Kunstherzen: Was der Praktiker darüber wissen muss

Paul Mohacsi

Prof. Dr. med., MBA, FHFA, FESC, FACC

HerzGefässZentrum Zürich

Klinik im Park, Hirslanden Zürich

und

Herzchirurgie, Universitätsspital Basel

paul.mohacsi@hirslanden.ch

I will not discuss off label use and/or investigational use of drugs/devices
No relevant financial relationships exist related to my role in this session

HIRSLANDEN
A MEDICLINIC INTERNATIONAL COMPANY

Relevantes für die Praxis 2018, Luzern, 25. Okt. 2018

HIRSLANDEN PROFESSIONAL

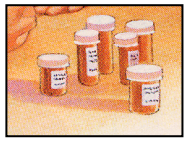
Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

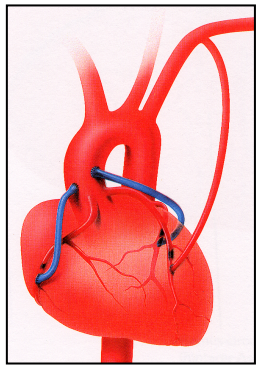
HIRSLANDEN
KLINIK IM PARK

Heart Failure Therapy

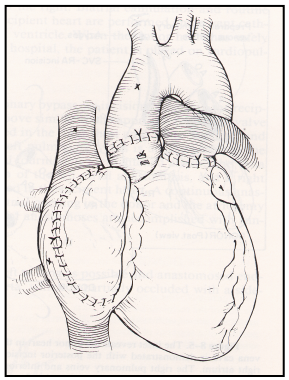
- Life Style
- Prophylaxis
- Palliation
- CRT /ICD
- Drugs for CHF



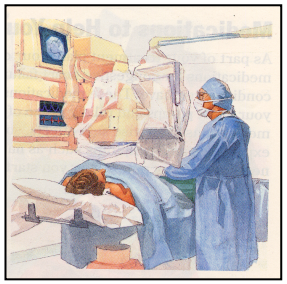
- Surgery



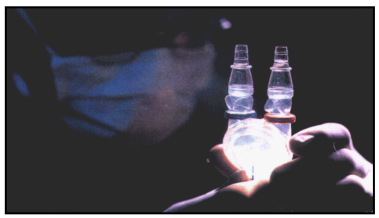
- Transplantation



- Cath Lab



- VADs



Sind Sie der Meinung, dass PatientInnen mit einer „schweren“ Herzinsuffizienz, (ähnlich wie PatientInnen mit einer schweren Aortenstenose für eine TAVI), für die Implantation einer Herzunterstützungspumpe zumindest erwogen werden sollten ?

a) Ja
b) Nein
c) Ja, jedoch nur im Alter von < 80 Jahren
d) Ja, jedoch nur im Alter von < 70 Jahren

Themen

- Zahlen & Definition
- Was ist ein Kunstherz ?
- Herzunterstützungspumpen
  Realität vs Experim. Medizin
- Patienten Selektion
- Outcome Data

Zahlen (CH)

- Ca 200‘000 herzinsuffiziente Patienten
- Ca 10‘000 „NYHA IV“ Pat

- Was ist eine „schwere“ Herzinsuffizienz ?

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

Advanced Heart Failure
(Definition of the HFA-SGAHF)

History of pre-existing HF with unstable clinical course shown by hospitalization for worsening HF

Severe symptoms of HF at rest or with minimal exertion (NYHA Functional class III or IV)

Episodes of fluid retention (congestion) and/or of reduced cardiac output at rest (peripheral hypoperfusion);

Objective evidence of severe cardiac dysfunction:

a) a low LVEF (≤ 30%) and/or a LV end-systolic volume >60 mL/m^2,
b) a severe abnormality of cardiac function in Doppler-Echo with a pseudonormal or restrictive mitral inflow pattern
c) high LV filling pressures (mean PCWP >16 mmHg, and/or mean RAP >12 mmHg at Swan-Ganz cath.)
d) high BNP or NT-ProBNP plasma levels, in the absence of non-cardiac causes

Severe impairment of functional capacity shown by one of the following:

a) inability to exercise,
b) 6MWT distance <300 meters
c) peak VO2 < 14 ml/kg/min[9,10]

Optimal medical therapy including diuretics, inhibitors of the RAAS, and beta-blockers, unless these are poorly tolerated or contraindicated and CRT, when indicated.

M. Metra et al 2006

Themen

- Zahlen
- Was ist ein Kunstherz ?
- Herzunterstützungspumpen
  Realität vs Experim. Medizin
- Patienten Selektion
- Outcome Data

Kunstherzen 1: The SynCardia Total Artificial Heart (TAH)

- ? Highest bridge to human heart transplant rate of any heart device, 79% (FDA PMA Study); Nantes is 75%
- About 1’500 implants account for more than 350 patient years on the Total Artificial Heart
- >100 centers ready or almost ready to implant
- Pneumatically powered through drivelines that connect to a driver

Kunstherzen 2: The Carmat TAH

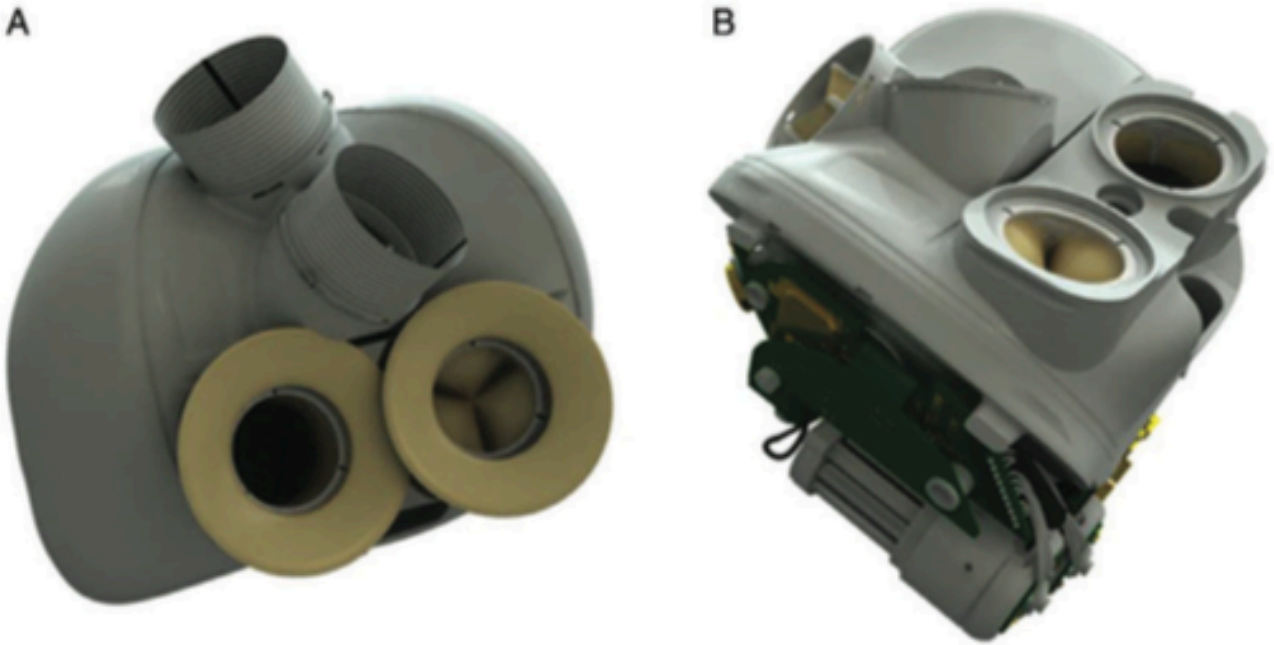


Figure 1: CARMAT TAH. (**A**) Compliance bag surrounding the prosthesis; atrial suture flanges and ejection conduits. (**B**) Partially open view of embedded electronics and motor-pump units.

European Journal of Cardio-Thoracic Surgery 46 (2014) 933–934
doi:10.1093/ejcts/ezu333 Advance Access publication 15 September 2014

Themen

- Zahlen
- Was ist ein Kunstherz ?
- Herzunterstützungspumpen
  Realität vs Experim. Medizin
- Patienten Selektion
- Outcome Data

Herzunterstützungspumpen gehören heute in der Medizin zum Alltag

- als „Rescue“ oder „Backup“
- als Ueberbrückung bis zur HTx
- als „Destination“-Therapie

Herzunterstützungspumpen (VADs) :

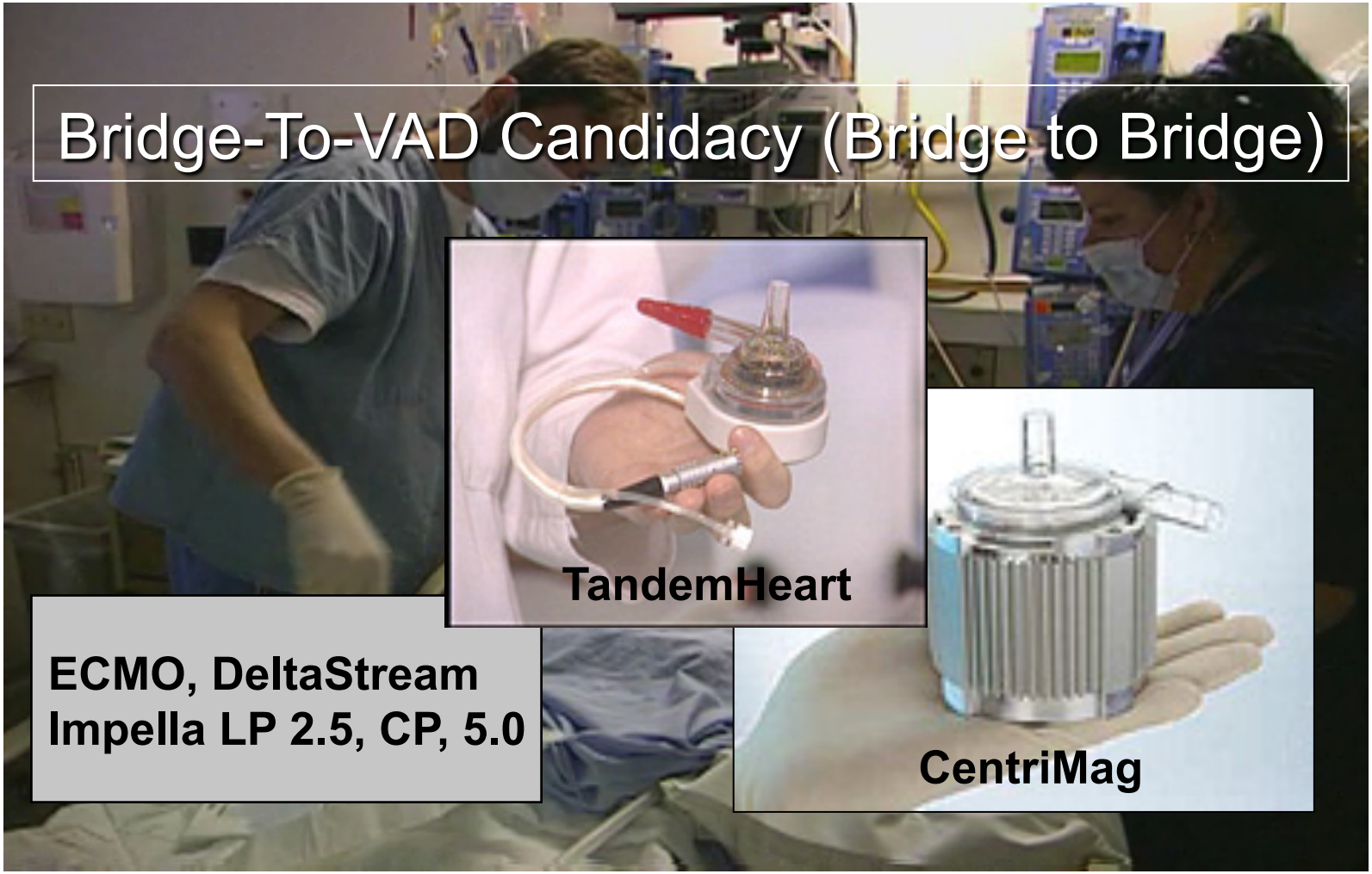
- Short term
- Long term (vor 20, vor 10, vor 7.5 und vor 3 Jahren)
- Zukünftige Long Term VADs

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

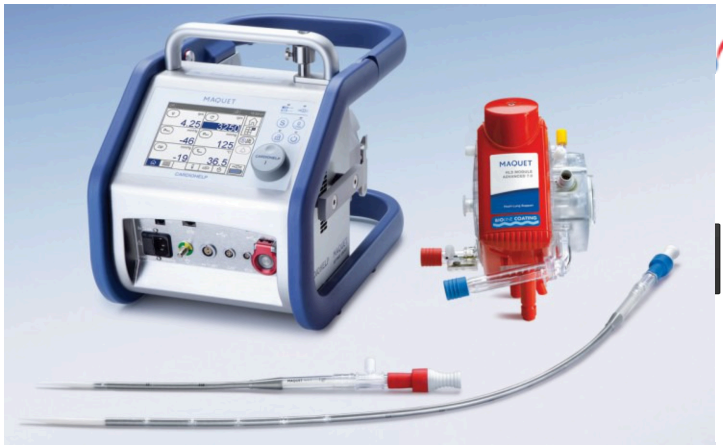
Bridge-to-Decision
(short term mechanical support)

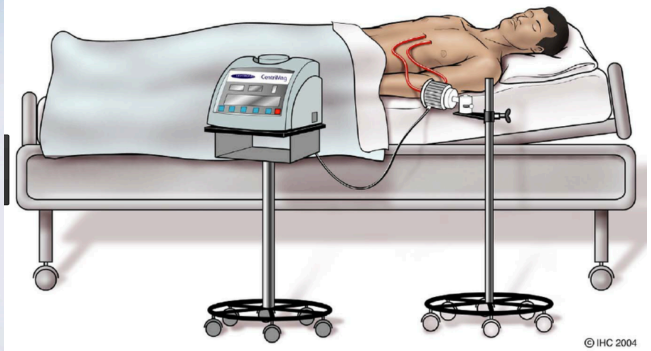


Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich | HIRSLANDEN

ECMO CardioHelp





Impella

Impella 2.5®
Impella® makes a Protected PCI procedure possible

Impella CP®
Percutaneous insertion and increased flow

Impella 5.0®/LD®
Delivers up to 5.0 L/min of forward blood flow from the left ventricle

Impella 5.0®/LD®
Delivers up to 5.0 L/min of forward blood flow from the left ventricle

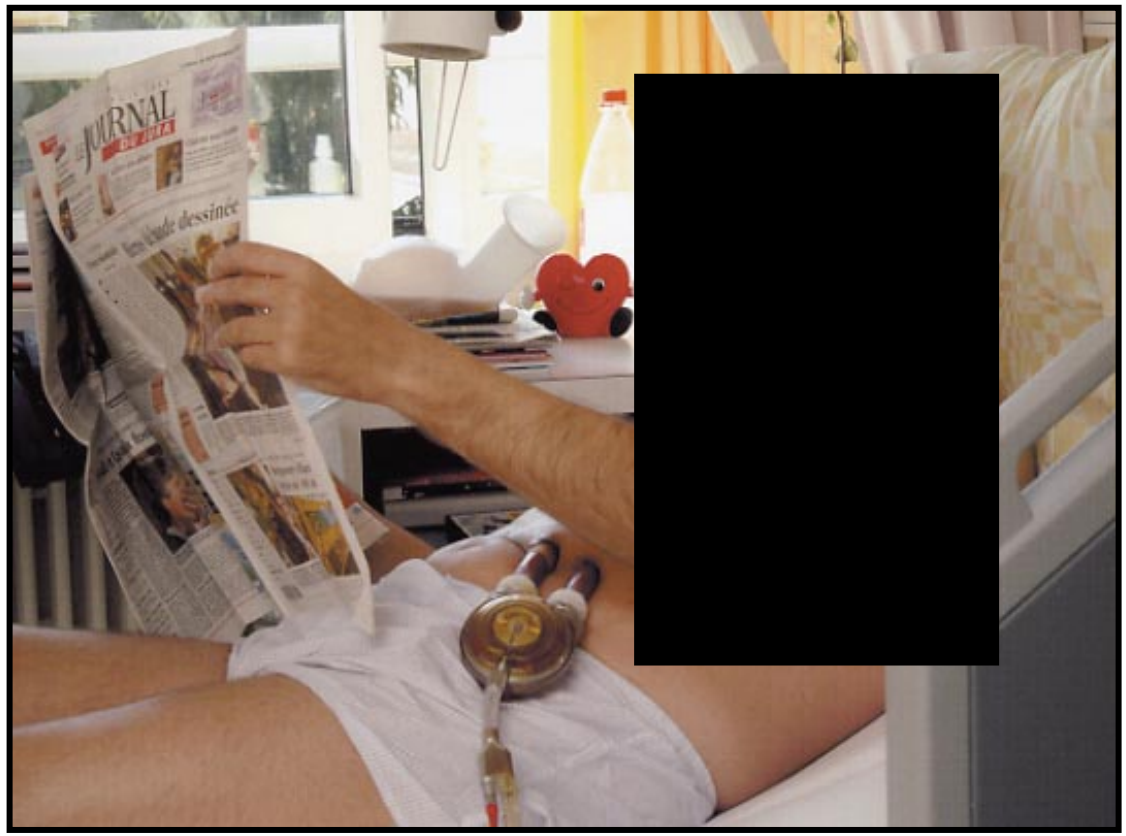
Impella RP®
The first percutaneous, single vascular access pump designed for right heart support

Automated Impella® Controller
The primary user control interface for the Impella platform

20 years ago: (Long term pVAD Thoratec)

Patient, 1959, BG 0, BW 88 kg

- 2002: Anterior Myocardial Infarction
- Cardiogenic Shock
- 5.7.02: Implantation of a Tandem-Heart (BtB)
- 23.7.02: Implantation of a pVAD Thoratec CI < 2 (BtT)
- 8 months on the HTx waiting list
- Successful HTx



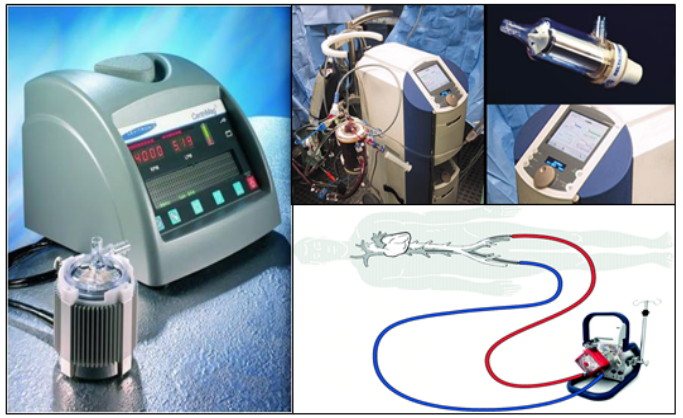
Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

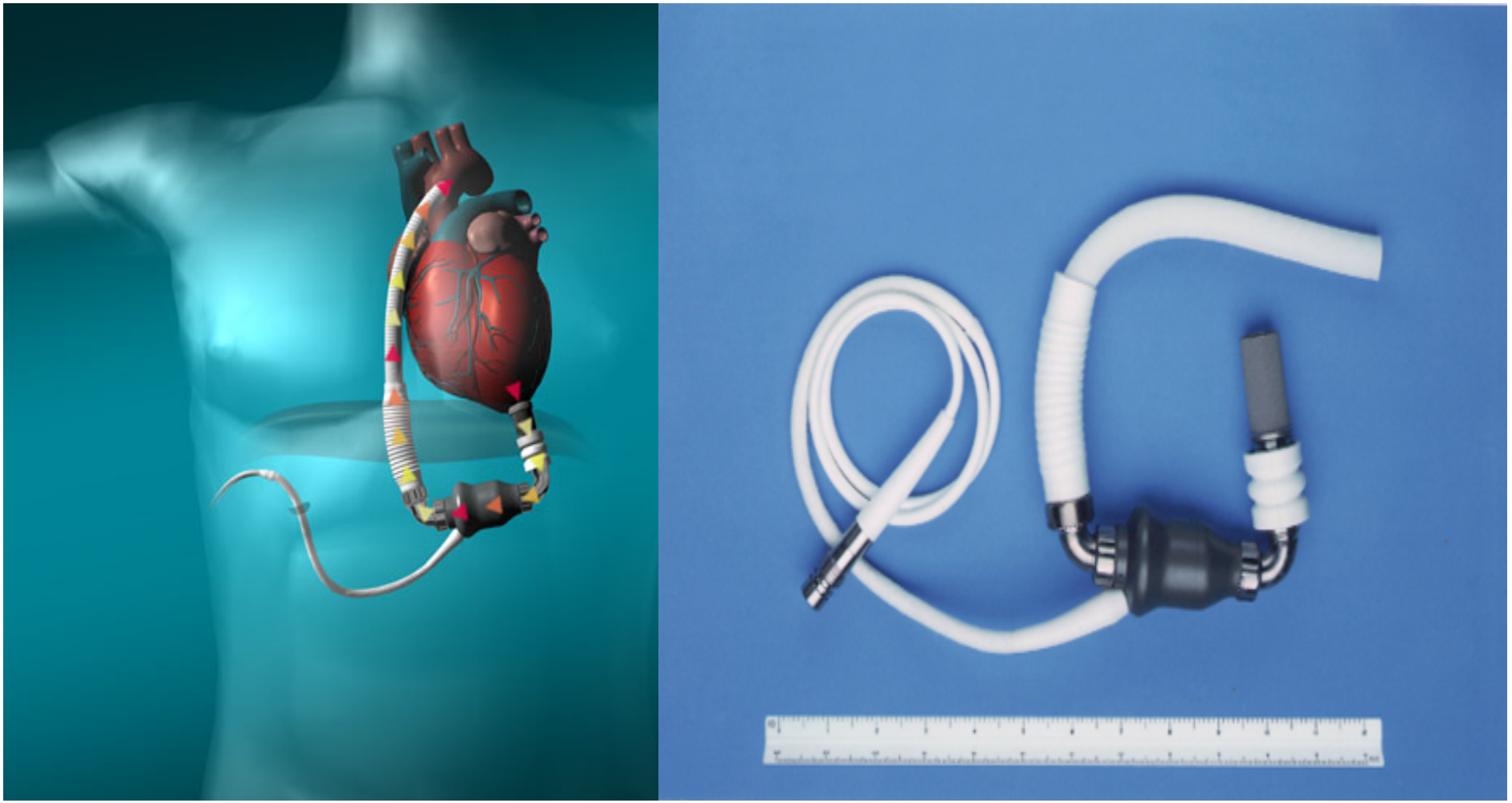
HIRSLANDEN
KLINIK IM PARK

Was ist die Intention ?
Bridge to what ... ?

1. Bridge to decision
2. Bridge to recovery
3. Bridge to bridge
4. Bridge to candidacy
5. Bridge to transplantation
6. Bridge to destination



10 years ago: (Long term VAD, HeartMate II)

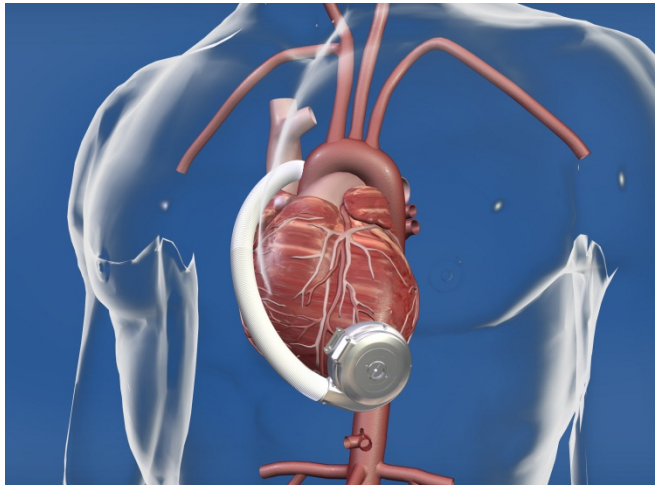


HeartMate® II

8 years ago: (Long term hVAD, HeartWare)

(HeartWare → Medtronic)

The HeartWare® Ventricular Assist System



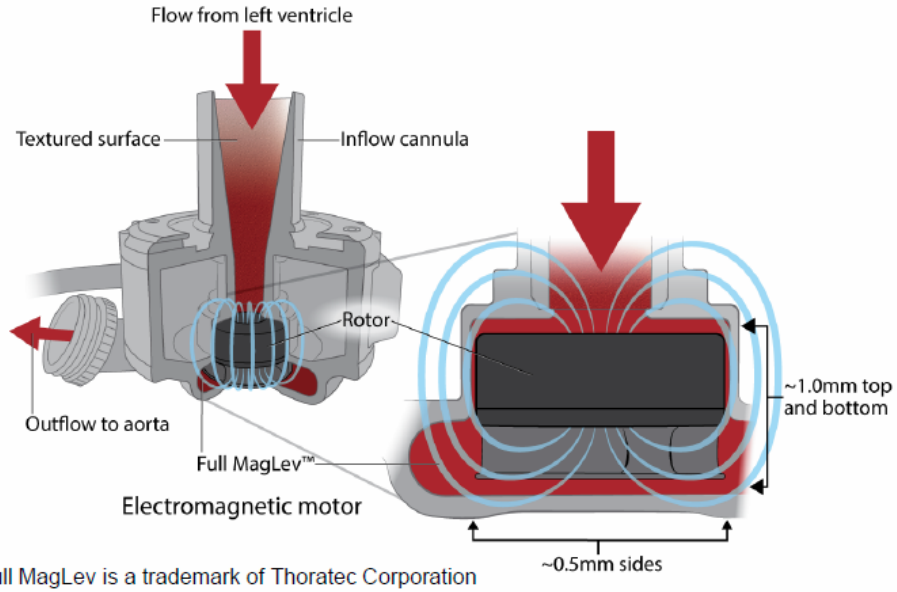
- Miniaturized implantable HVAD® pump
  - 50cc displacement volume
  - 50mm outside diameter
- Up to 10 liters of flow/min
- Hybrid magnetic and hydrodynamic impeller suspension.
  - Wearless blood contacting surface

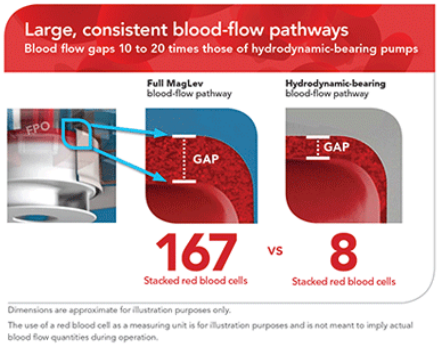
3 years ago: (Long term HM 3, Thoratec)

(Thoratec → SJM → Abbott)

HeartMate 3: Innovative Device Design

- Full MagLev™ Flow Technology
  - Wide range of flow (2-10 L/min)
  - Artificial pulse
  - Larger, consistent pump gaps designed to reduce shear stress





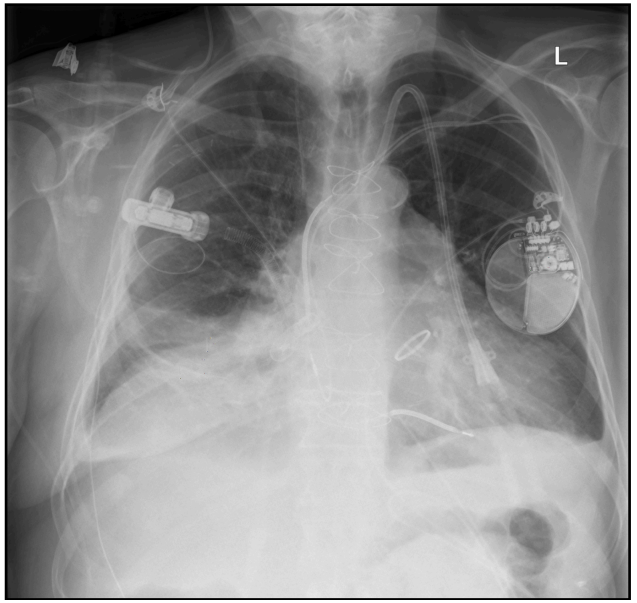
™Full MagLev is a trademark of Thoratec Corporation

HeartMate 3 CE Mark Trial

The Future: (MVAD, “CircuLite”)

MVAD (Medtronic)

CircuLite (Medtronic)



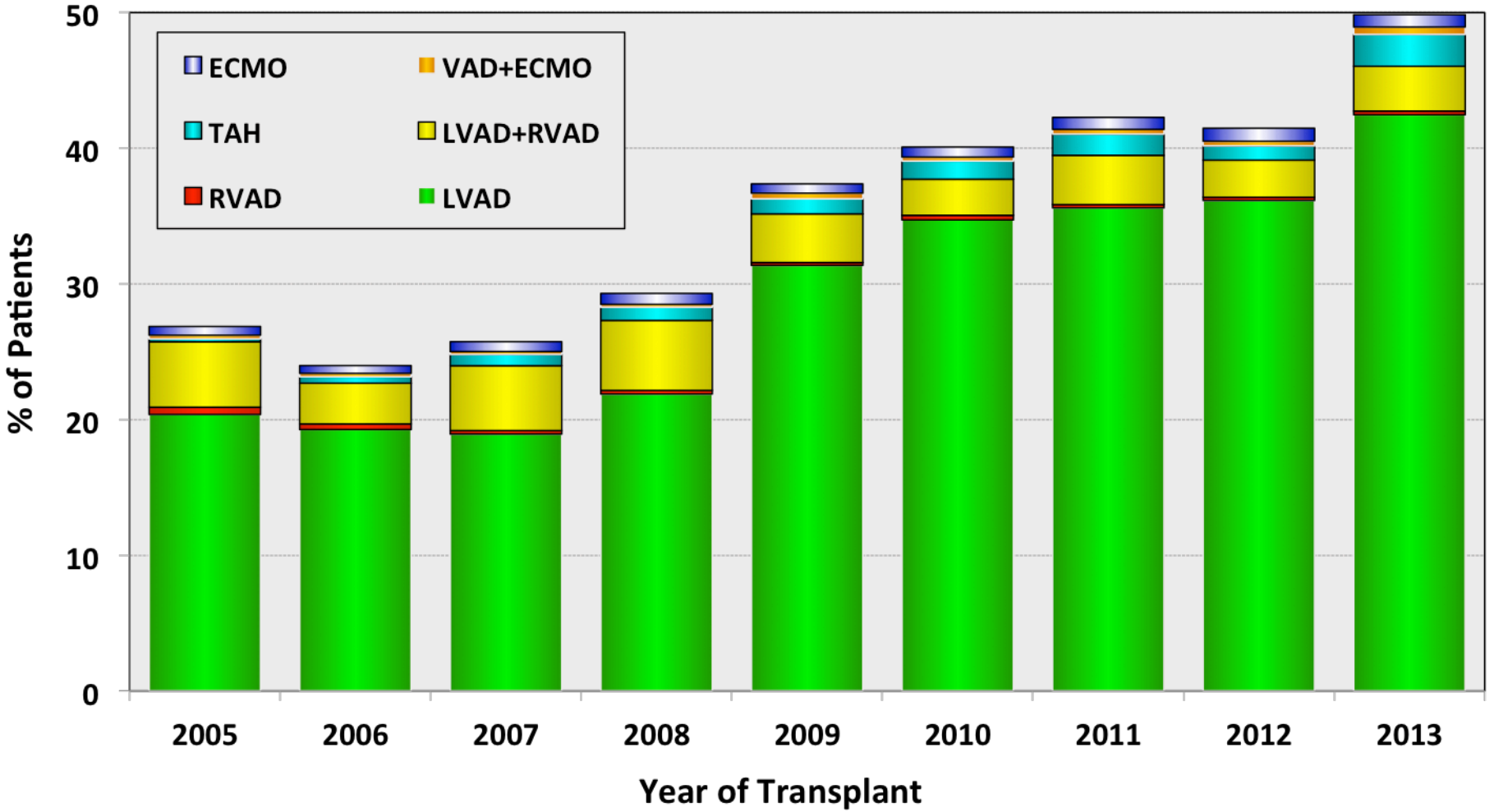
Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

Adult Heart Transplants

% of Patients Bridged with Mechanical Circulatory Support* by Year and Device Type



ISHLT • INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION

* LVAD, RVAD, TAH, ECMO

Themen

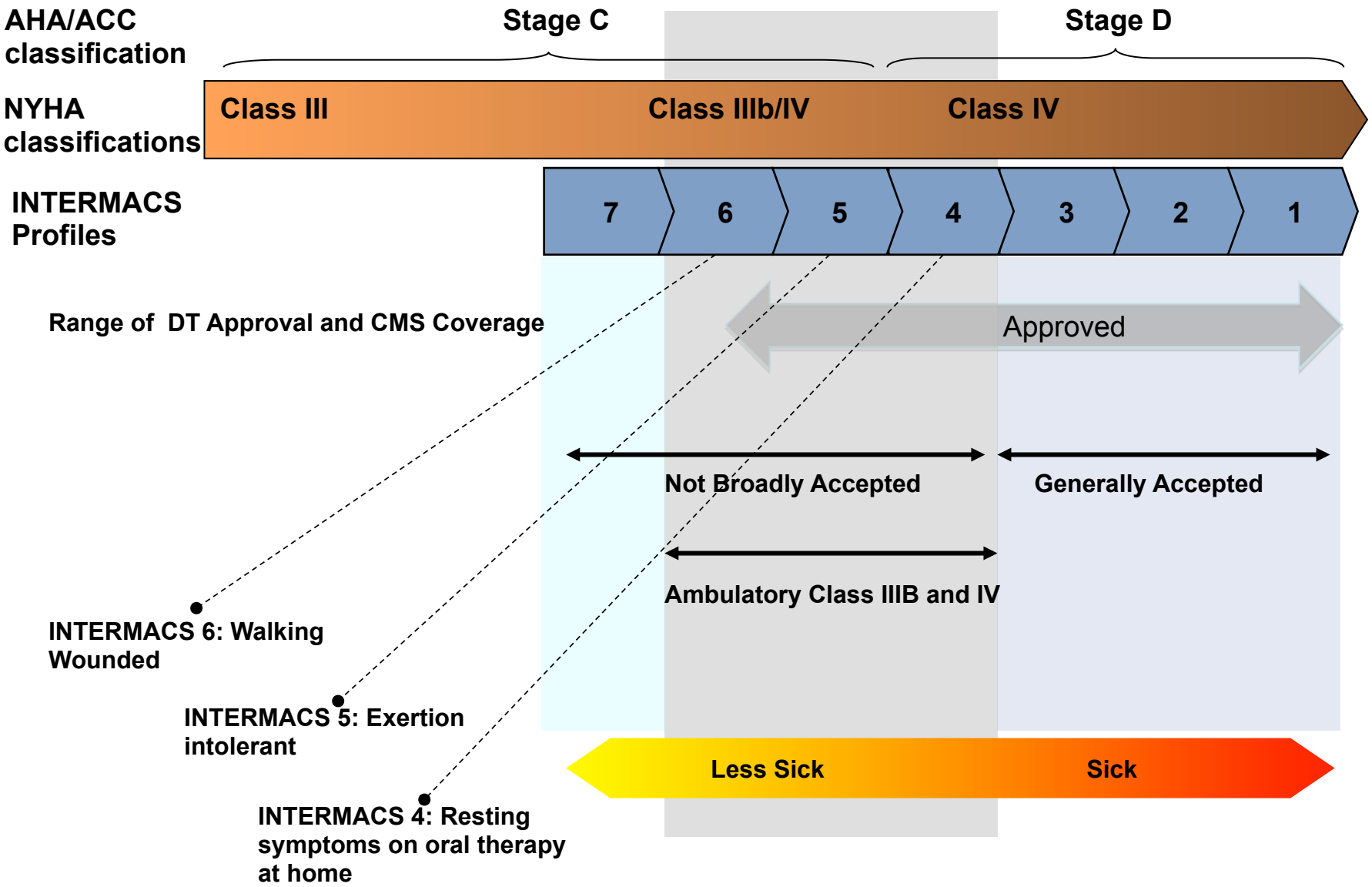
- Zahlen
- Was ist ein Kunstherz ?
- Herzunterstützungspumpen
  Realität vs Experim. Medizin
- Patienten Selektion (terminal)
- Outcome Data

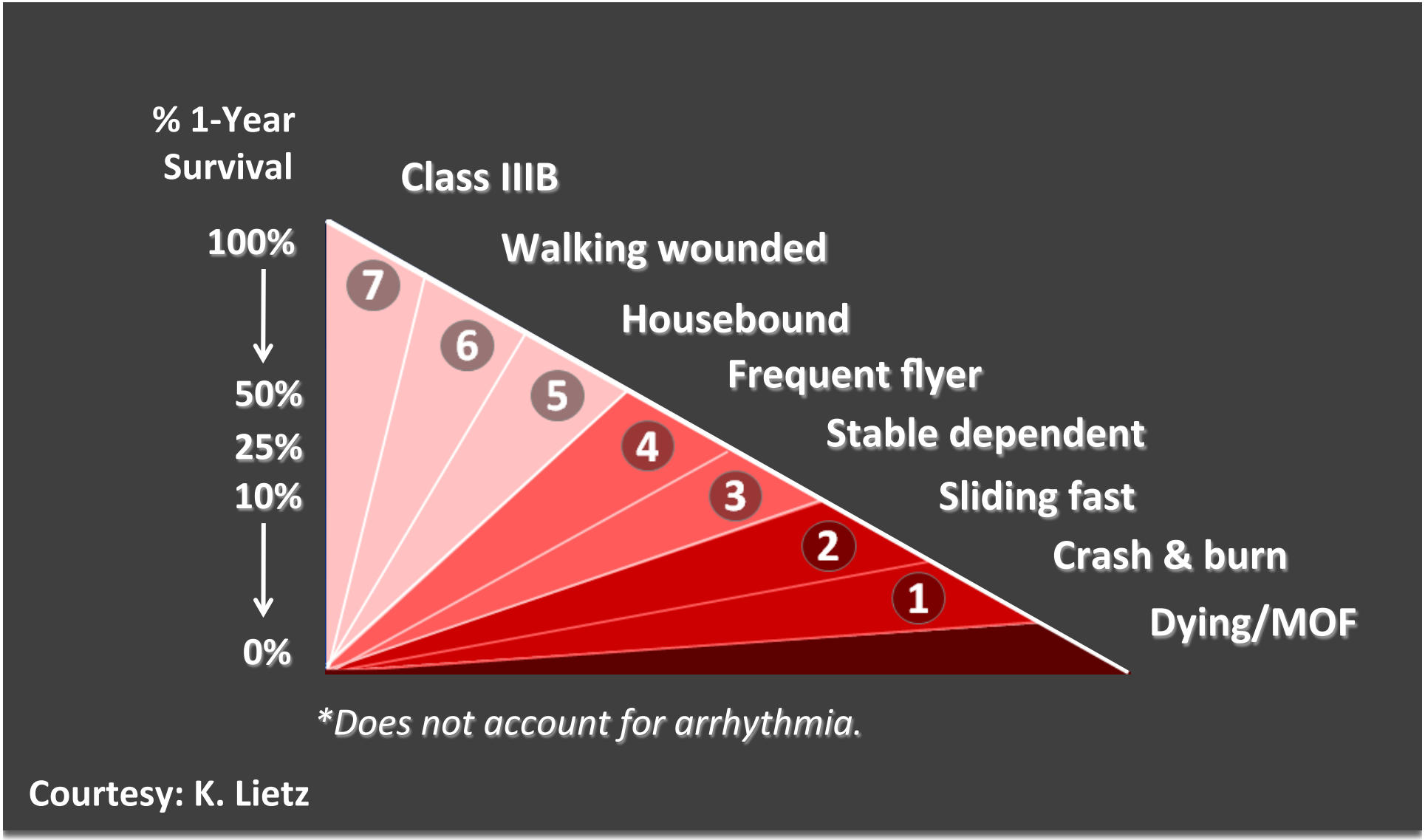
Universitätsspital Basel
Herzzentrum

intermacs

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK




% 1-Year Survival
100%
50%
25%
10%
0%
Class IIIB
7
Walking wounded
6
Housebound
5
Frequent flyer
4
Stable dependent
3
Sliding fast
2
Crash & burn
1
Dying/MOF
*Does not account for arrhythmia.
Courtesy: K. Lietz

ESC / HFA Herzinsuffizienz Guidelines 2012

Recommendations for surgical implantation of LVADs in patients with systolic heart failure

Recommendations	Class[a]	Level[b]	Ref[c]
An LVAD or BiVAD is recommended in selected patients[d] with end-stage HF despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplantation, to improve symptoms and reduce the risk of HF hospitalization for worsening HF and to reduce the risk of premature death while awaiting transplantation.	I	B	254, 255, 258
An LVAD should be considered in highly selected patients[d] who have end-stage HF despite optimal pharmacological and device therapy and who are not suitable for heart transplantation, but are expected to survive >1 year with good functional status, to improve symptoms, and reduce the risk of HF hospitalization and of premature death.	IIa	B	254

BiVAD = bi-ventricular assist device; HF = heart failure; LVAD = left ventricular assist device.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.
[d]See text and *Table 25*.

References
254. Rose EA, et al, NEJM 2001
255. Slaughter MS et al, NEJM 2009
258. Pagani FD, et al, JACC 2009

Table 25 Patients potentially eligible for implantation of a ventricular assist device

Patients with >2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:
• LVEF <25% and, if measured, peak VO_2 < 12 mL/kg/min
• ≥3 HF hospitalizations in previous 12 months without an obvious precipitating cause
• Dependence on i.v. inotropic therapy
• Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP ≥20 mm Hg and SBP ≤80–90 mmHg or CI ≤2 L/min/m²)
• Deteriorating right ventricular function

CI = cardiac index; HF = heart failure; i.v. = intravenous; LVEF = left ventricular ejection fraction; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure.

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich KLINIK IM F | HIRSLANDEN

Indication for LVAD-Implantation

Guidelines 2012

Table 25 Patients potentially eligible for implantation of a ventricular assist device

Patients with >2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:
• LVEF <25% and, if measured, peak VO_2 < 12 mL/kg/min
• ≥3 HF hospitalizations in previous 12 months without an obvious precipitating cause
• Dependence on i.v. inotropic therapy
• Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP ≥20 mm Hg and SBP ≤80–90 mmHg or CI ≤2 L/min/m²)
• Deteriorating right ventricular function

CI = cardiac index; HF = heart failure; i.v. = intravenous; LVEF = left ventricular ejection fraction; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure.

Guidelines 2016

European Heart Journal Advance Access published May 20, 2016
European Heart Journal doi:10.1093/eurheartj/ehw128
ESC GUIDELINES

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Developed with the special contribution of the Heart Failure Association (HFA) of the ESC

Authors/Task Force Members: Piotr Ponikowski* (Chairperson) (Poland),

Table 13.3 Patients potentially eligible for implantation of a left ventricular assist device

Patients with >2 months of severe symptoms despite optimal medical and device therapy and more than one of the following:
LVEF <25% and, if measured, peak VO_2 <12 mL/kg/min.
≥3 HF hospitalizations in previous 12 months without an obvious precipitating cause.
Dependence on i.v. inotropic therapy.
Progressive end-organ dysfunction (worsening renal and/or hepatic function) due to reduced perfusion and not to inadequate ventricular filling pressure (PCWP ≥20 mmHg and SBP ≤80–90 mmHg or CI ≤2 L/min/m²).
Absence of severe right ventricular dysfunction together with severe tricuspid regurgitation.

CI = cardiac index; HF = heart failure; i.v. = intravenous; LVEF = left ventricular ejection fraction; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure; VO_2 = oxygen consumption.

Timing (der richtige Zeitpunkt ?)

1. Reduzierte Nierenfunktion (Cardiorenales Syndrom)
2. Pulmonale Hypertonie (meist sekundär)
3. Reduzierter klinischer Status, siehe INTERMACS „Levels“
4. Kardiale Kachexie (→ protrahierte Reha)
5. Reduzierte RV Funktion (→ zu spät für LVAD)

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich KLINIK IM F | HIRSLANDEN

European Heart Journal Advance Access published May 20, 2016
European Heart Journal doi:10.1093/eurheartj/ehw128
ESC GUIDELINES

Recommendations- and Evidence Levels

Guidelines 2012

Recommendations for surgical implantation of LVADs in patients with systolic heart failure

Recommendations	Class[a]	Level[b]	Ref[c]
An LVAD or BiVAD is recommended in selected patients[d] with end-stage HF despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplantation, to improve symptoms and reduce the risk of HF hospitalization for worsening HF and to reduce the risk of premature death while awaiting transplantation.	I	B	254, 255, 258
An LVAD should be considered in highly selected patients[d] who have end-stage HF despite optimal pharmacological and device therapy and who are not suitable for heart transplantation, but are expected to survive >1 year with good functional status, to improve symptoms, and reduce the risk of HF hospitalization and of premature death.	IIa	B	254

BiVAD = bi-ventricular assist device; HF = heart failure; LVAD = left ventricular assist device.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.
[d]See text and *Table 25*.

Guidelines 2016

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Developed with the special contribution of the Heart Failure Association (HFA) of the ESC

Authors/Task Force Members: Piotr Ponikowski* (Chairperson) (Poland),

Recommendations for implantation of mechanical circulatory support in patients with refractory heart failure

Recommendations	Class[a]	Level[b]	Ref[c]
An LVAD should be considered in patients who have end- stage HFrEF despite optimal medical and device therapy and who are eligible for heart transplantation in order to improve symptoms, reduce the risk of HF hospitalization and the risk of premature death (Bridge to transplant indication).	IIa	C	
An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are not eligible for heart transplantation to, reduce the risk of premature death.	IIa	B	605, 612, 613

HF = heart failure; HFrEF = heart failure with reduced ejection fraction; LVAD = left ventricular assist device.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting levels of evidence.

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

(*Circulation*. 1997;95:2660-2667.)

Articles

Development and Prospective Validation of a Clinical Index to Predict Survival in Ambulatory Patients Referred for Cardiac Transplant Evaluation

Keith D. Aaronson, MD, MS; J. Sanford Schwartz, MD; Tze-Ming Chen, BS; Kar-Lai Wong, MD; James E. Goin, PhD; Donna M. Mancini, MD

From the Division of Circulatory Physiology, Heart Failure and Cardiac Transplant Programs, College of Physicians and Surgeons, Columbia University (K.D.A., D.M.M.), New York, NY, and the Division of General Medicine and the Leonard Davis Institute for Health Economics (J.S.S.), University of Pennsylvania School of Medicine (J.S.S., T.-M.C., K.-L.W., J.E.G.), Philadelphia.

Correspondence to Dr Keith D. Aaronson, Division of Cardiology, University of Michigan Medical Center, Taubman 3910, Ann Arbor, MI 48109-0366. E-mail keith@umich.edu

Aaronson KD, Mancini DM. Circulation 1997; 95: 2660

Heart Failure Survival Score

CAD (y=1,n=0) x -0.6931

HR at rest x -0.0216

LVEF (%) x 0.0464

MAP x 0.0255

QRS > 0.12sec (y=1,n=0) x -0.6083

pO2max (ml/kg/min) x 0.0546

Na (mmol/l) x 0.047.

Heart Failure Survival Score

CAD (y=1,n=0) x -0.6931

HR at rest x -0.0216

LVEF (%) x 0.0464

MAP x 0.0255

QRS > 0.12sec (y=1,n=0) x -0.6083

pO2max (ml/kg/min) x 0.0546

Na (mmol/l) x 0.047.

Apps: -> Mediquations -> HFSS

HFSS = CAD (y=1,n=0) x -0.6931 + HR at rest x -0.0216 + LVEF (%) x 0.0464 + MAP x 0.0255 + QRS > 0.12sec (y=1,n=0) x -0.6083 + pO2max (ml/kg/min) x 0.0546 + Na (mmol/l) x 0.047. (R. Gamma et al, 2003)

	Low risk	medium risk	high risk
patients (n)	67	31	18
observation time (years)	2.45	1.27	0.66
alive n (%)	45 (67%)	11 (35.5%)	1 (6%)
HTX	13 (20%)	15 (48%)	11 (61%)
dead	9 (13%)	5 (16.5%)	6 (33%)
mean HFSS	9.23	7.72	6.75

HFSS = 8.1-10.5 (low risk), 7.2-8.1 (med.risk), 5.8-7.2 high risk

Heart Failure Survival Score

CAD (y=1,n=0) x -0.6931

HR at rest x -0.0216

LVEF (%) x 0.0464

MAP x 0.0255

QRS > 0.12sec (y=1,n=0) x -0.6083

pO2max (ml/kg/min) x 0.0546

Na (mmol/l) x 0.047.

ohne ICD !
ohne BNP !

Apps: -> Mediquations -> HFSS

Aminoterminal pro Type B Natriuretic Peptide as a Predictive and Prognostic Marker in Patients With Chronic Heart Failure

Markus Rothenburger, MD,[a] Thomas Wichter, MD,[b] Christof Schmid, MD,[a] Jörg Stypmann, MD,[b] Tonny D. T. Tjan, MD,[a] Elmar Berendes, MD,[c] Christian Etz, MD,[a] Aurélien Pioux, MD,[d] Andreas Löher, MD,[a] Frauke Wenzelburger, MD,[a] Gabriele Drees, MD,[a] Andreas Hoffmeier, MD,[a] Günter Breithardt, MD,[b] and Hans Heinrich Scheld, MD[a]

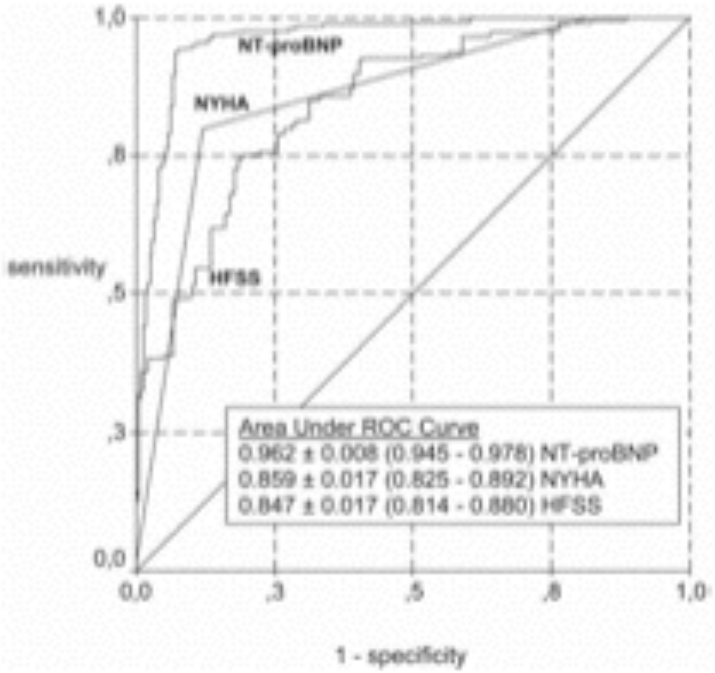


Figure 4. Receiver operating characteristic (ROC) curves for the sensitivity and specificity of NT-proBNP, Heart Failure Survival Score (HFSS), and New York Heart Association (NYHA) class and assignment to heart transplantation; ($p < 0.001$ for all pairwise comparisons of area under ROC curve). BNP, B-type natriuretic peptide.

N = 550 pts

J Heart Lung Transplant 2004

The Seattle Heart Failure Model

Prediction of Survival in Heart Failure

Wayne C. Levy, MD; Dariush Mozaffarian, MD, MPH; David T. Linker, MD; Santosh C. Sutradhar, PhD; Stefan D. Anker, MD; Anne B. Cropp, PharmD; Inder Anand, MD; Aldo Maggioni, MD; Paul Burton, MBBS, PhD; Mark D. Sullivan, MD, PhD; Bertram Pitt, MD; Philip A. Poole-Wilson, MD; Douglas L. Mann, MD; Milton Packer, MD

Circulation 2006

Derived in a cohort N = 1125 CHF pts

Prospectively validated in 5 additional cohorts of total 9942 pts

Purpose: Multivariate risk model to predict 1, 2, and 3 yr mortality

PRAISE (amlodipine, 1153 pts, EF<30%, NYHA IIIB-IV

ELITE 2 (captopril vs losartan, 3152 pts, EF≤40%, age > 60yrs, NYHA II-IV

ValHeFT (valsartan vs PBO, 5010 pts, EF≤40%, NYHA II-IV

UW (prospective cohort study of 148 consecutive outpts)

RENAISSANCE (enbrel, 925 pts, EF≤30%, NYHA II-IV)

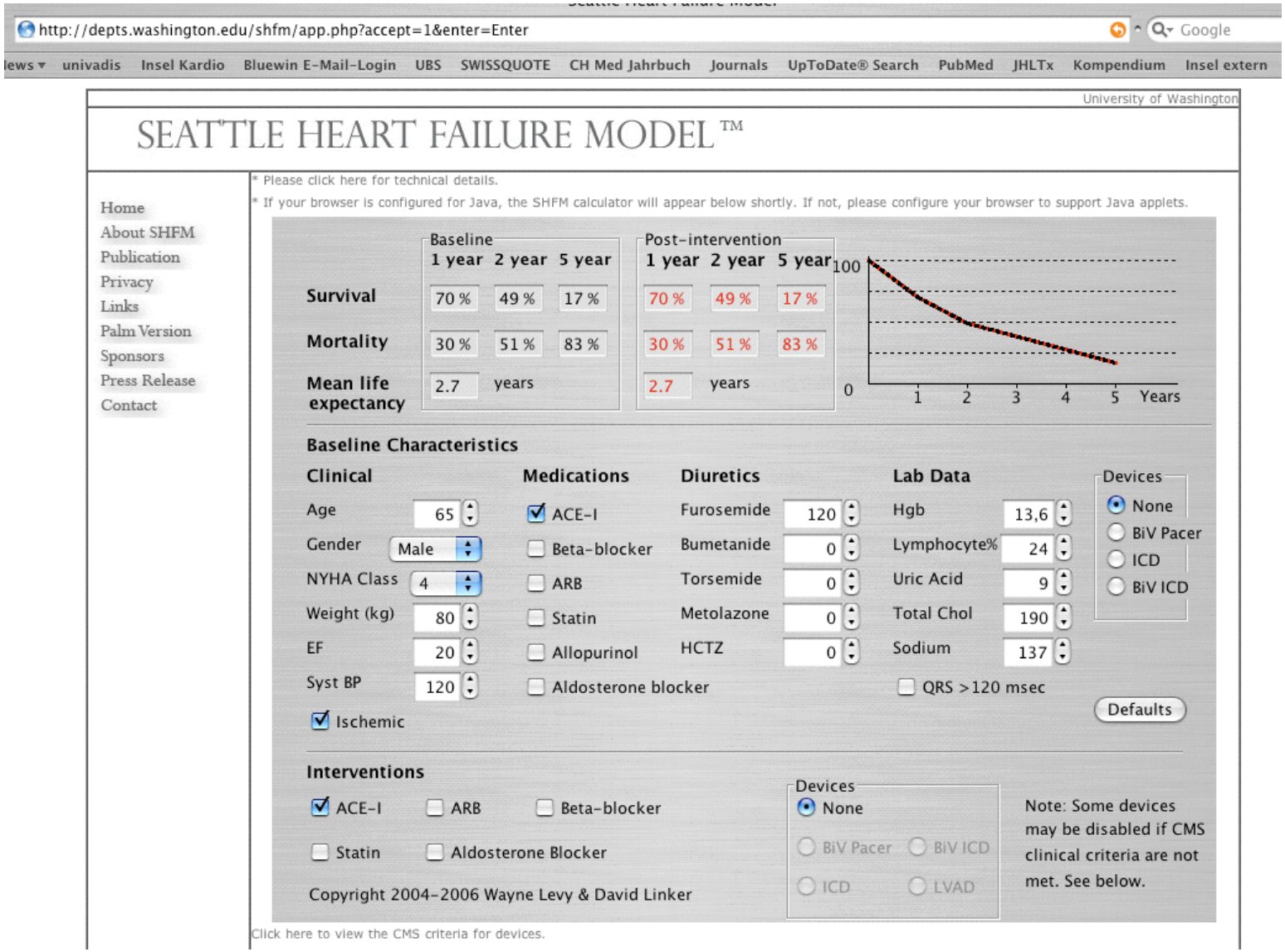
IN-CHF (Registry, 872 pts, EF 35±11%, NYHA I-II)

Universitätsspital Basel
Herzzentrum

www.SeattleHeartFailureModel.org

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

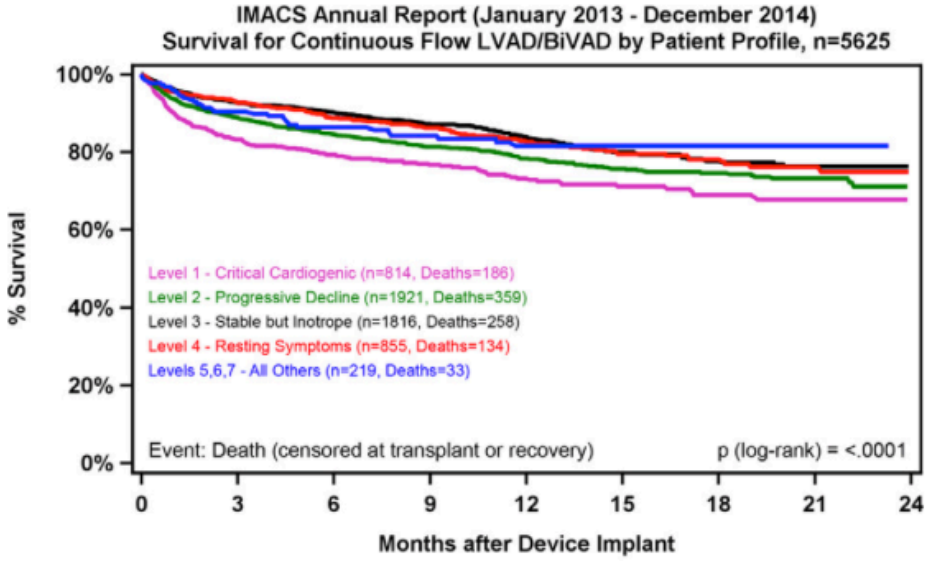


Levy W, et al. The Seattle Heart Failure Model: Prediction of Survival in Heart Failure. Circulation 2006; 113: 1424

Themen

- Zahlen
- Was ist ein Kunstherz ?
- Herzunterstützungspumpen
  Realität vs Experim. Medizin
- Patienten Selektion
- Outcome Data

Outcome und Zeitpunkt der VAD - Implantation



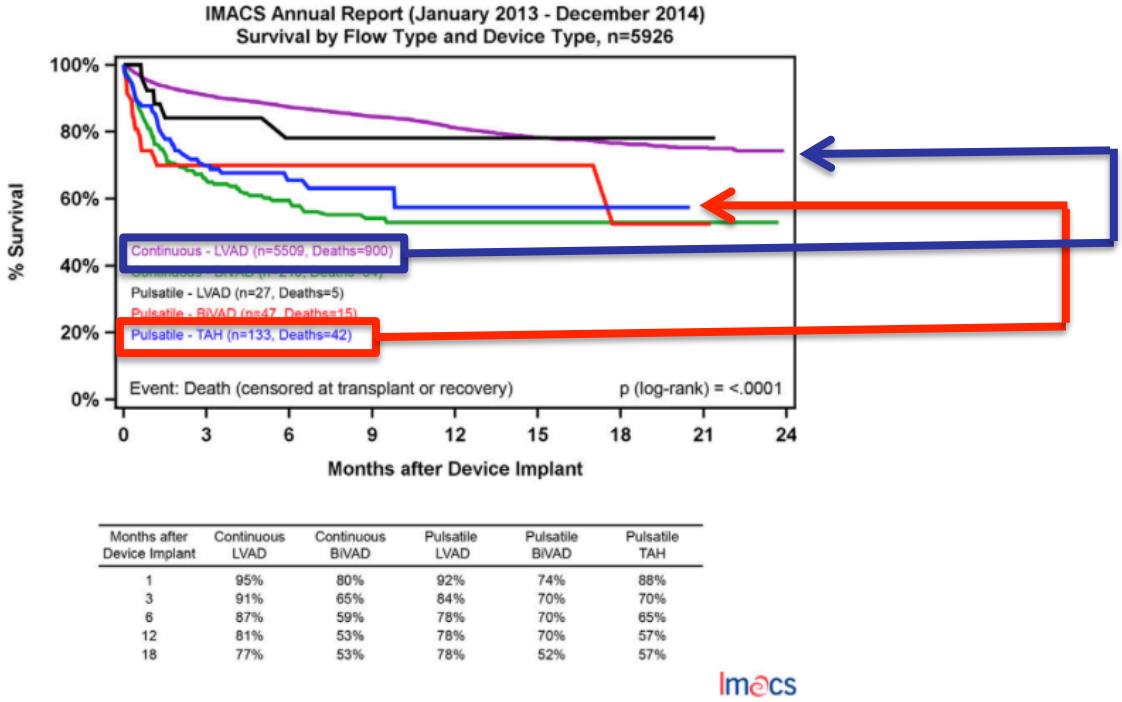
Months after Device Implant	1 - Critical Cardiogenic	2 - Progress Decline	3 - Stable but Inotrope	4 - Resting Symptoms	5,6,7 - All Others
1	90%	94%	96%	96%	96%
3	83%	89%	93%	93%	90%
6	79%	85%	90%	89%	86%
12	73%	78%	84%	83%	82%
18	69%	75%	78%	78%	82%

Imacs

Figure 4 Actuarial survival for patients in the International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support (IMACS) registry receiving continuous-flow pumps, stratified by patient profile at implant. BiVAD, biventricular assist device; LVAD, left ventricular assist device.

1st Annual IMACS Report. JHLTx 2016
http://dx.doi.org/10.1016/j.healun.2016.01.002

Survival after MCS



Months after Device Implant	Continuous LVAD	Continuous BiVAD	Pulsatile LVAD	Pulsatile BiVAD	Pulsatile TAH
1	95%	80%	92%	74%	88%
3	91%	65%	84%	70%	70%
6	87%	59%	78%	70%	65%
12	81%	53%	78%	70%	57%
18	77%	53%	78%	52%	57%

Imacs

Figure 2 Actuarial survival for patients in the International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support (IMACS) registry stratified by type of device. BiVAD, biventricular assist device; LVAD, left ventricular assist device; TAH, total artificial heart.

1st Annual IMACS Report. JHLTx 2016
http://dx.doi.org/10.1016/j.healun.2016.01.002

Universitätsspital Basel
Herzzentrum

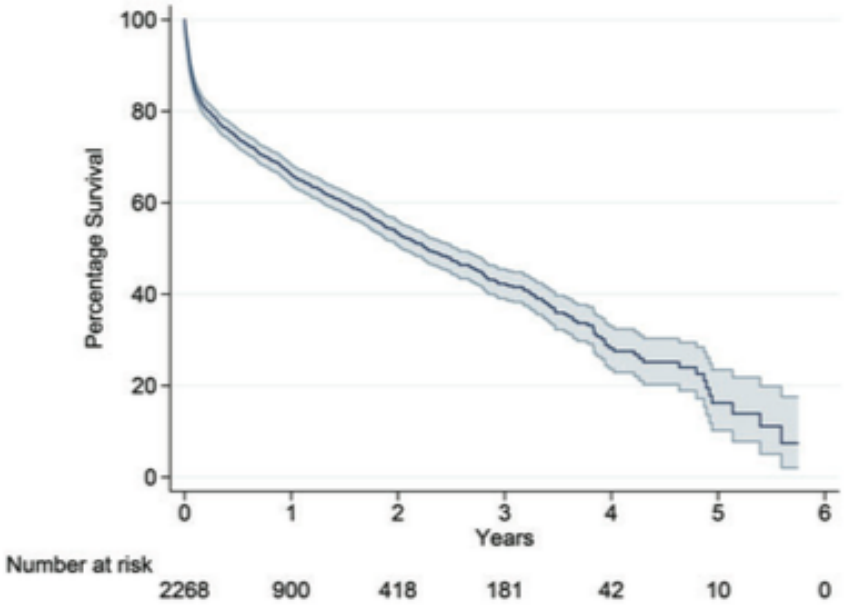
HerzGefässZentrum Zürich KLINIK IM PARK | HIRSLANDEN KLINIK IM PARK

Survival after MCS

The European Registry for Patients with Mechanical Circulatory Support (EUROMACS) of the European Association for Cardio-Thoracic Surgery (EACTS): second report

Theo M.M.H. de By[a,*,†], Paul Mohacsi[b,*,†], Brigitta Gahl[b], Armin Zittermann[c], Thomas Krabatsch[d], Finn Gustafsson[e], Pascal Leprince[f], Bart Meyns[g], Ivan Netuka[h], Kadir Caliskan[i], Evaristo Castedo[j], Francesco Musumeci[k], André Vincentelli[l], Roland Hetzer[m] and Jan Gummert[c], on behalf of the EUROMACS members

European Journal of Cardio-Thoracic Surgery 0 (2017) 1–8
doi:10.1093/ejcts/ezx320



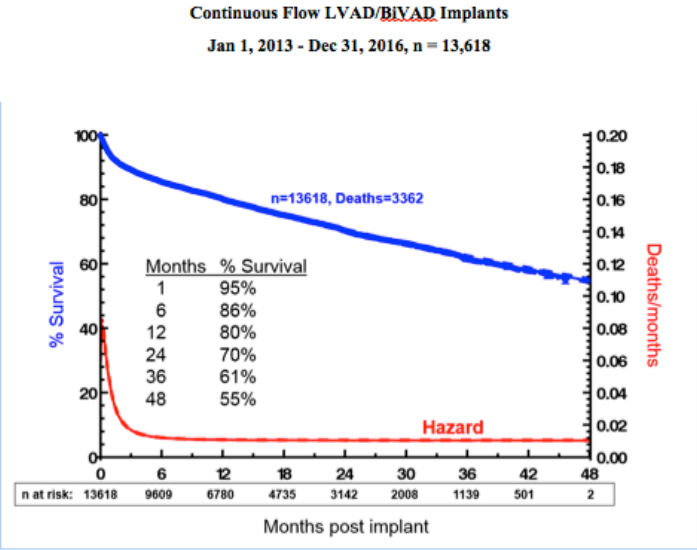
EUROMACS 2nd report. Eur J Cardiothoracic Surg 2017

Second annual report from the ISHLT Mechanically Assisted Circulatory Support Registry.

Kirklin JK, Xie R, Cowger J, de By TMMH, Nakatani T, Schueler S, Taylor R, Lannon J, **Mohacsi P**, Gummert J, Goldstein D, Caliskan K, Hannan MM.

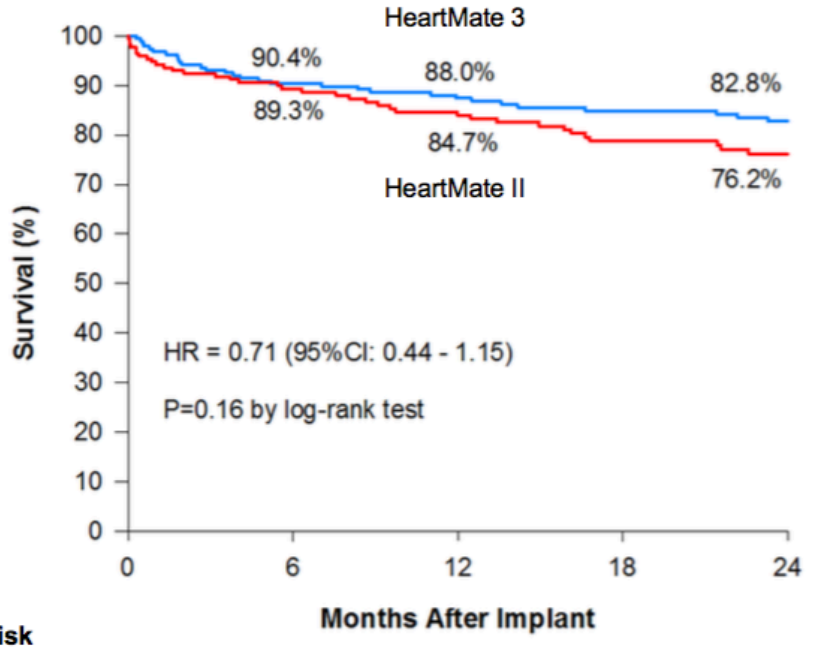
J Heart Lung Transplant. 2018 Jan 31. pii: S1053-2498(18)31295-6. doi: 10.1016/j.healun.2018.01.1294. [Epub ahead of print]

Figure 1. Parametric survival curve and associated hazard function with the 70% confidence limit for survival after implantation of a continuous-flow left ventricular assist device (LVAD) or biventricular assist device (BiVAD), Jan 1, 2013-Dec 31, 2016, n=13,618. The number of patients at risk during each time interval is indicated below the diagram.



2nd imacs-Report. JHLTx 2018

Primary Endpoint Component 1
Overall Survival



No. at Risk					
HeartMate 3	189	165	146	127	117
HeartMate II	172	141	121	98	86

MOMENTUM 3

HR denotes hazard ratio; CI, confidence interval

Adverse Events of MCS

Table 10: Major adverse event rates

	Within 3 months after implant		More than 3 months after implant	
	Event counts	Events per 100 patient-months (CI)	Event counts	Events per 100 patient-months (CI)
Device malfunction	120	3.56 (2.96–4.26)	334	2.88 (2.58–3.21)
Major bleeding	217	6.45 (5.62–7.36)	216	1.86 (1.62–2.13)
Major infection	208	6.18 (5.37–7.08)	637	5.49 (5.08–5.94)
Neurological event	102	3.03 (2.47–3.68)	217	1.87 (1.63–2.14)

CI: confidence interval.

EUROMACS 2nd Report

European Journal of Cardio-Thoracic Surgery 0 (2017) 1–8
doi:10.1093/ejcts/ezx320

Table 6 Major Adverse Events, Continuous-flow LVAD/BiVAD, IMACS, January 1, 2013 to December 31, 2016 (n = 13,618)

Adverse event type	Patient experiencing event	Percentage of all patients
Infection	5,439	40%
Bleeding	4,745	35%
Neurologic dysfunction	2,638	19%
Respiratory failure	2,205	16%
Device malfunction	233	2%
Arterial non-CNS thromboembolism	159	1%

BiVAD, biventricular assist device; CNS, central nervous system; IMACS, International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support; LVAD, left ventricular assist device.

IMACS 2nd Report

1053-2498/
https://doi.org/10.1016/j.healun.2018.01.1294

Bridge-to-Transplant (BtT): the European Perspective

Table 7: Device strategy at the time of implantation, stratified by age categories, *n* (%)

Strategy	<50 years	50–64 years	65–70 years	>70 years	Total
Bridge to recovery	24 (2)	28 (2)	3 (1)	2 (1)	57 (2)
Bridge to candidacy	402 (42)	568 (39)	60 (18)	22 (12)	1052 (36)
Bridge to transplant	332 (34)	414 (28)	48 (14)	19 (10)	813 (28)
Destination therapy	22 (2)	170 (12)	157 (47)	109 (60)	458 (16)
Rescue therapy	68 (7)	105 (7)	19 (6)	18 (10)	210 (7)
Other	4 (0)	5 (0)	2 (1)	0 (0)	11 (0)
Unknown	112 (12)	176 (12)	45 (13)	13 (7)	346 (12)
Total	964	1466	334	183	2947

EUROMACS 2nd report. Eur J Cardiothoracic Surg 2017

Kirklin et al. Second IMACS Report

Table 4 Device Strategy, IMACS, January 1, 2013 to December 31, 2016 ($n = 14{,}062$)

Device strategy	N	%
Listed for transplant	3,984	28%
Bridge to candidacy	4,072	29%
Destination therapy	5,724	41%
Other	282	2%
Total	14,062	100%

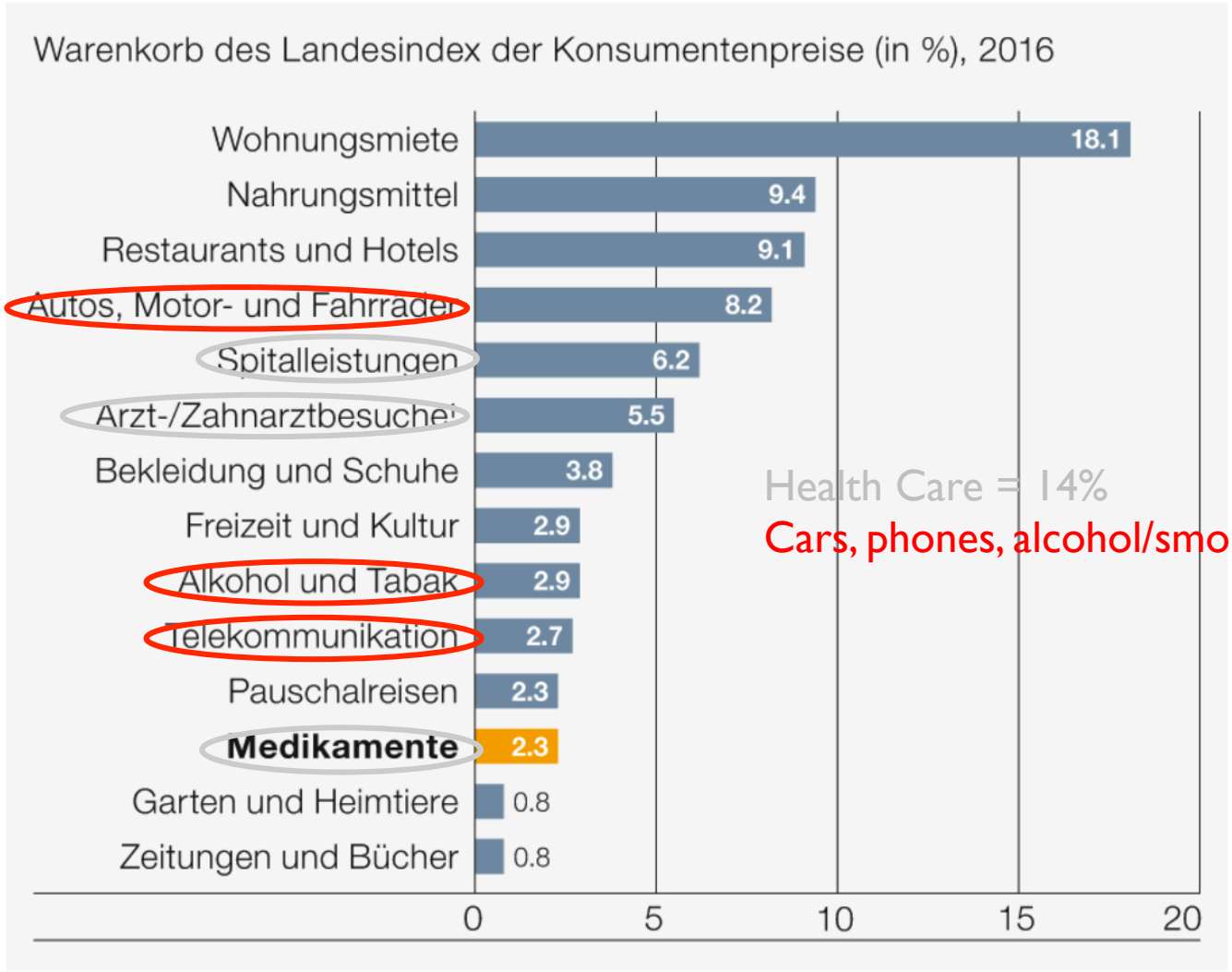
IMACS, International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support.

2nd imacs-Report. JHLTx 2018

Tailored Algorithm (HTx or VAD)

1) Patient data (e.g. blood group, BW)
2) EuroScore
3) Strategy „BtC“
4) Donor availabilty
5) MCS outcome data
6) Local Issues
7) Financial issues
8) Legal aspects

Ausgabenstruktur der Schweizer Haushalte



Health Care = 14%

Cars, phones, alcohol/smoking = 13.8%

Quelle: Landesindex der Konsumentenpreise, Gewichtung 2016, Bundesamt für Statistik, 2016.

[1] Ambulante Leistungen (ohne Spital ambulant), ohne Medikamente.

http://www.interpharma.ch/fakten-statistiken/1868-ausgaben-fuer-medikamente-tiefer-als-fuers-telefonieren

Universitätsspital Basel
Herzzentrum

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
KLINIK IM PARK

The World`s Priorities
(Annual Expenditure in Billions (US$)

Basic Education for all	6
Cosmetics in the US	8
Safe water and sanitation for all	9
Ice cream in Europe	11
Reproductive health for all women	12
Perfume in Europe and US	12
Basic health and nutrition	13
Pet food in Europe and US	17
Business entertainment in Japan	35
Cigarettes in Europe	50
Alcoholic drinks in Europe	105
Narcotic drugs in the world	400
Military spending in the world	780

Source: Human Development Report, 1998

ZUSAMMENFASSUNG

Mechanische Kreislaufunterstützung ist heute klinischer Alltag

Die Erfolge der Forschung & Entwicklung der VAD Technologie ist eindrücklich.

Die Zuweisungspraxis lässt zu wünschen übrig. Die Herzinsuffizienz wird in der CH auch heute noch oft nicht adäquat behandelt.

Potentielle KandidatInnen für ein VAD-Therapie werden oft zuerst anderweitig voll „durchtherapiert“, (zu späte Zuweisung: cave RV!)

Es besteht die falsche Wahrnehmung, die VAD-Therapie sei immer noch „ultima ratio“ (Experimentalmedizin) und zu teuer (siehe z.B. Vergleich mit der Onkologie).