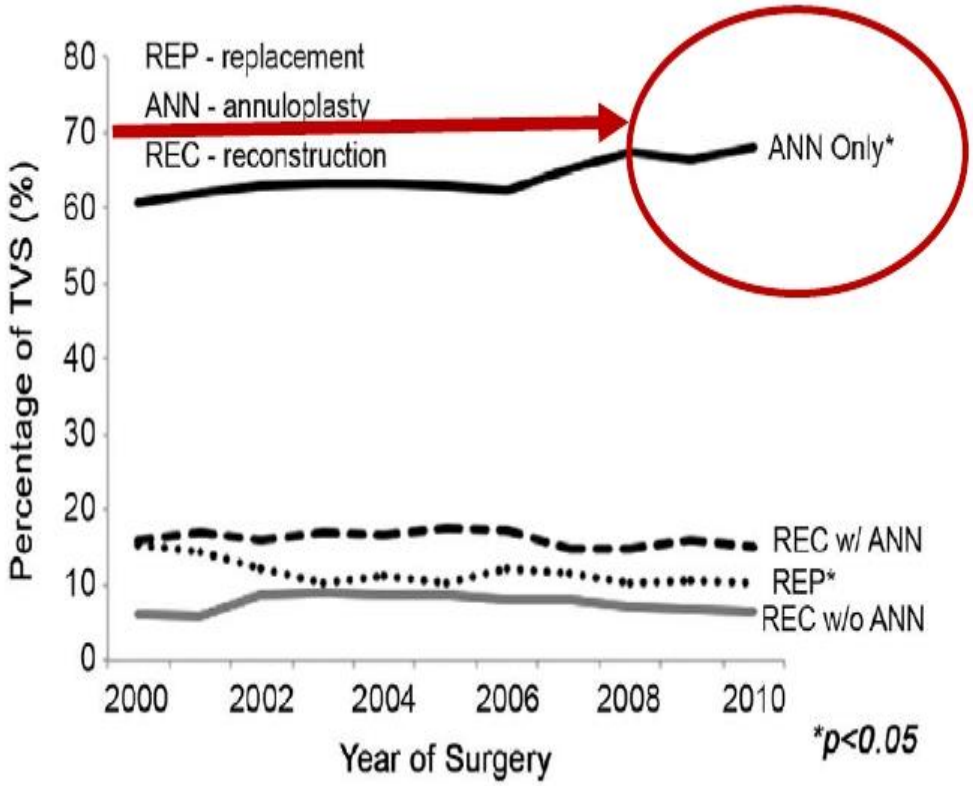


Nach MitraClip



STS database for tricuspid valve surgery 200

70% had annuloplasty only

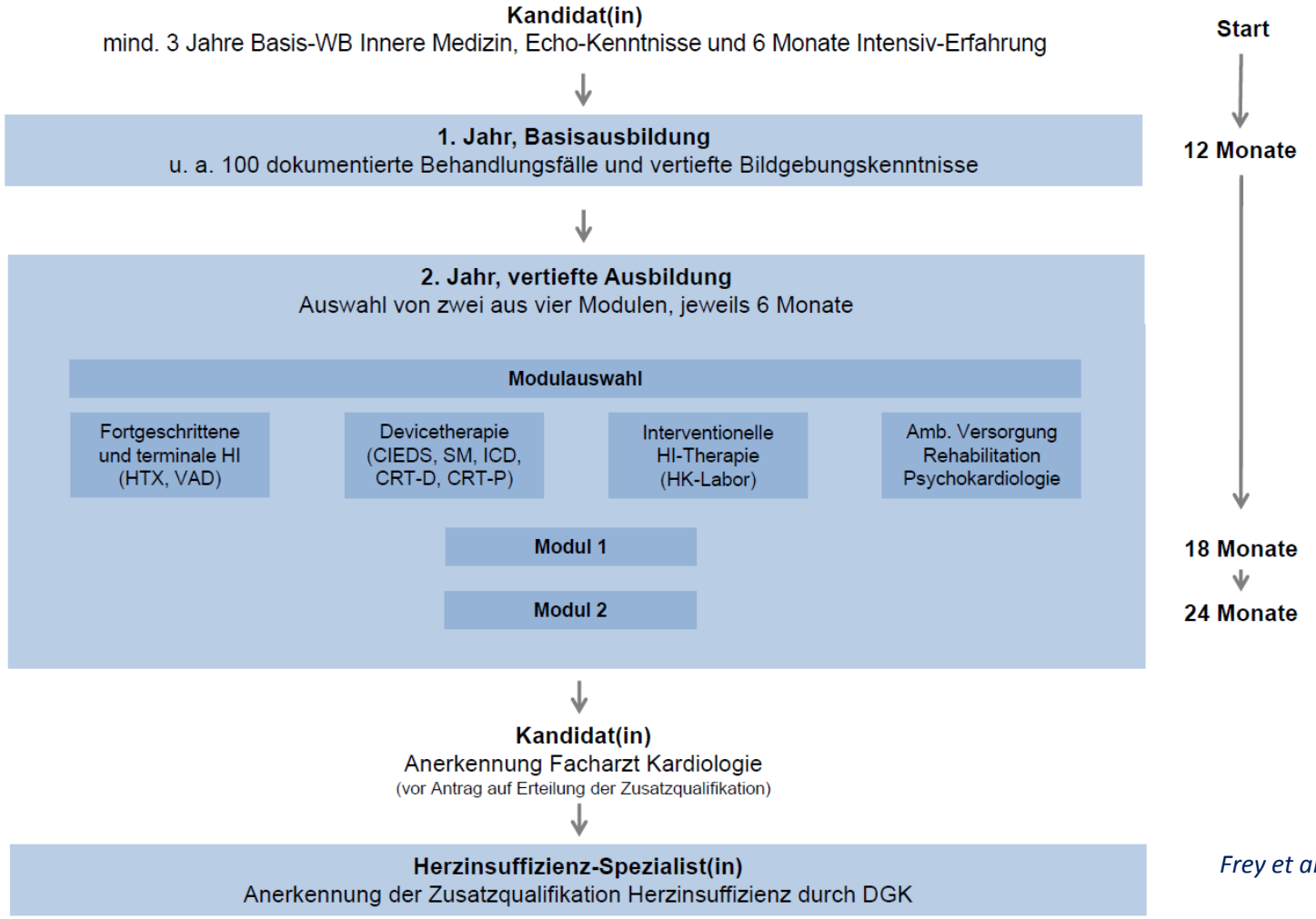


Remaining 30%:

- Annuloplasty + leaflet reconst
- Replacement
- Reconstruction alone

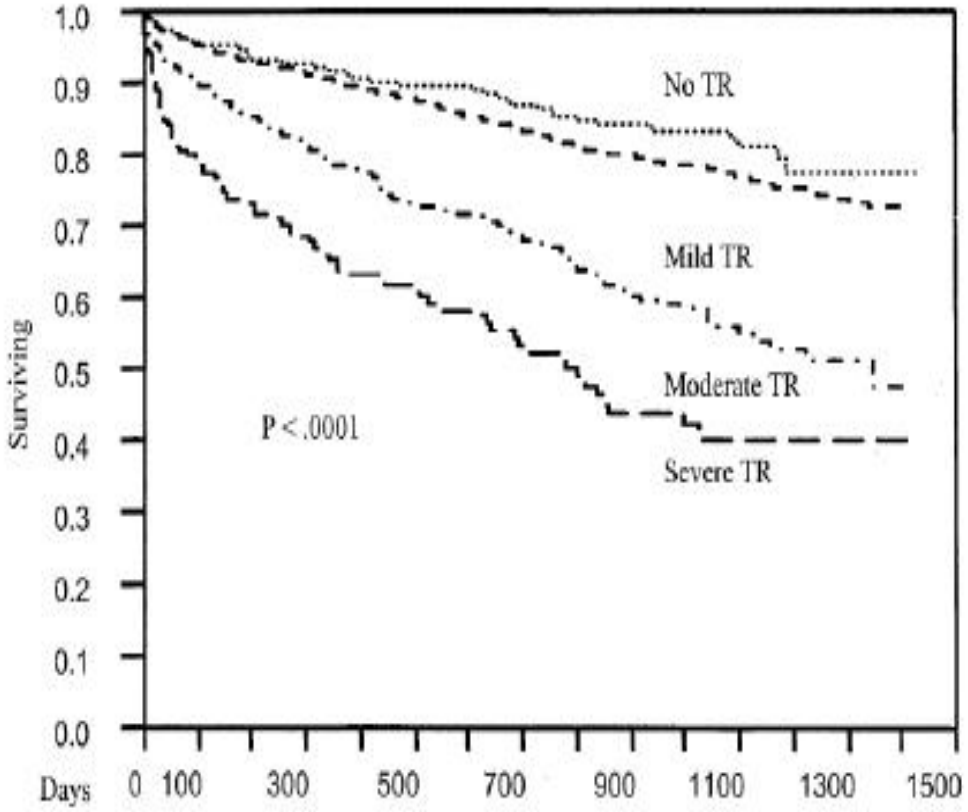
Kilic et al. Ann Thorac Surg 2013;96:

Curriculum Herzinsuffizienz (DGK)



Frey et al. (2018)

Prognostische Bedeutung der TI

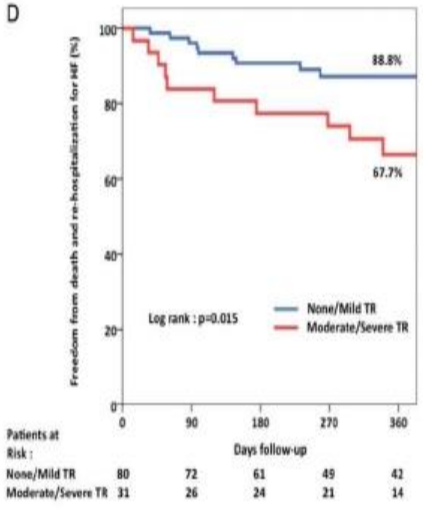


Nath et al. J Am Coll Cardiol 2004

146 MitraClip patients (GRASP regist
32% with moderate-severe TR

1-year death/re-hospitalization
mod-severe TR (vs. 11% with none-m

Freedom from death or re-hospitalization



None-mild TR

Mod-severe TR

No difference in 1 year
all-cause mortality

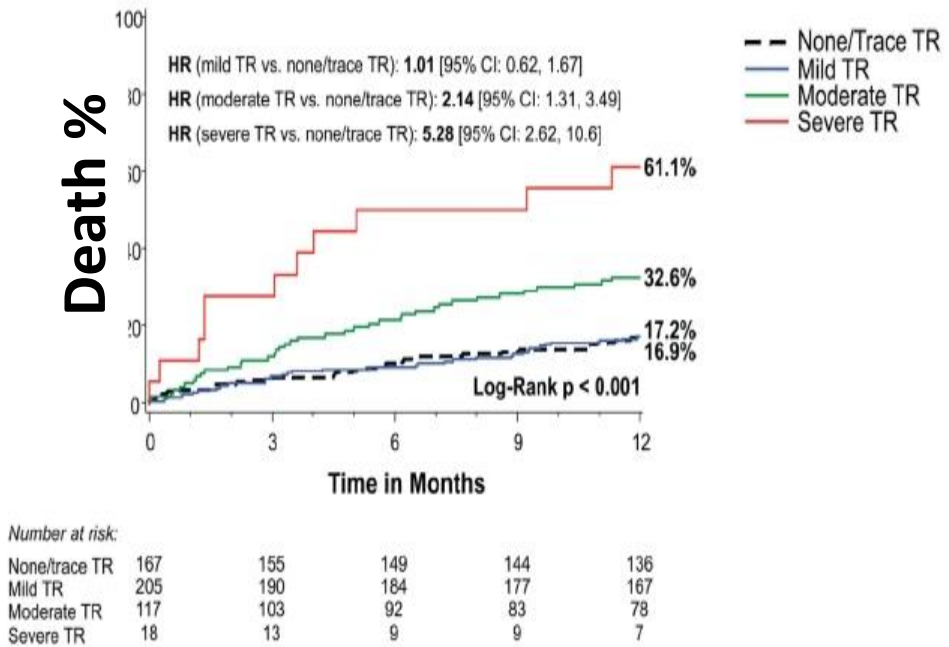
Ohno et al. Eur Heart J Cardiovasc Img 2014;

PCR innovators day

507 patients undergoing TAVR from PART
27% with moderate-severe TR

1-year mortality 61% with mod-s

(vs.17% with none-mild)



Number at risk:

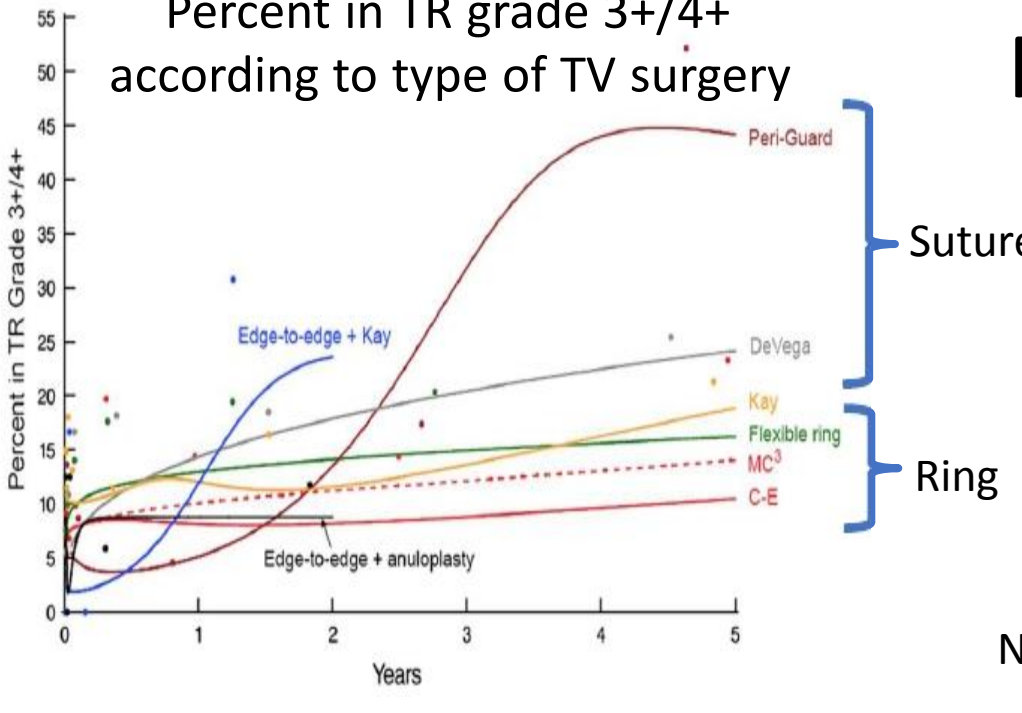
None/trace TR	167	155	149	144	136
Mild TR	205	190	184	177	167
Moderate TR	117	103	92	83	78
Severe TR	18	13	9	9	7

Lindman et al. Circ Cardiovasc Interv 2

2277 patients undergoing various TV repair p

Recurrent 3+/4+ TR
11% at 3 months and 17% at 5

Percent in TR grade 3+/4+
according to type of TV surgery



Ring better than sutur
recurrent TR

No difference in mortality
across techniques
(5-year mortality 35-45%)

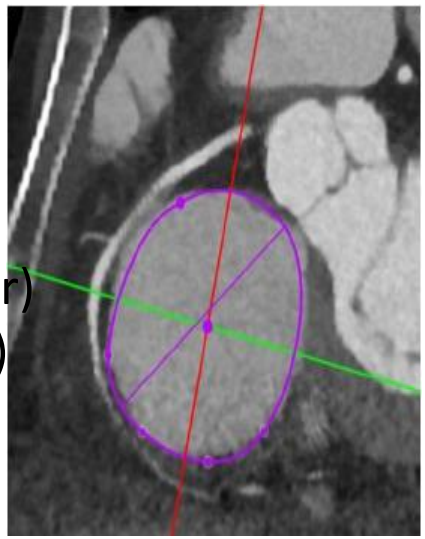
Navia et al. J Thorac Cardiovasc Surg 2010;13

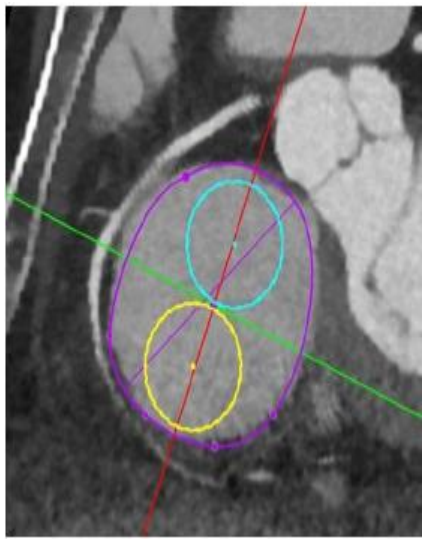
PCR innovators day

Normal tricuspid valve dimensions (3-D

4 cm (diameter)
10 cm_2(area)

~~Severe~~ TR
6.2 cm (diameter)
25.8 cm_2 (area)

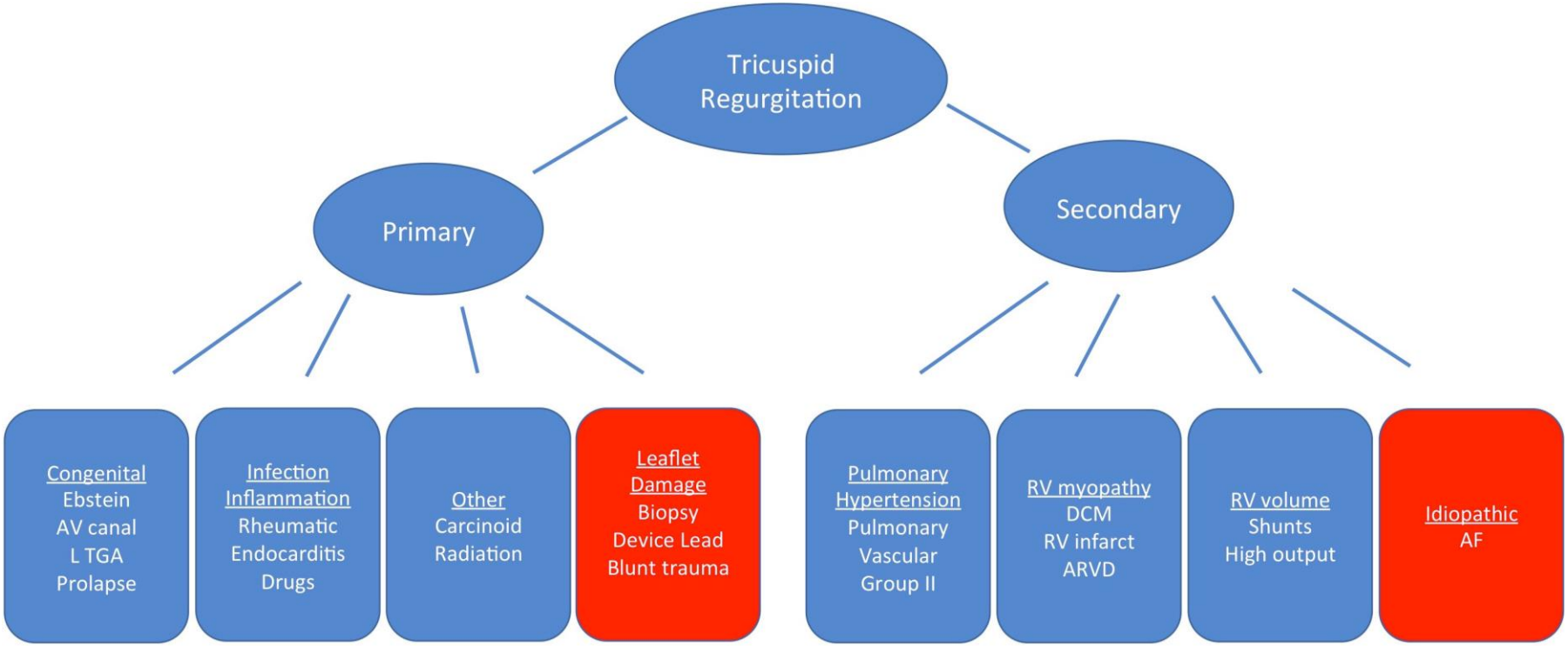




2 x Lotus 27 mm valv

Int J Cardiovasc Imaging 2007;23

Ursachen der Trikuspidalklappeninsuffizienz

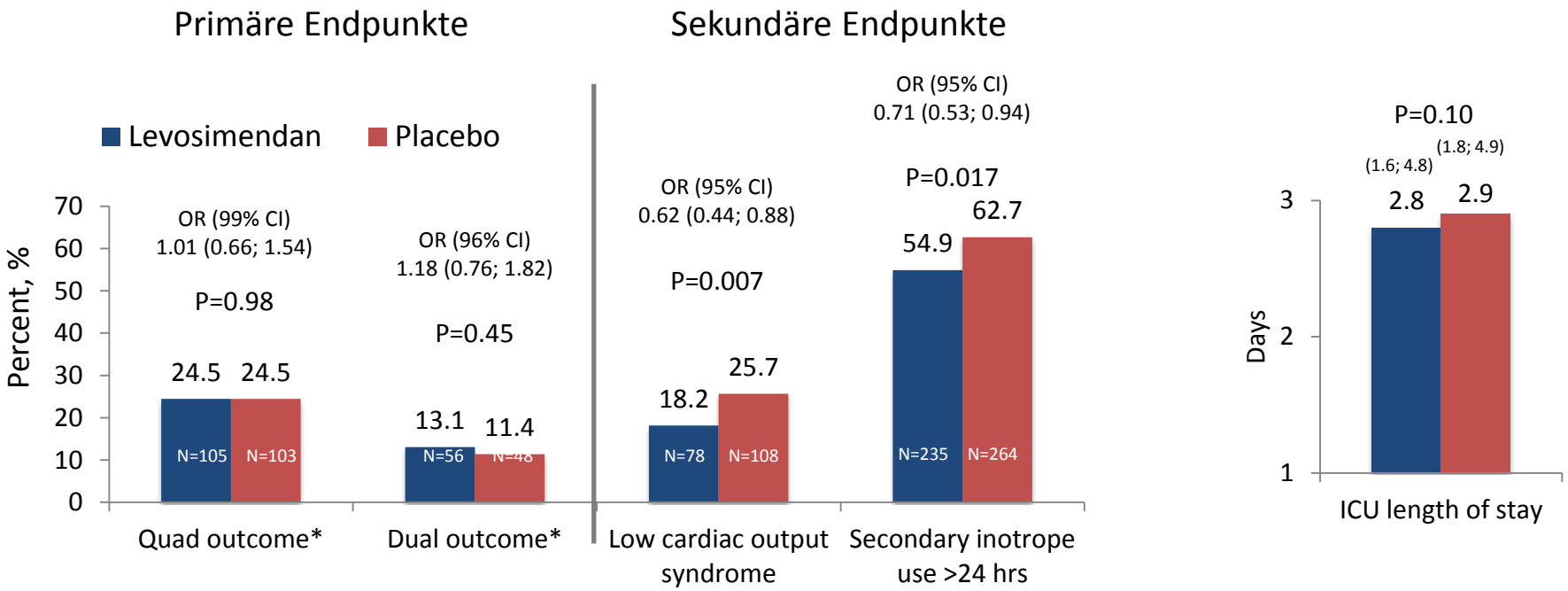


Fender et al. Heart 2017

Transcatheter tricuspid valve inter
Landscape

Direct annuloplasty	Edge-to-Edge	Coaptation enhancement	Replacement
• Cardioband • Trialign / Mitralign • Millipede • MicroInterventional MIA	• TriClip / MitraClip	• 4Tech Tricinch • Edwards FORMA • TRAIPTA	• Navigate • TriCares • TricValve

Levosimendan bei herzchirurgischen Eingriffen



*Primäre Endpunkte:

- Quad: Tod (≤30d), Dialyse (≤30d), Myokardinfarkt (≤5d) oder VAD (≤5d)
- Dual: Tod (≤30d) oder VAD (≤5d)

Mehra et al. New Engl J Med, 2017

Tufts Interventional Heart Failure Training Curriculum	
Advanced HF/Transplant (12 months)	Interventional Cardiology (12 months)
Inpatient Management	Complex Coronary Intervention
Outpatient Clinic	Structural Heart Intervention
Endomyocardial Biopsy	Advanced Hemodynamics
Invasive Hemodynamics	Acute Circulatory Support (Acute MCS)
LVAD and Transplant Management	LVAD Interrogation and Intervention
End of Life Decision Making	Emerging Devices for Heart Failure
Clinical and Preclinical Research	
Dual Board Certification (Interventional and Advanced Heart Failure)	

Interventionelle Entwicklungen

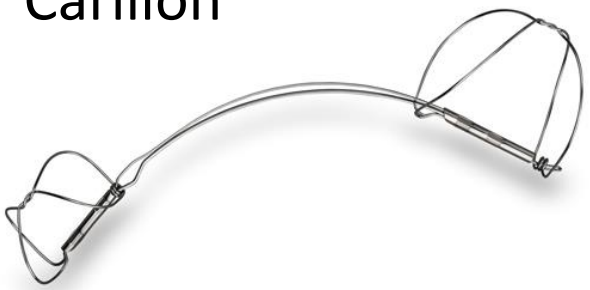
Erste TAVI 2002
Alain Cribier

Erster MitraClip 2003

cxvascular.com
www.medtronic.com
www.abbottvascular.com

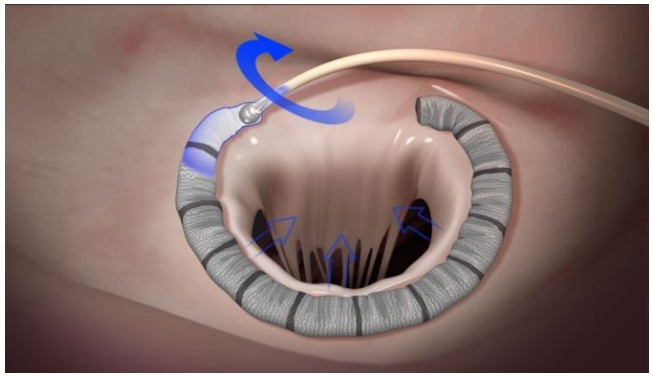
Transvaskuläre MK-Interventionen (CE-Mark)

Carillon

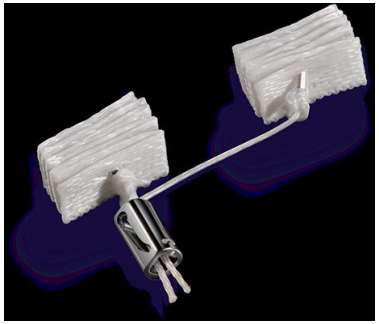


MitraClip

Cardioband



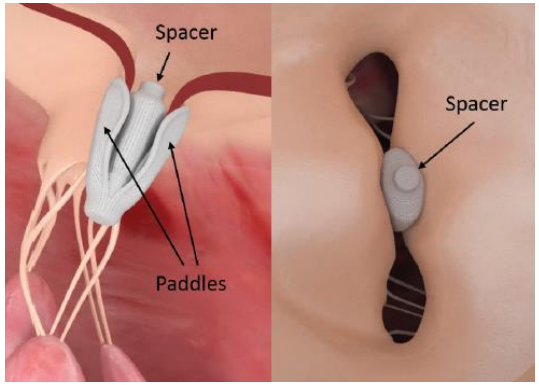
Mitralign



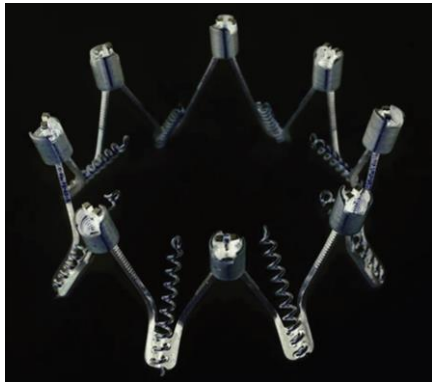
http://www.abbottvascular.com, http://www.cardiacdimensions.com, Feldman et al. JACC 2011, Valtech/Edwards, Mitralign Inc.

Entwicklung: MK Rekonstruktion und MK-Ersatz

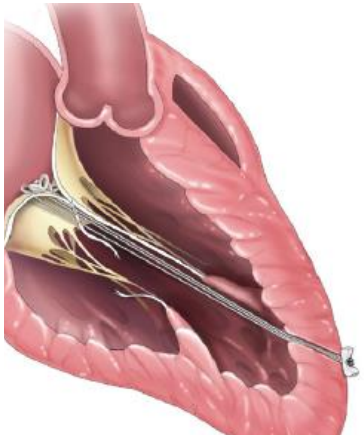
Edge-to-Edge



Annuloplasty



Chordal Repair



Replacement

Image courtesy Edwards, Harpoon Medical, Millipede, Neovasc

Ursachen der akuten Rechtsherzinsuffizienz

- Akuter RV-Myokardinfarkt
- Fulminante Myokarditis
- Akute Dekompensation bei chronischer Herzinsuffizienz
- Lungenarterienembolie
- Dekompensierte pulmonale Hypertonie
- Post-Kardiochirurgie (0,1%)
- Nach Herztransplantation (2-3%)
- Nach Left Ventricular Assist Device (LVAD)-Implantation (30-40%)

Thoennes & Garan JACC, 2017

Perkutan implantierte RVAD-Systeme - Impella RP

- RECOVER RIGHT-Studie

- 30 Patienten erhielten Impella RP
- 18 nach LVAD-Implantation, 12 nach Herzchirurgie oder RV-Infarkt

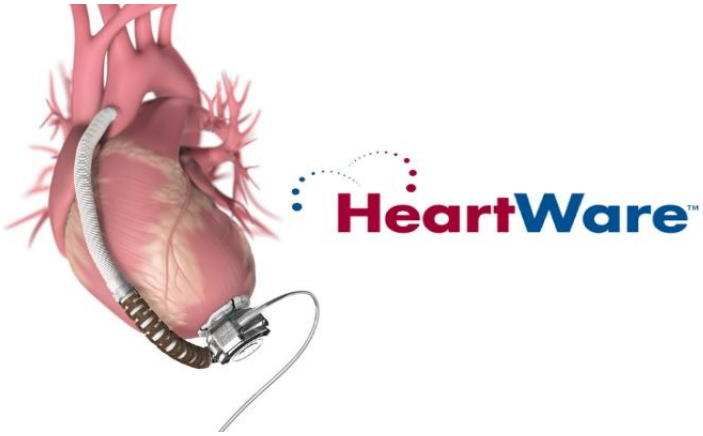
- Nur in einem Patienten konnte Device nicht eingebracht werden

- 30-Tagesüberleben 77%
- Alle entlassenen Patienten überlebten 180 Tage

- Bei fulminanter Lungenembolie: nur Fallberichte

Anderson et al. J Heart Lung Transplant, 2015

Chirurgisch dauerhaft implantierte Systeme?
- Funktioniert als LVAD



Chirurgisch dauerhaft implantierte Systeme?
- Funktioniert als LVAD

Chirurgisch dauerhaft implantierte Systeme?
- Funktioniert als BiVAD

Berlin Heart®

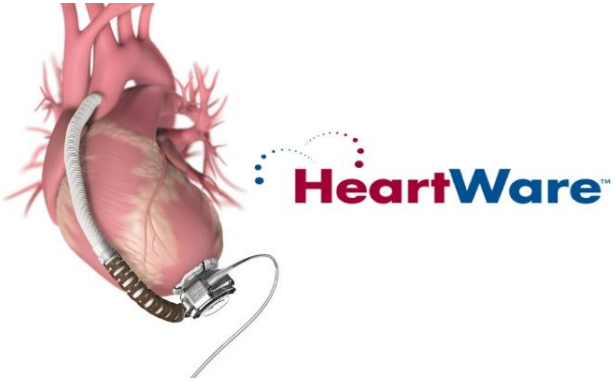
Gibt es dauerhaft implantierte Systeme für den rechten Ventrikel (RVAD)?

Chirurgisch implantierte RVAD-Systeme?

Table 2: Characteristics of 8 patients of the EUROMACS registry with isolated RVAD implantation

Patient	Age (years)	Gender	VAD indication	Cardiac arrest	Dialysis	Intubation	Previous cardiac surgery	IABP	ECMO	INTERMACS class	Device strategy	CPB used	RVAD configuration
1	64	Male	Myocardial infarction	No	No	No	No	No	No	3	Destination therapy	No	RA-PA
2	71	Male	Post-cardiotomy RV failure	No	No	No	No	No	No	2	Rescue therapy	No	RA-PA
3	66	Male	Post-cardiotomy RV failure, tricuspid valve replacement 12 years after HTx	No	Yes	Yes	Yes	No	No	3	Destination therapy	Yes	RA-RPA
4	63	Male	RCA dissection, CABG failure to wean from CPB	Yes	No	Yes	Yes	Yes	Yes	2	Rescue therapy	Yes	RV-PA
5	46	Male	Failure to wean from CBP after postinfarction VSD closure	No	No	Yes	No	Yes	No	1	Rescue therapy	Yes	RA-PA
6	61	Male	Myocardial infarction after Type A aortic dissection with RCA dissection	No	Yes	No	Yes	No	No	1	Rescue therapy	Yes	RA-PA
7	17	Male	Myocardial infarction, congenital heart disease (ASD/VSD)	No	No	No	Yes	No	Yes	2	Rescue therapy	Yes	RA-PA
8	52	Male	Myocardial infarction	Yes	No	Yes	No	No	No	1	Rescue therapy	Yes	RV-PA

VAD: ventricular assist device; IABP: intra-aortic balloon pump; ECMO: extracorporeal membrane oxygenation; ASD: atrial septal defect; VSD: ventricular septal defect; RCA: right coronary artery; CABG: coronary artery bypass grafting; CPB: cardiopulmonary bypass; RVAD: right ventricular assist device.



Bernhardt et al. Eur J of Cardioth Surg, 2015

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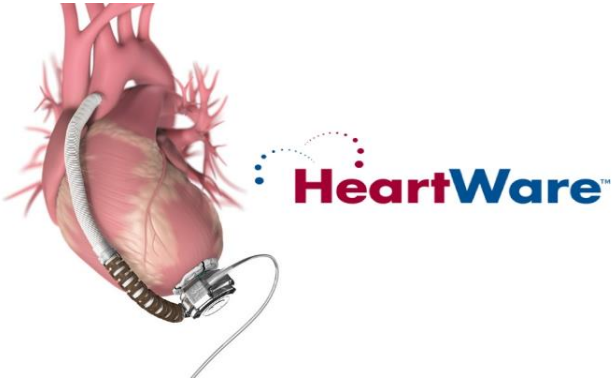

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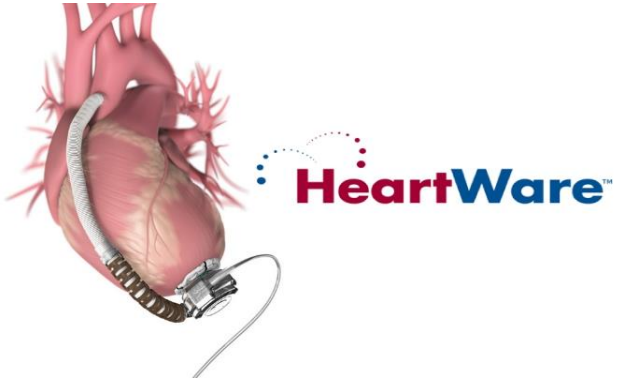
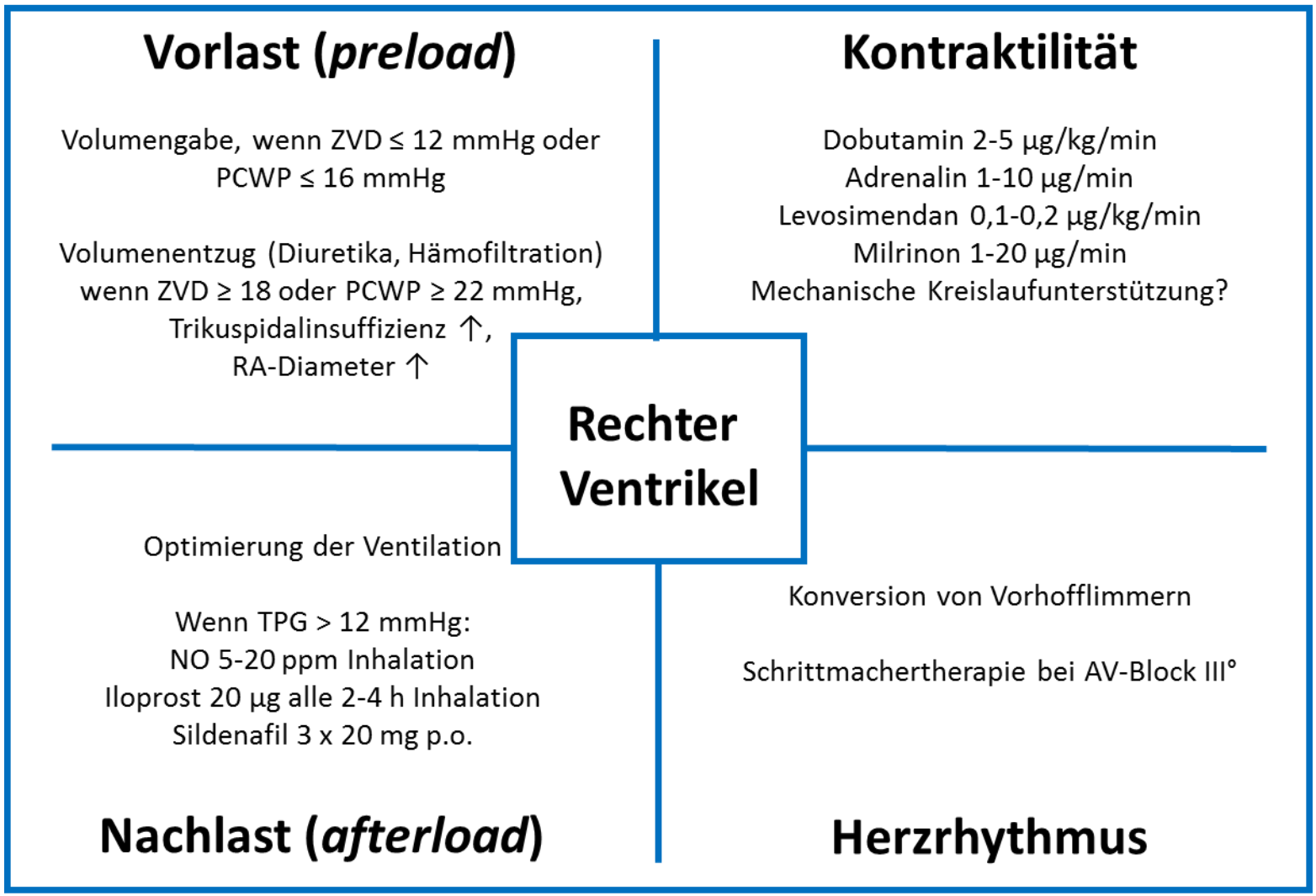


Bernhardt et al. Eur J of Cardioth Surg, 2015



ZVD: zentraler Venendruck, PCWP: pulmonal-kapillärer Verschlussdruck, RA: rechter Vorhof, TGP: transpulmonaler Gradient

Diagnostik bei Trikuspidalinsuffizienz

	Tricuspid regurgitation
Qualitative	
Valve morphology	Abnormal/flail/large coaptation defect
Colour flow regurgitant jet	Very large central jet or eccentric wall impinging jet[a]
CW signal of regurgitant jet	Dense/triangular with early peaking (peak <2 m/s in massive TR)
Other	–
Semiquantitative	
Vena contracta width (mm)	≥7[a]
Upstream vein flow[c]	Systolic hepatic vein flow reversal
Inflow	E-wave dominant ≥1 m/s[e]
Other	PISA radius >9 mm[g]
Quantitative	
EROA (mm^2)	≥40
Regurgitant volume (mL/beat)	≥45
+ enlargement of cardiac chambers/vessels	RV, RA, inferior vena cava

Baumgärtner et al. Eur. Heart Journal 2017

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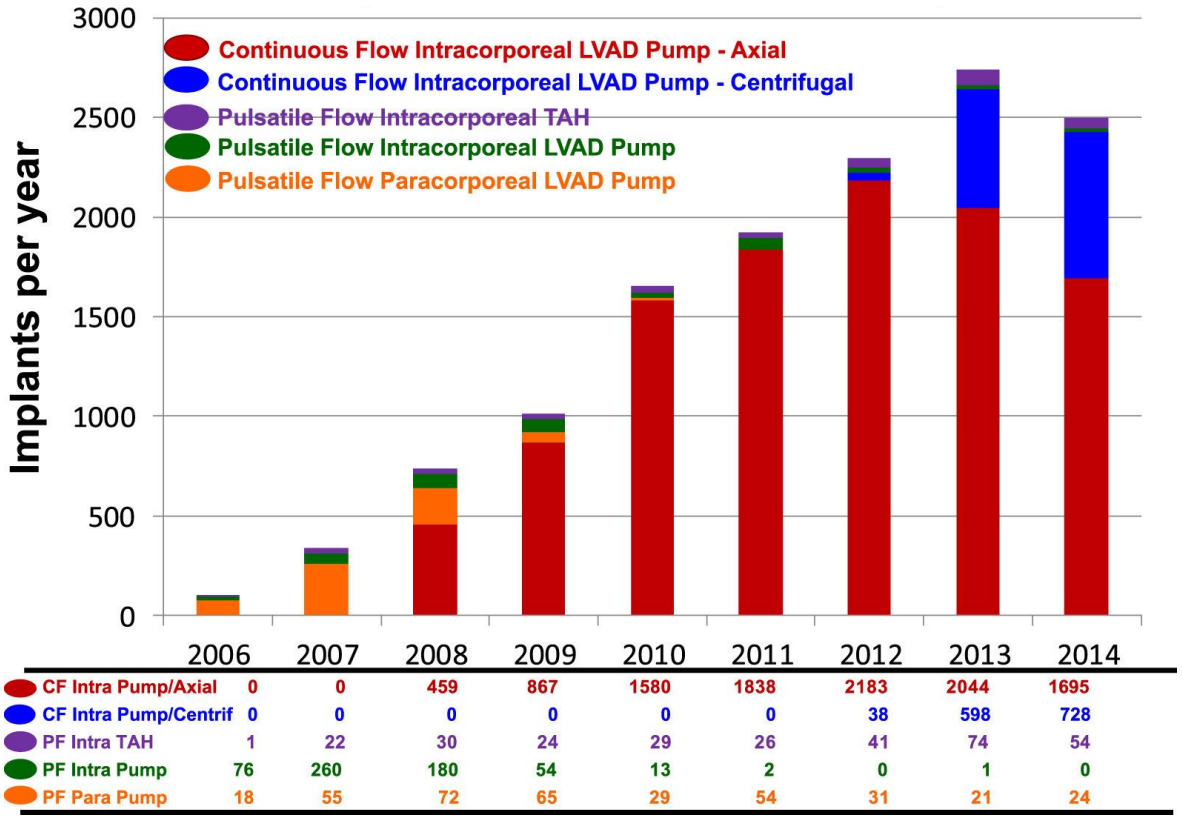
Baumgärtner et al. Eur. Heart Journal 2017

Chirurgisch dauerhaft implantierte Systeme?
- Funktioniert als LVAD

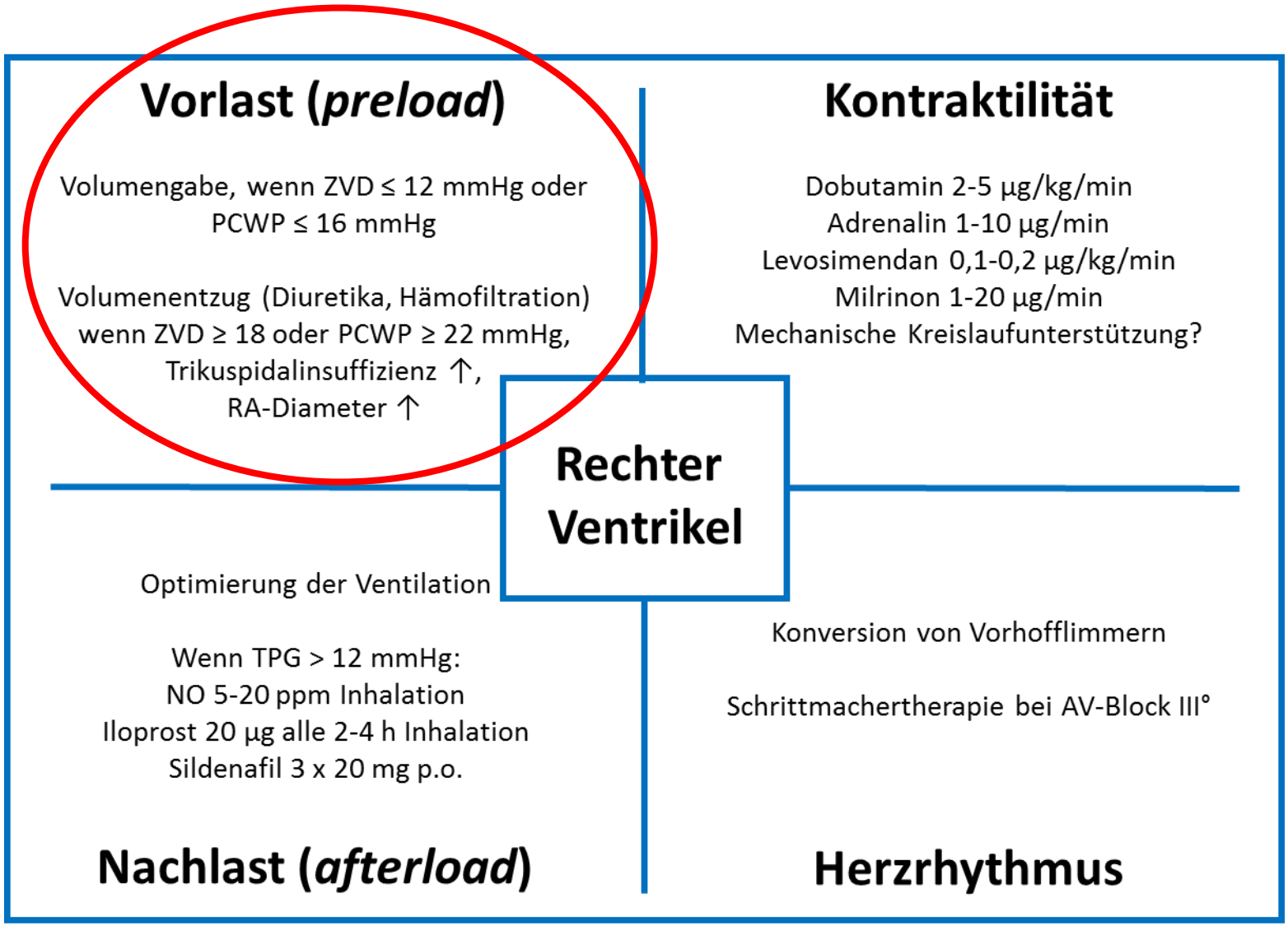


Kirklin et al. J Heart Lung Transplant, 2015

Ätiologie

- Nur 10% primäre Trikuspidalklappeninsuffizienz
  - Schrittmachersonde
  - Ebsteinanomalie
  - RV-Biopsie (25% der Herztransplantierten)
  - Endokarditis
  - Traumatisch
- Mit Abstand führend: sekundäre Trikuspidalklappeninsuffizienz
  - 30% bei Mitralinsuffizienz/-stenose

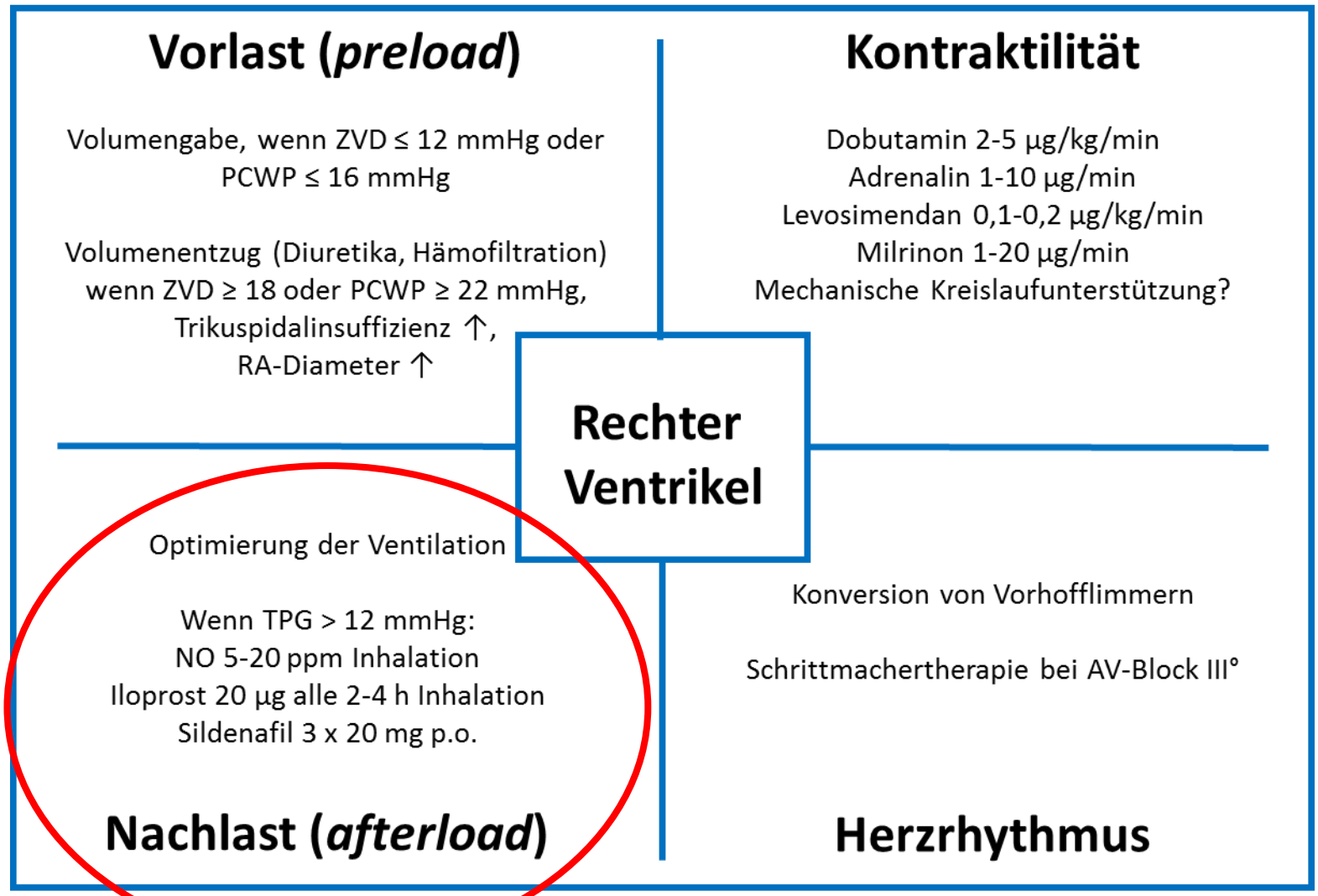
Dreyfuss et al. JACC 2015
Nguyen et al. J Heart and Lung Transpl. 2005
Nath et al. JACC 2004



ZVD: zentraler Venendruck, PCWP: pulmonal-kapillärer Verschlussdruck, RA: rechter Vorhof, TGP: transpulmonaler Gradient

Optimierung der Vorlast

- Die Optimierung des Blutvolumens ist ein schwieriges, aber wichtiges Behandlungsziel bei Patienten mit RV-Insuffizienz.
- Volumenzufuhr oder -entzug: keine eindeutigen Parameter für die Steuerung der RV-Vorlast vorhanden
- Rasche Volumenzufuhr: falls der ZVD ≤ 12 mmHg
- Stopp der Volumenzufuhr: bei schnellem Anstieg der RV-Füllungsdrücke oder Zunahme der Trikuspidalinsuffizienz, des RV-Diameters
- Gegebenenfalls Diuretika, Hämofiltration



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Senkung Nachlast des RV

- Optimale Oxygenation und Ventilation, um die durch Hypoxie und Hyperkapnie bedingte Vasokonstriktion zu reduzieren

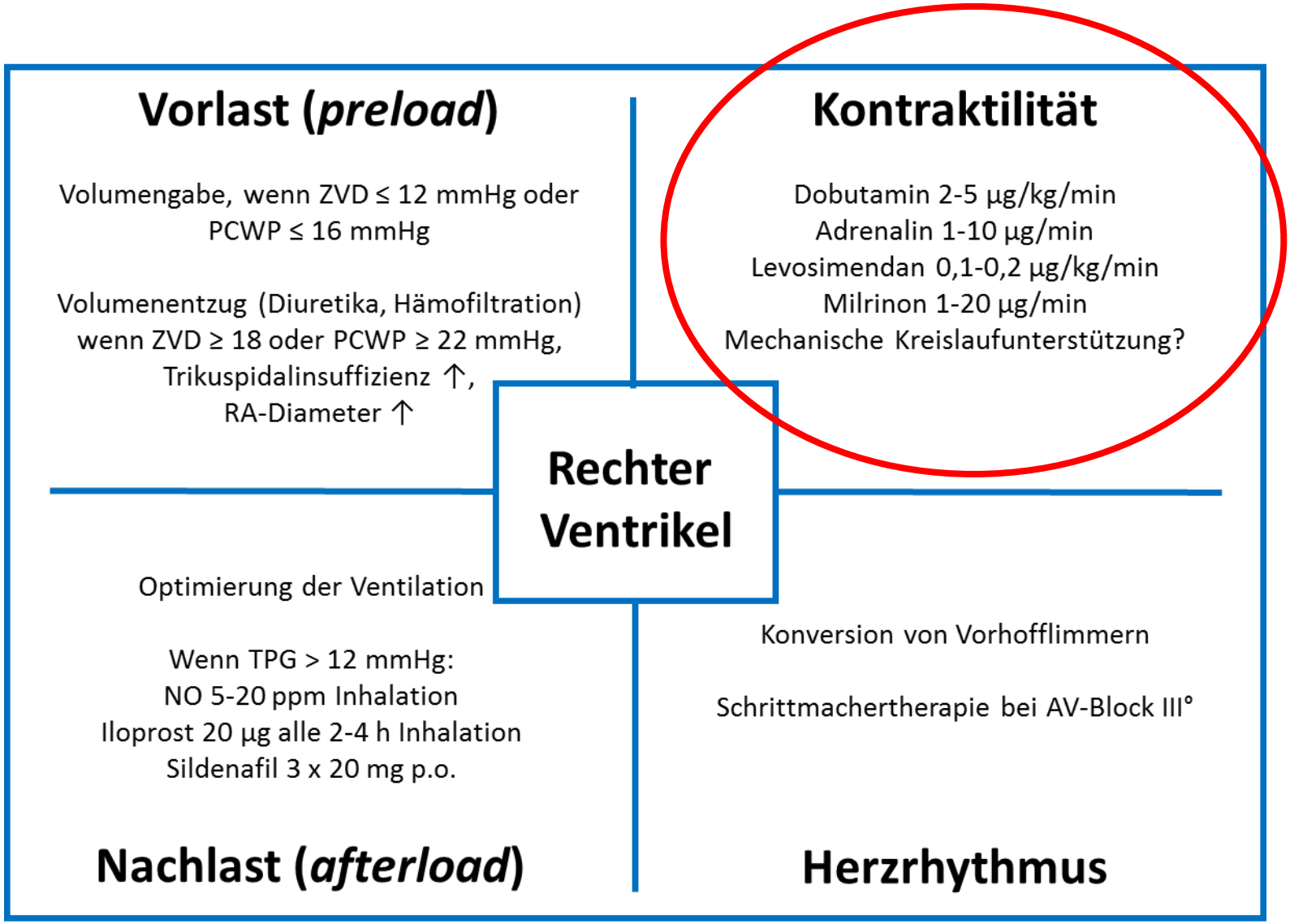
- Zur medikamentösen Senkung des pulmonalarteriellen Gefäßwiderstands stehen diverse Medikamente wie

  Prostazykline,

  Phosphodiesterase-5-Hemmer,

  und Stickstoffmonoxid zur Verfügung.

- Diese sollten im akuten Rechtsherzversagen mit intravenös applizierten Inodilatatoren wie Milrinon oder Levosimendan kombiniert werden.



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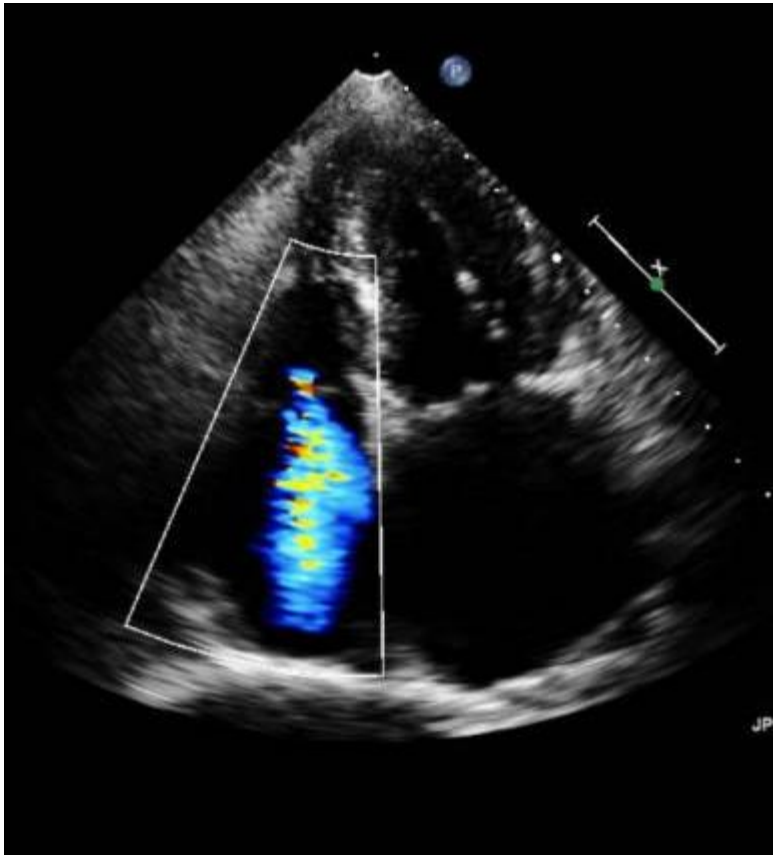
Trikuspidalklappeninsuffizienz

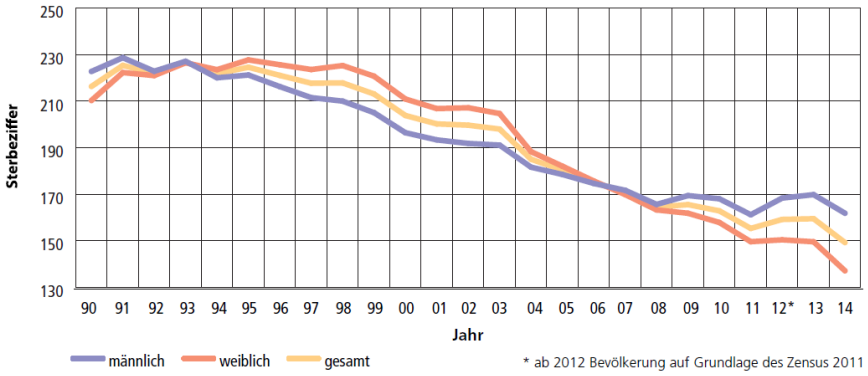
- 80-90% der Bevölkerung
- 0,8% mittel- bis höhergradig
- 1-Jahresüberleben
  - 91,7% keine TI
  - 90,3% leichtgradige TI
  - 78,9% mittelgradige TI
  - 63,9% hochgradige TI



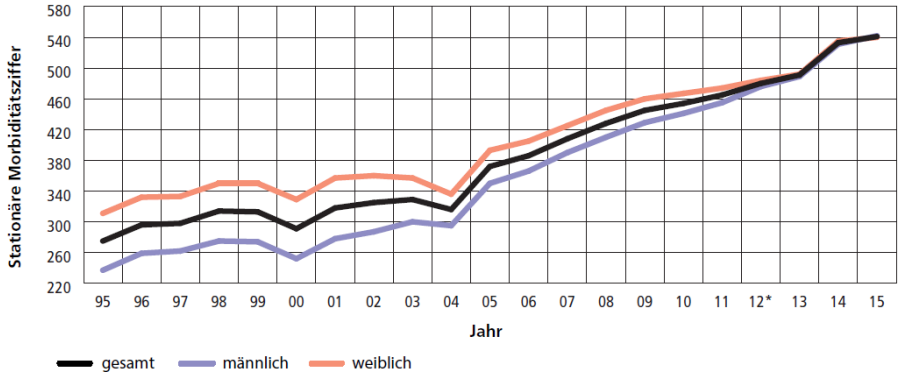
Singh et al. Am J Cardiol 1999
Nath et al. JACC 2003

Epidemie Herzinsuffizienz

Todesursache Herzinfarkt/KHK



Zunahme der Herzinsuffizienz

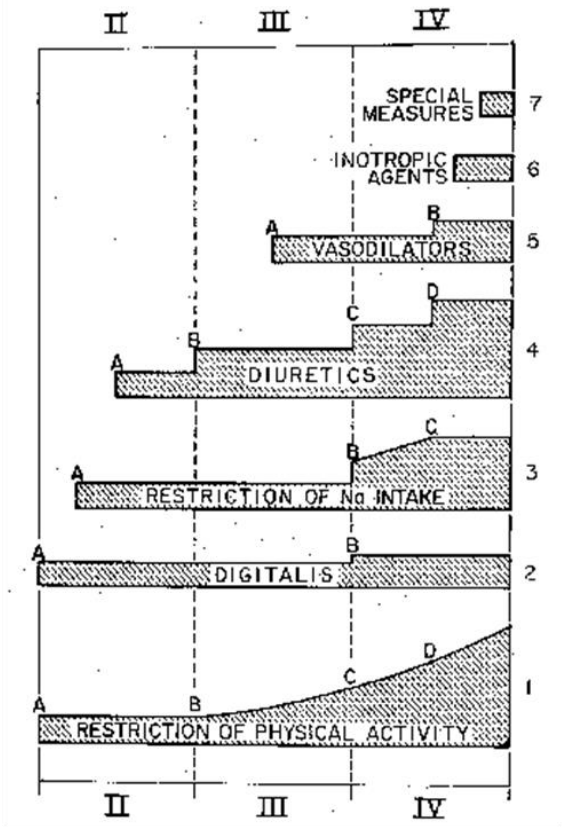


Deutscher Herzbericht 2016, Statistisches Bundesamt

Therapie der Herzinsuffizienz 1984

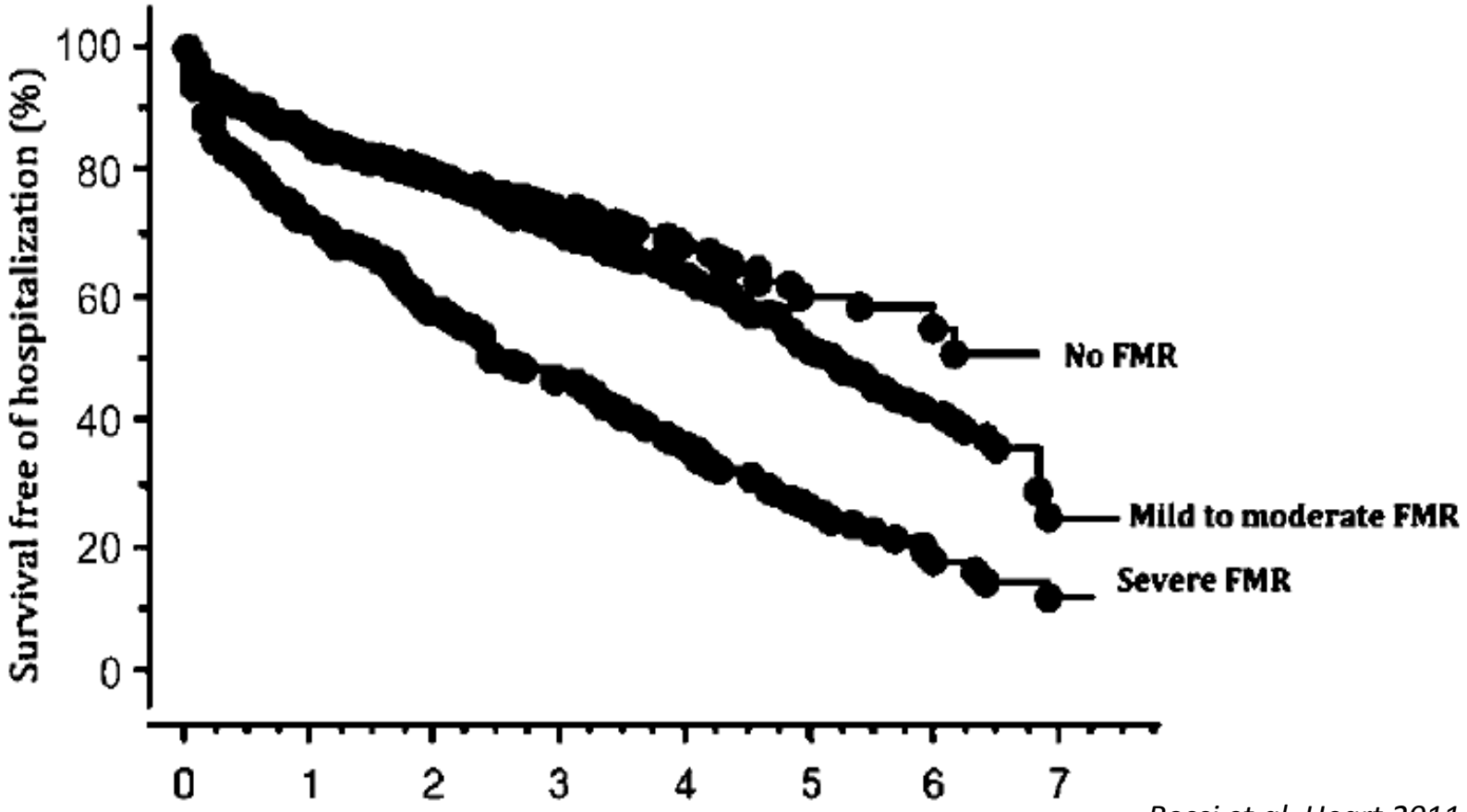
Restriction of Na^+ Intake

Restriction of Physical Activity



Brauwnwald E. Management of heart failure. Heart Disease 2nd ed. 1984; 503-550.

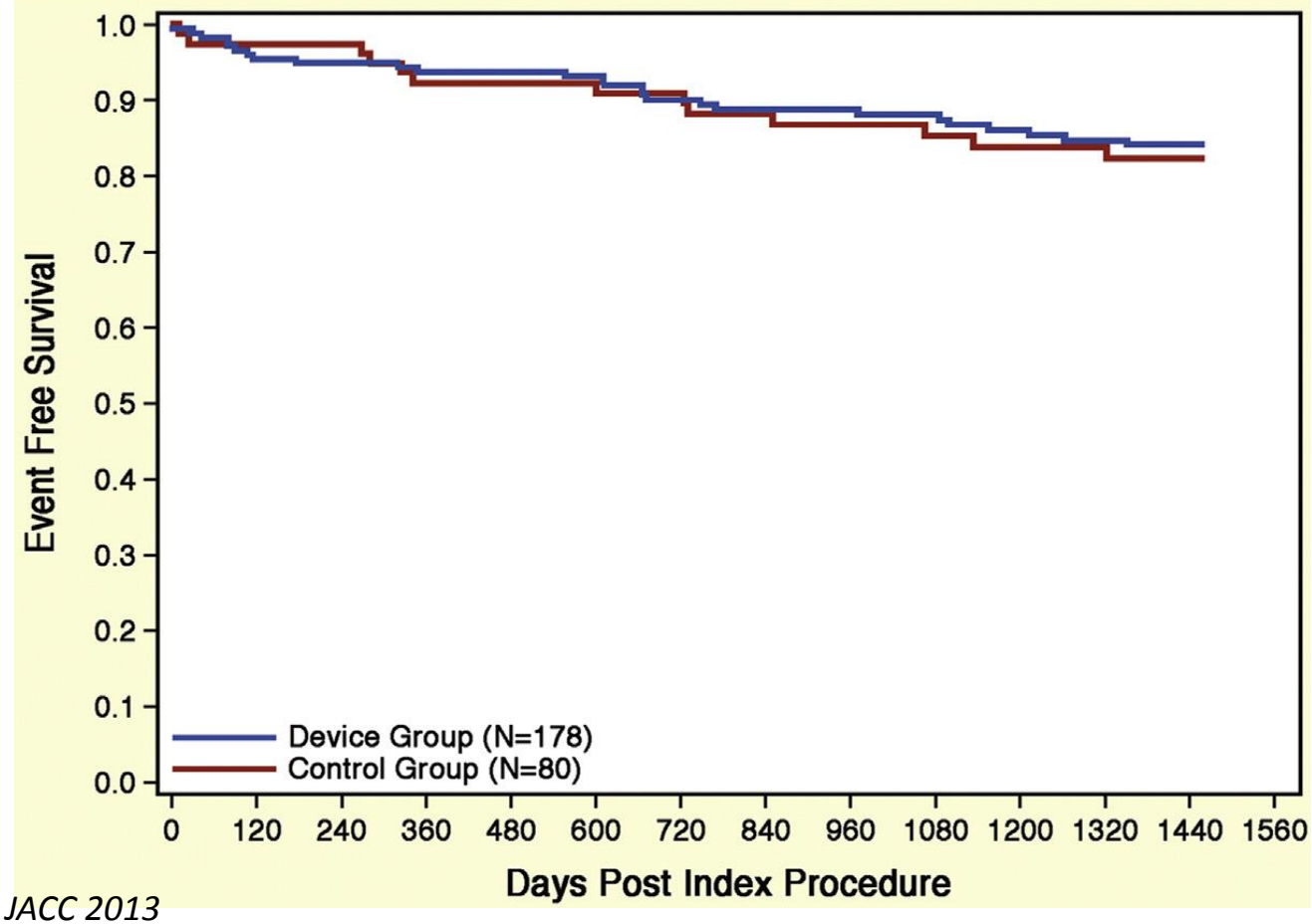
Sekundäre MI bei Herzinsuffizienz



Rossi et al. Heart 2011

EVEREST II 4 year results

Freedom from death and surgery



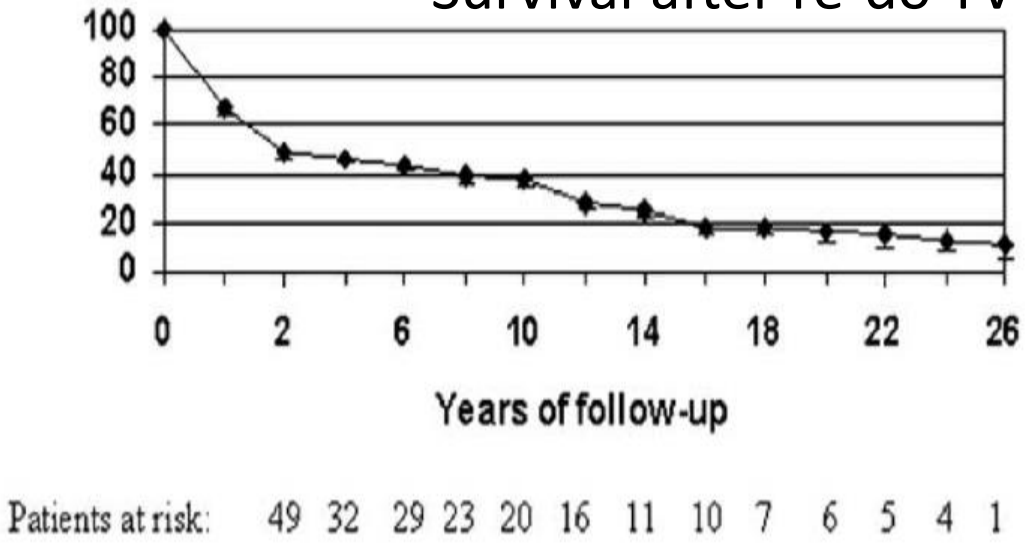
Mauri et al. JACC 2013

PCR innovators day

74 patients undergoing re-do tricuspid valv

35% operative mortality

Survival after re-do TV surgery



Bernal et al. J Thorac Cardiovasc Surg 2005;13

RV-Failure Risk Scores

Matthews[5] [2008]		Fitzpatrick[31] [2009]	Drakos[14] [2010]	
Preoperative variables	Points	Preoperative variables	Preoperative variables	Points
Vasopressor use	4	Cardiac index $\leq$ 2.2 L/min/m^2	Destination therapy	3.5
Cr $\geq$ 2.3 mg/dl	3	RVSWI $\leq$ 0.25 mmHg L/m^2	IABP	4
Bilirubin $\geq$ 2 mg/dl	2.5	Severe RV dysfunction	PVR	
AST $\geq$ 80 IU/L	2	Cr $\geq$ 1.9 mg/dl	1.7	1
		Previous cardiac surgery	1.8–2.7	2
		SBP $\leq$ 96 mmHg	2.8–4.2	3
			>4.3	4
			Inotrope dependency	2.5
			Obesity	2
			ACE or ARB	2.5
			B-Blocker	2
Risk score		Risk score	Risk score	
Total points	Odds ratio	Each variable valued:	Total points	Risk RVF [%]
$\leq$3.0	0.49	1 [abnormal] or 0 [normal] use	<5	11
4.0–5.0	2.8	These cut offs for abnormal	5.5–8.0	37
		Dichotomic variable yes = 1	8.5–12	56
$\geq$5.5	7.6	**Risk Score** = 18 * [CI] + 18 * [RVSWI] + 17 * [Cr] + 16 * [Previous Cardiac Surgery] + 16 * [RV dysfunction] + 13 * [SBP]	>12.5	83
		Score < 50 predicts need for BiVAD		

Meieneri et al. 2012