UNIVERSITÄTS
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HERZZENTRUM

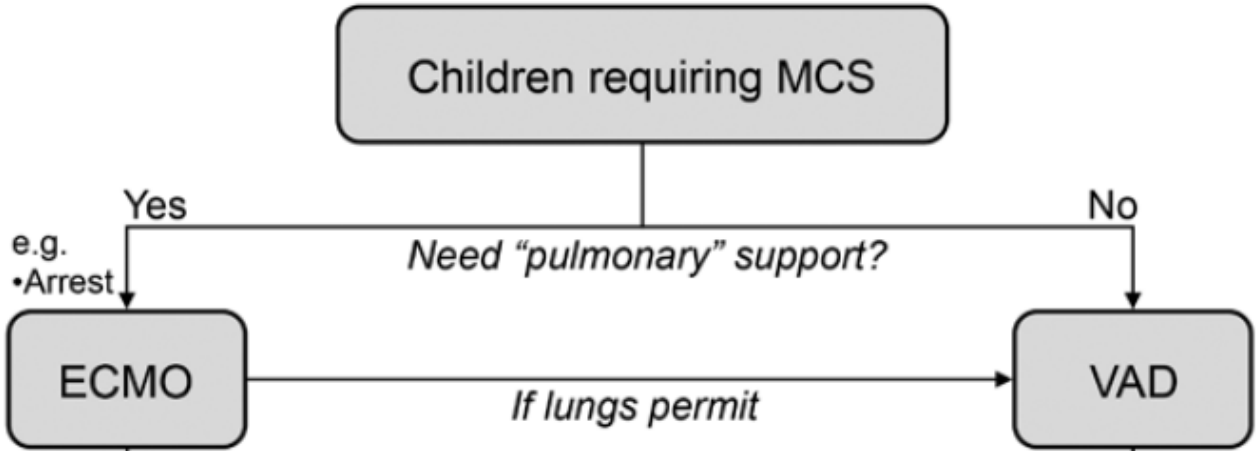
Pediatric heart replacement-2016

Brigitte Stiller

Heart Center Freiburg University, Germany

Bern, 24.-25.6.2016
3rd European Training Symposium (ETS) for HF cardiologists and cardiac surgeons

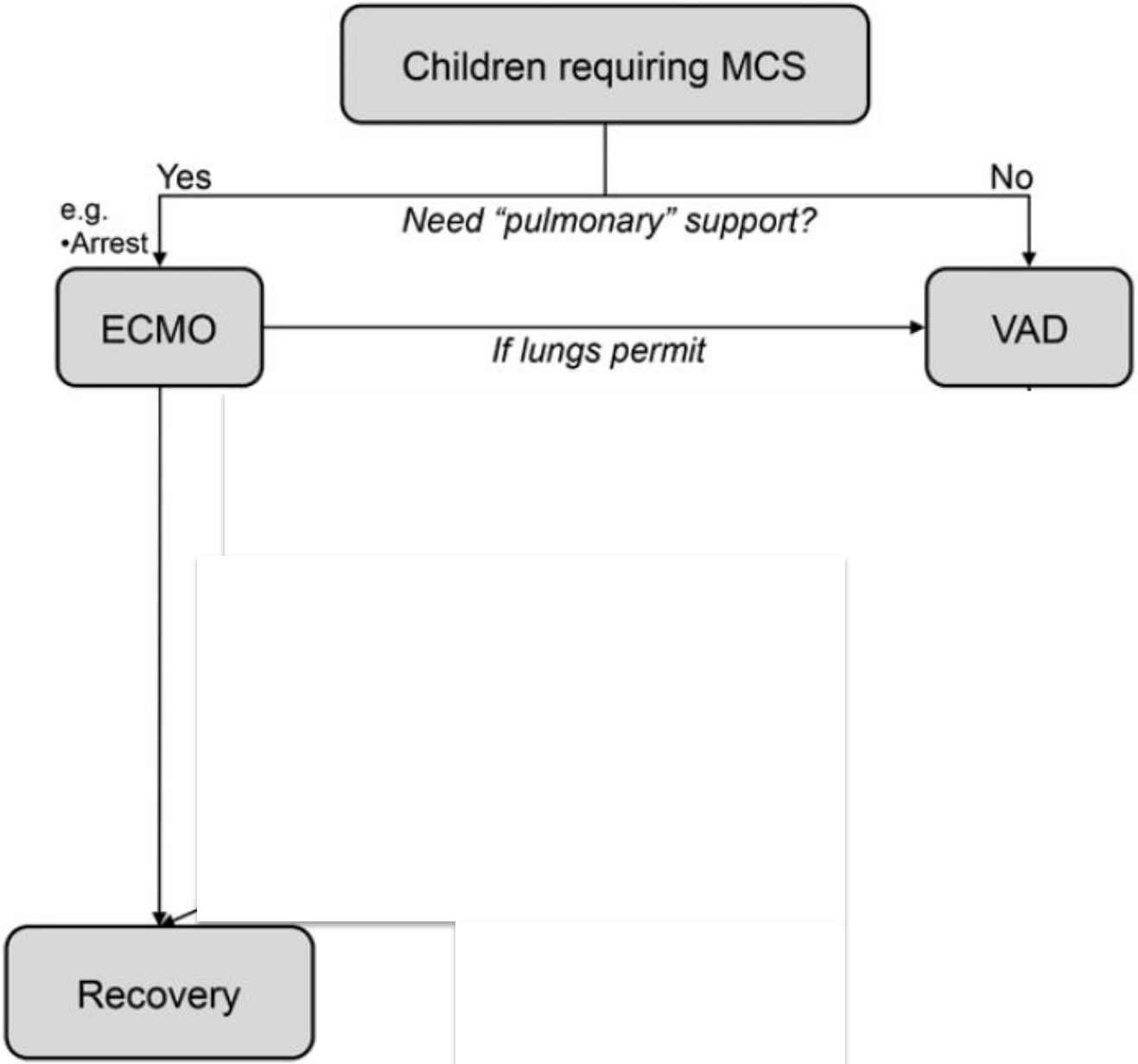
ECMO or VAD …….. Patient + Device Selection



The ECMO circuit is associated with a higher rate of complications compared to VAD circuits.

In case of preserved lung function choose a VAD as the more simple circuit to prevent complications.

ECMO or VAD …….. Patient + Device Selection



Stiller B et al,
PedCritCare 2013

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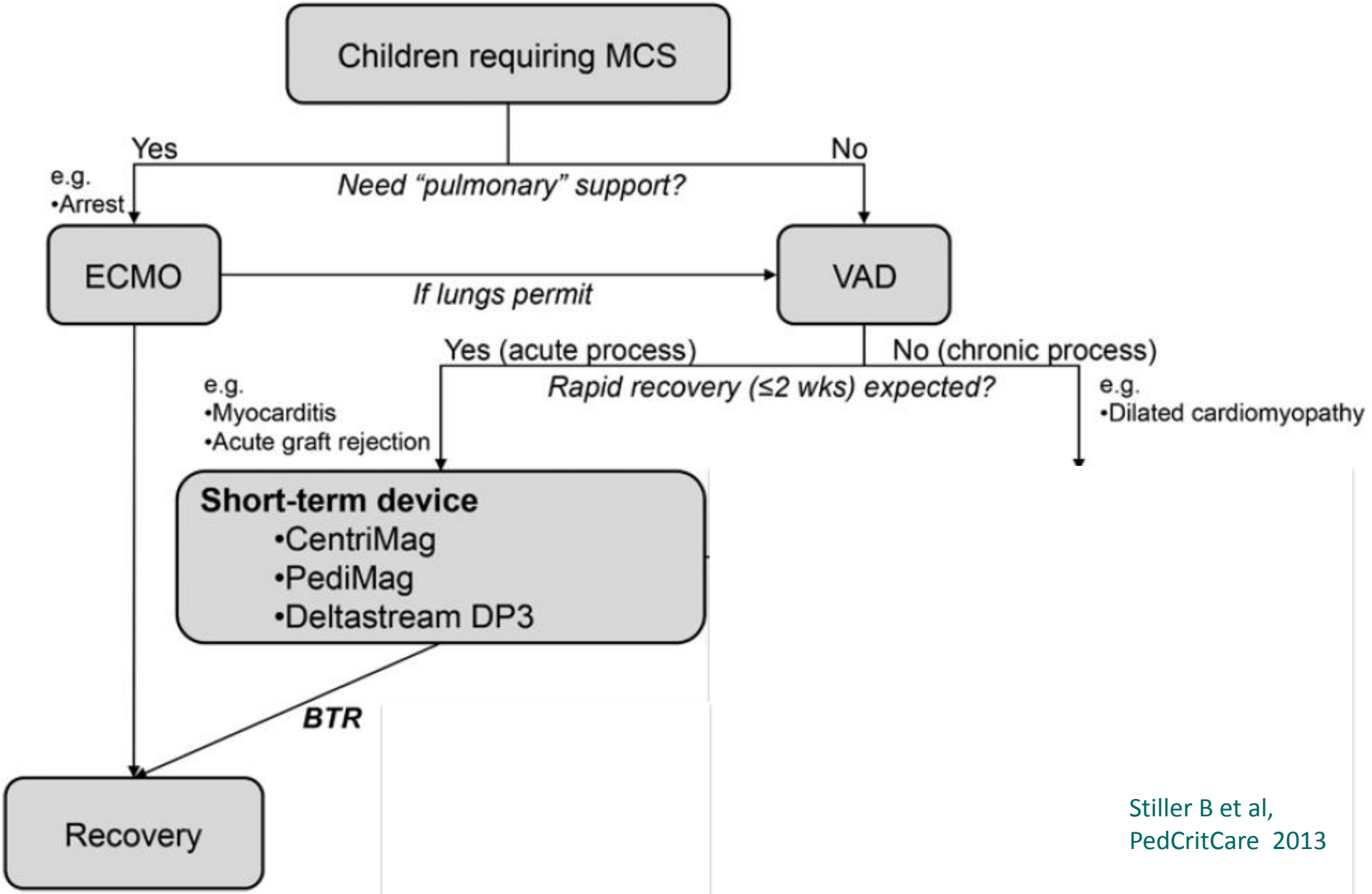

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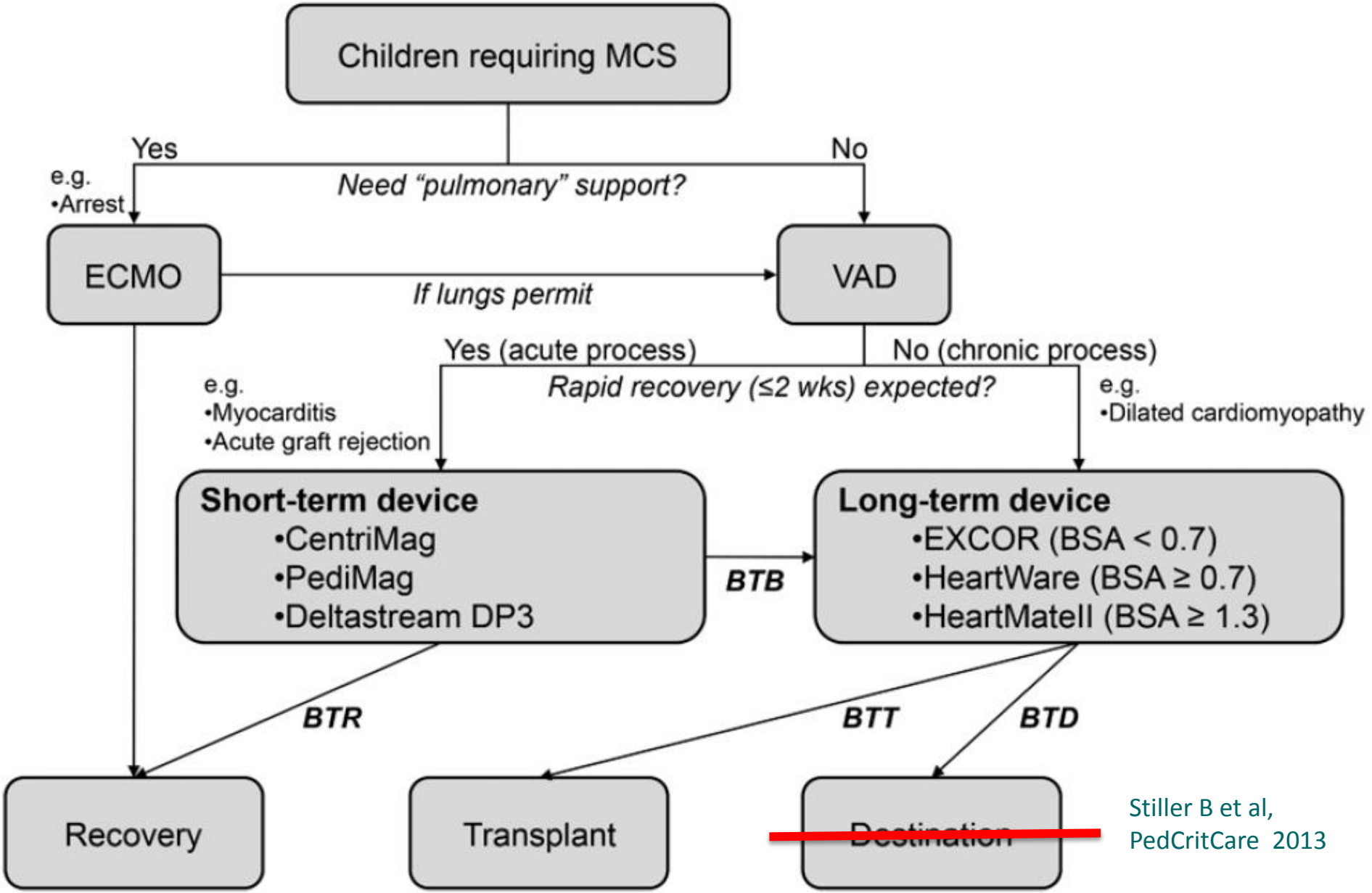

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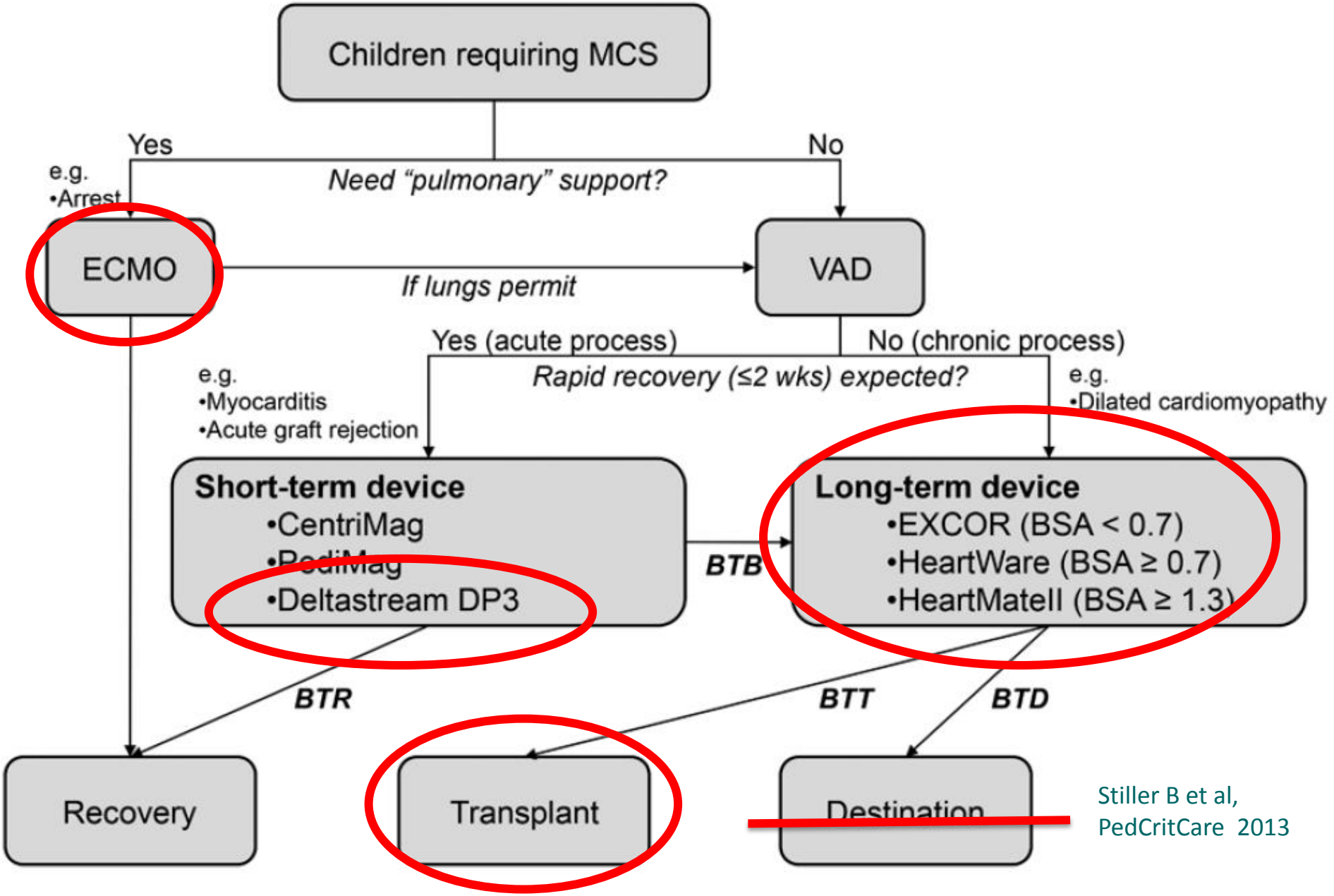


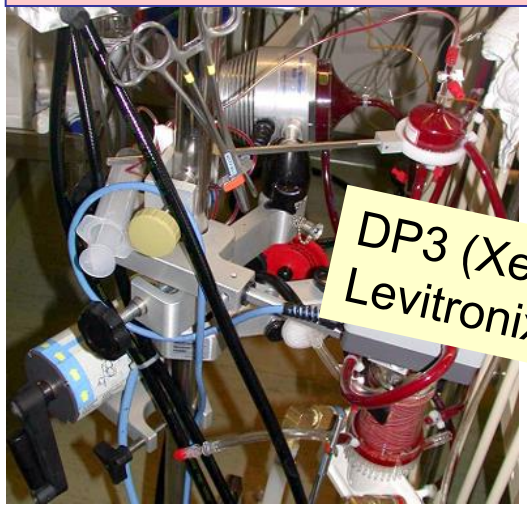
Stiller B et al, PedCritCare 2013

Heart replacement therapies for children

ECMO / ECLS

= modified and trans-portable CPB.

Permits diagnostics, treatment and recovery during severe cardiac and / or pulmonary failure.



DP3 (Xenios)
Levitronix PediVAS

Centrifugal or axial pumps

extracorp.

= uni- or bi ventr. heart support for up to 30 d

Pulsatile VADs

paracorporal

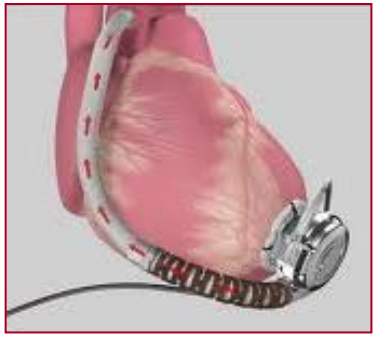
= pneumatic driven pump for uni- or bi ventricular long term heart support

BerlinHeartEXCOR

Centrif. Pump

intracorporal

children > 20 kgBW



Heartware
Heart mate II

Heart replacement therapies for children

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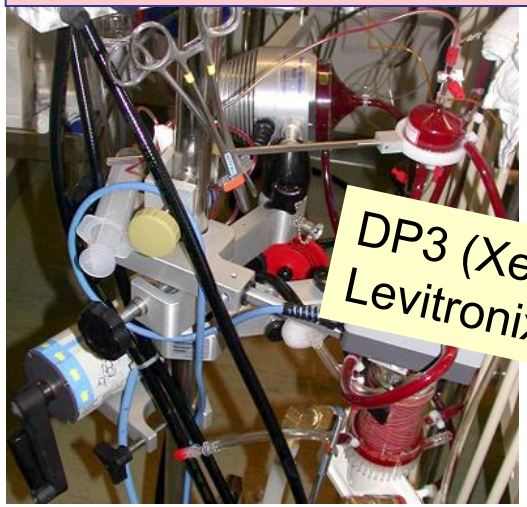

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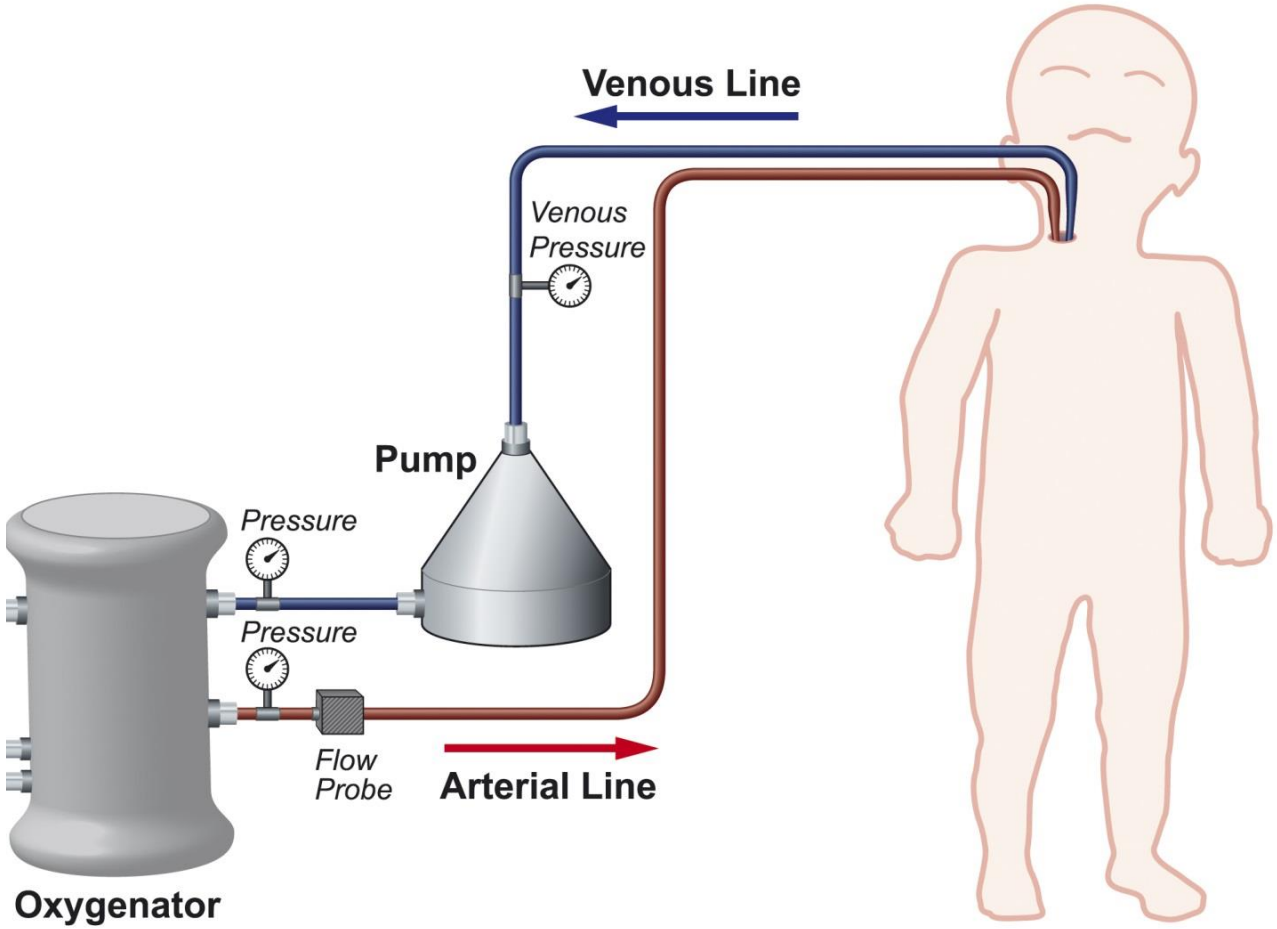


ECMO = Extra Corporal Membrane Oxygenation

(synonym: V-V-ECMO)

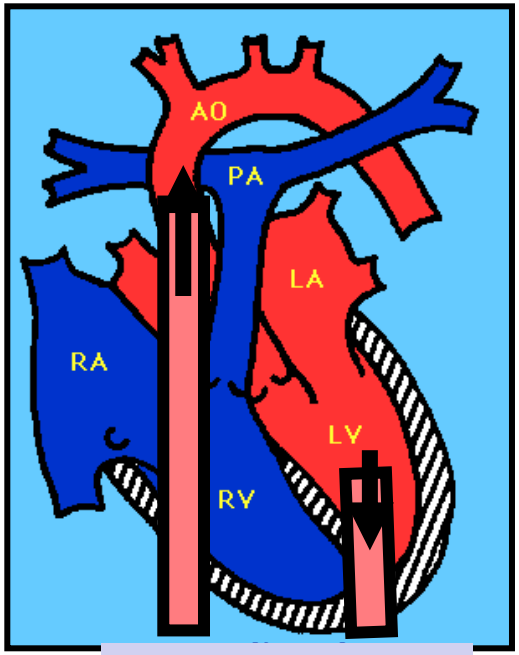
ECLS = Extra Corporal Life Support

(synonym: V-A-ECMO)

VAD = Ventricular assist device

(no oxygenator, LVAD, RVAD)

LVAD = pump only, no oxygenator



Levitronix CentriMag

Xenios Medos DP3

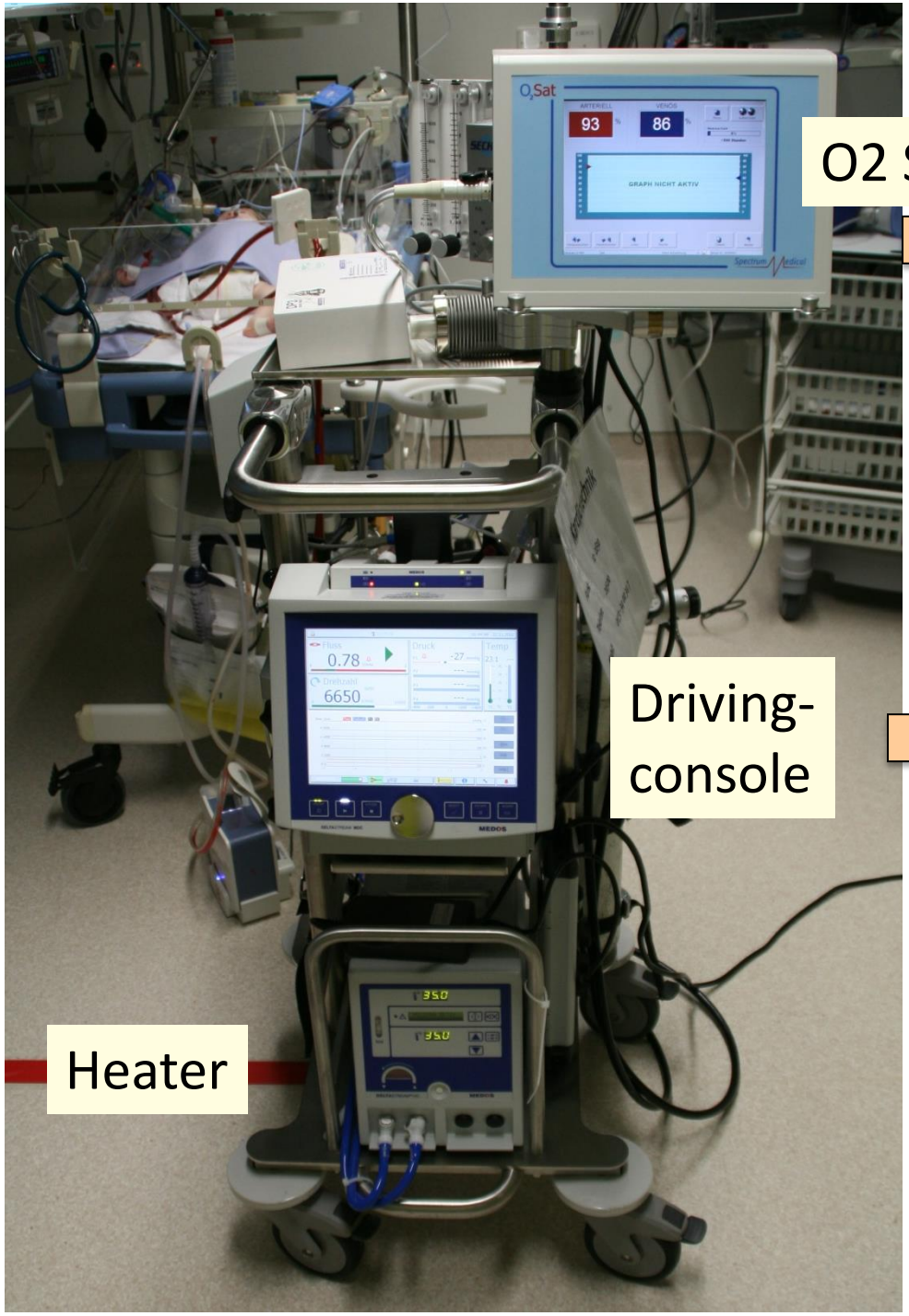
Deltastream® DP3, (Medos / Xenios, Germany) **a diagonal rotational pump**

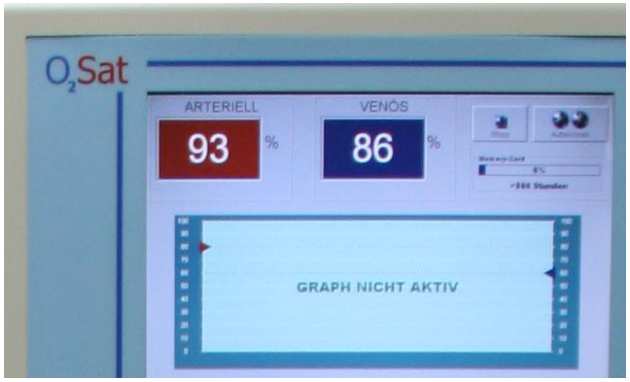
Impeller pump with high hydraulic performance

Flow 0- 8 l/min

Rotational speed: 500 - 10.000 U/min

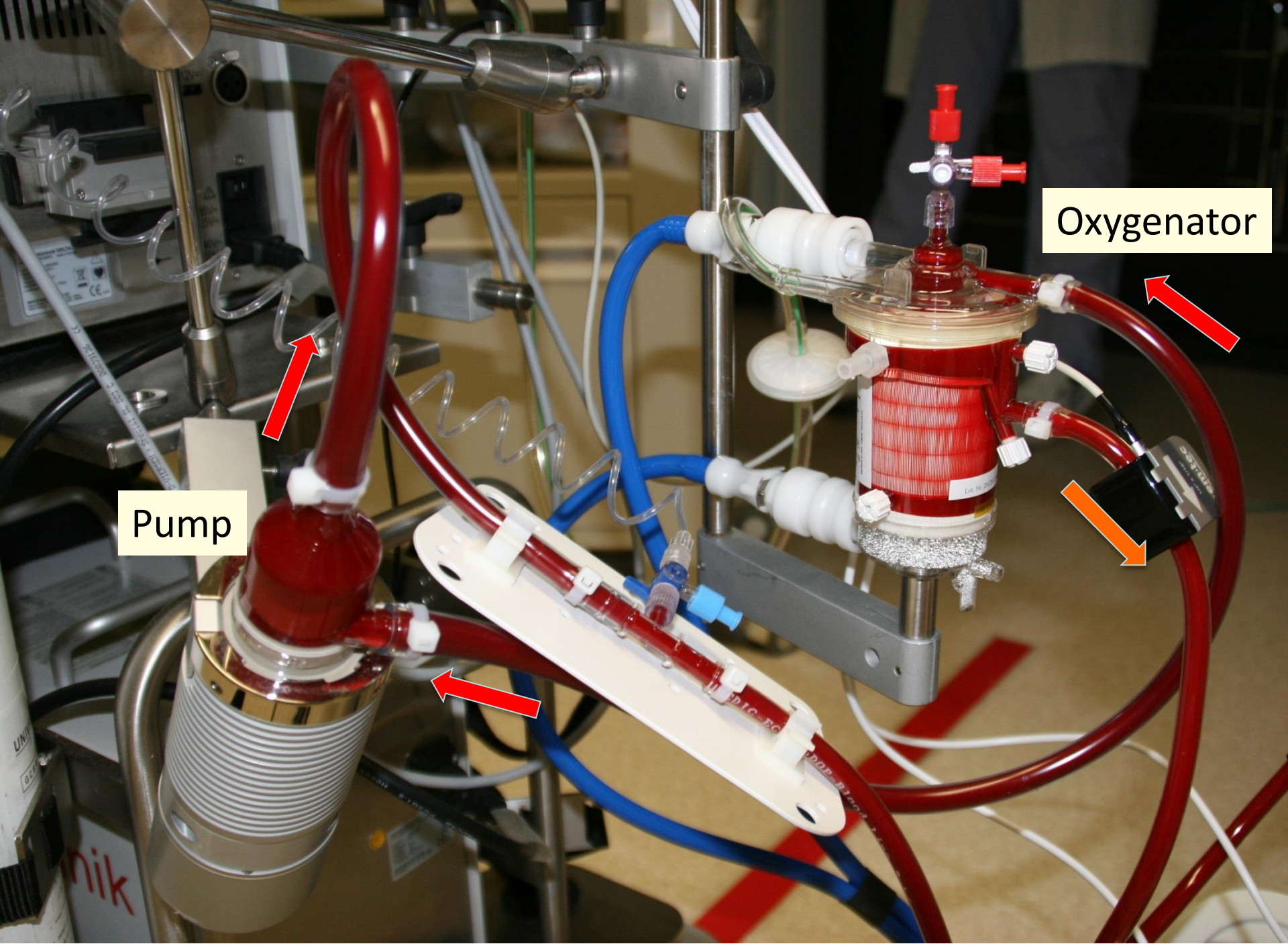
- low priming volume (16 ml)
- ceramic ball-bearing for the impeller: low friction loss

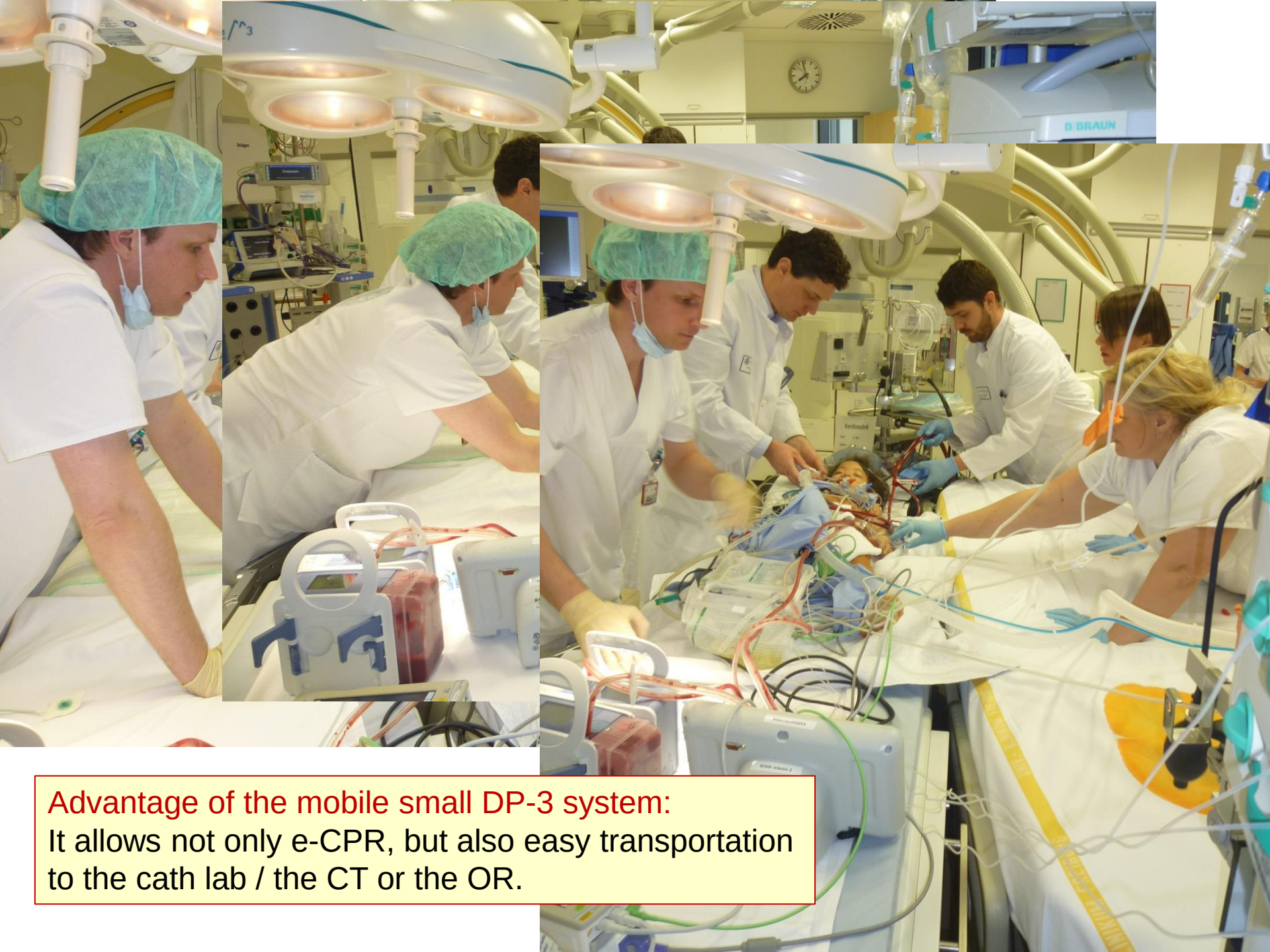

O2 Sat.
Driving-console
Heater


O2Sat
ARTERIELL
VENÖS
93
86
GRAPH NICHT AKTIV

ECLS / ECMO


Fluss
0.78
Druck
-27
Temp
23.1
Drehzahl
6650

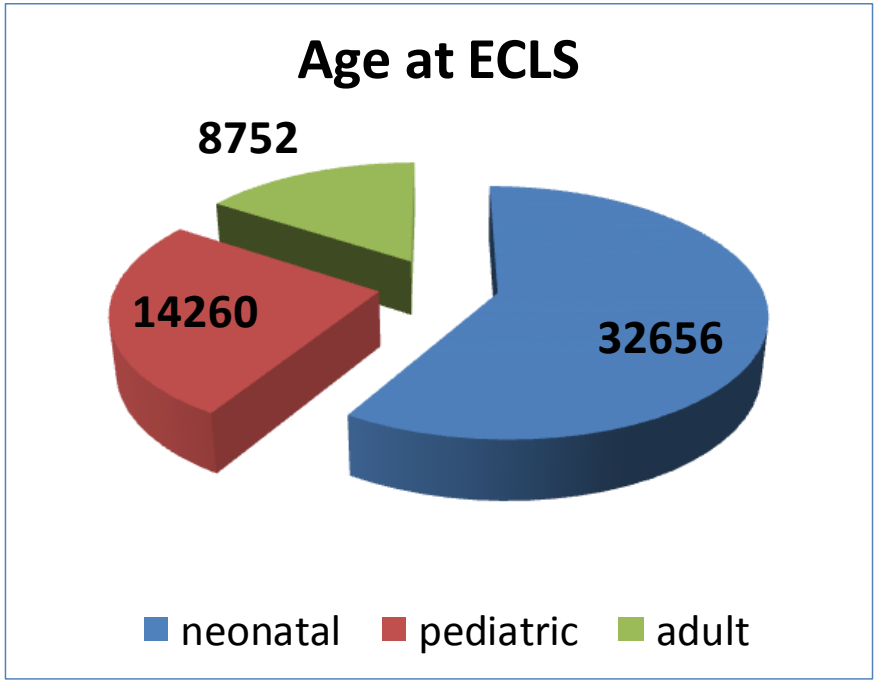

Oxygenator
Pump



Advantage of the mobile small DP-3 system:
It allows not only e-CPR, but also easy transportation to the cath lab / the CT or the OR.

Update and outcomes in extracorporeal life support

Matthew L. Paden, MD[a,], Peter T. Rycus, MPH[b], and Ravi R. Thiagarajan, MD, MPH[c,d], on Behalf of the ELSO Registry*



	Total cases	Survival %
Neonatal		
Respiratory	26.583	**75**
Cardiac	5.159	**40**
ECPR	914	**39**
Pediatric		
Respiratory	5.923	**57**
Cardiac	6.459	**49**
ECPR	1.878	**41**
Adult		
Respiratory	4.382	**56**
Cardiac	3.401	**40**
ECPR	969	**28**
Total	55.668	**60 %**

Seminars in Perinatology 38 (2014) 65–70

Age distribution and survival in cardiac ECLS

About 15.000 ECLS-runs for cardiac indication 1989 -2013	Age 1 - 30 d		Age 2 - 12 m		Age 2 - 15 y		Age > 15 y	
	Total	%	Total	%	Total	%	Total	%
Congen. Defect	4694	39	2725	45	1341	47	239	33
Cardiogenic Shock	77	38	47	38	105	52	549	37
Cardiomyopathy	121	60	169	56	473	62	372	49
Myocarditis	66	50	80	76	241	70	123	67
Other	487	43	480	50	729	54	2243	39

SEMINARS IN PERINATOLOGY 38 (2014) 65–70

Heart replacement therapies for children

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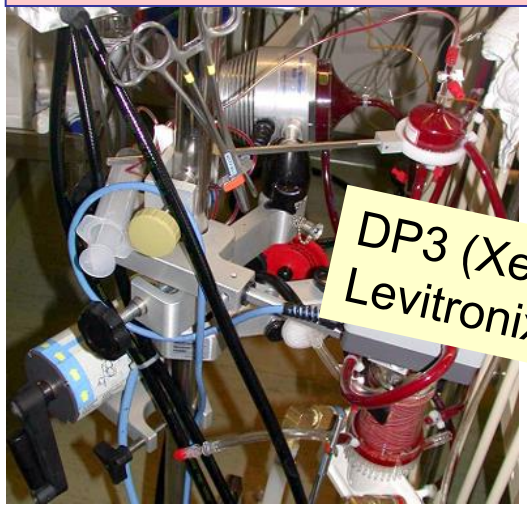

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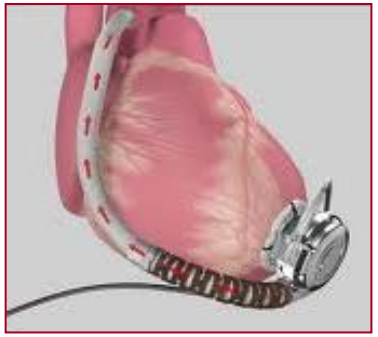


Heartware
Heart mate II

Heart replacement therapies for children

Chances:
- long term support (months)
- extubation, mobilisation
- reliable neurologic examination
- enteral nutrition
- recovery of all organs

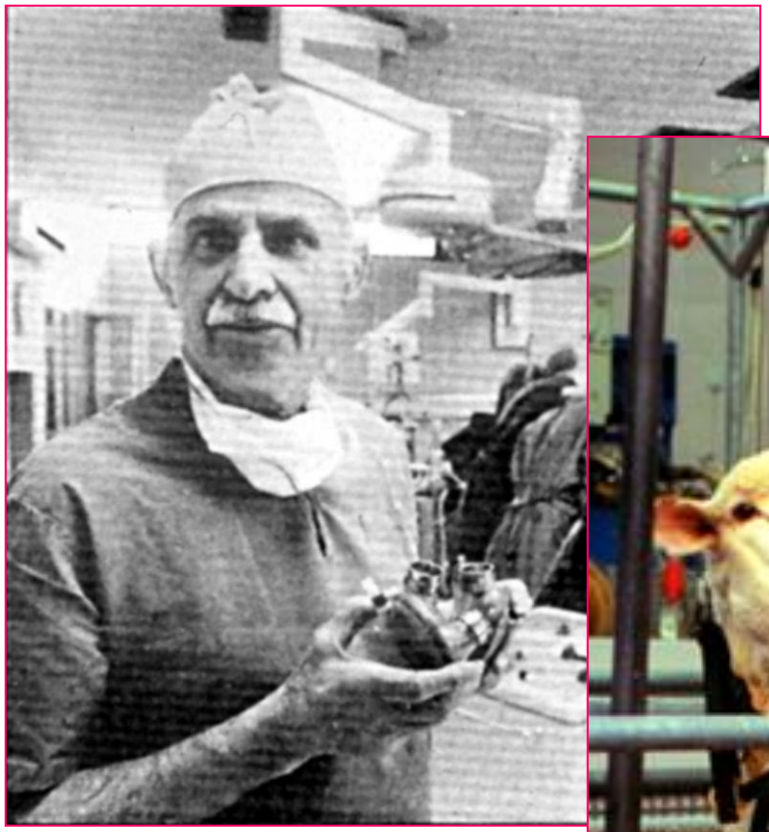
Pitfalls:
- anticoagulation
- bleeding / embolism
- complex cannulation
- infections are dangerous

Pulsatile VADs

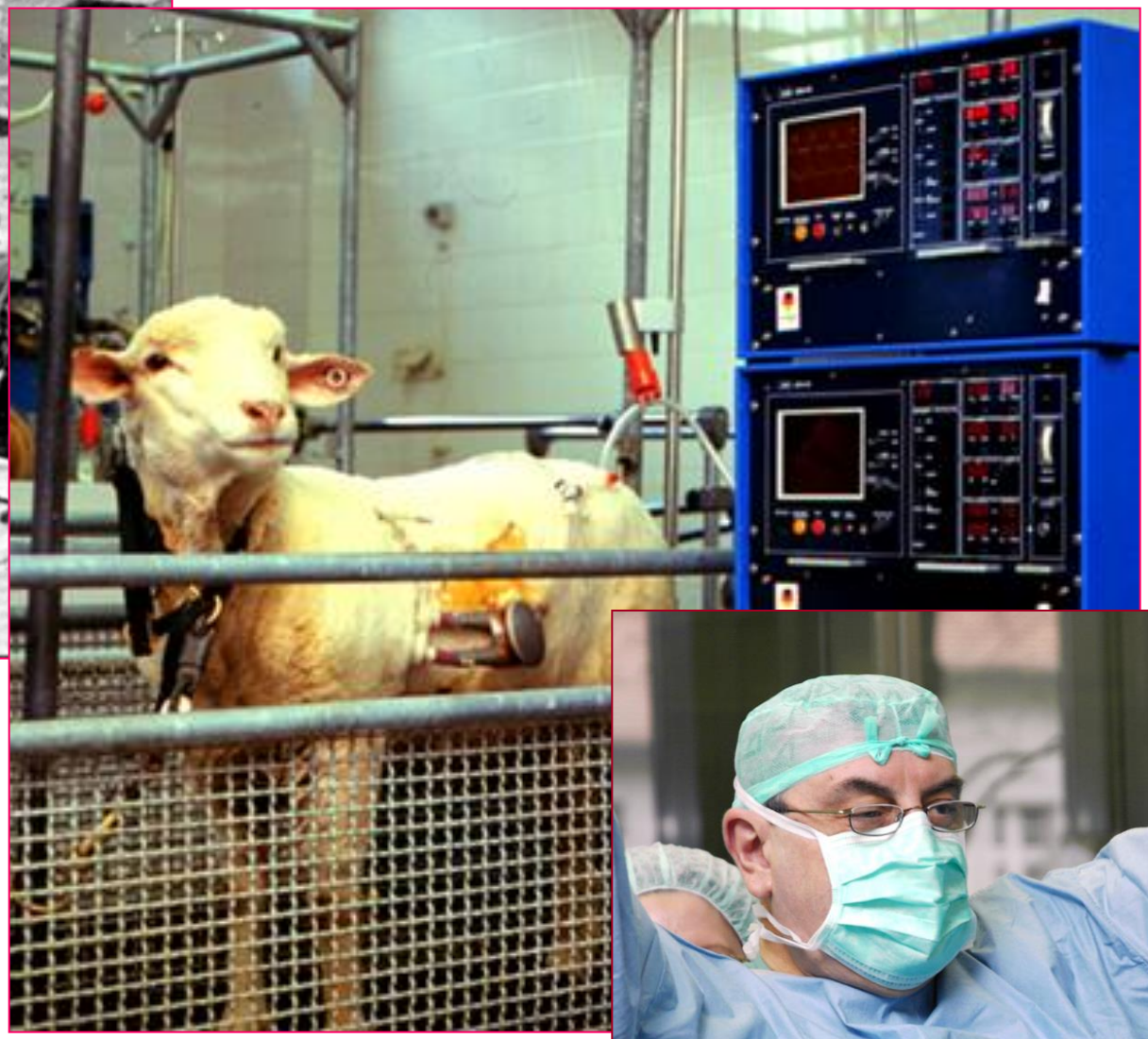
paracorporal

= pneumatic driven pump for uni- or bi ventricular long term heart support

Berlin Heart, Excor

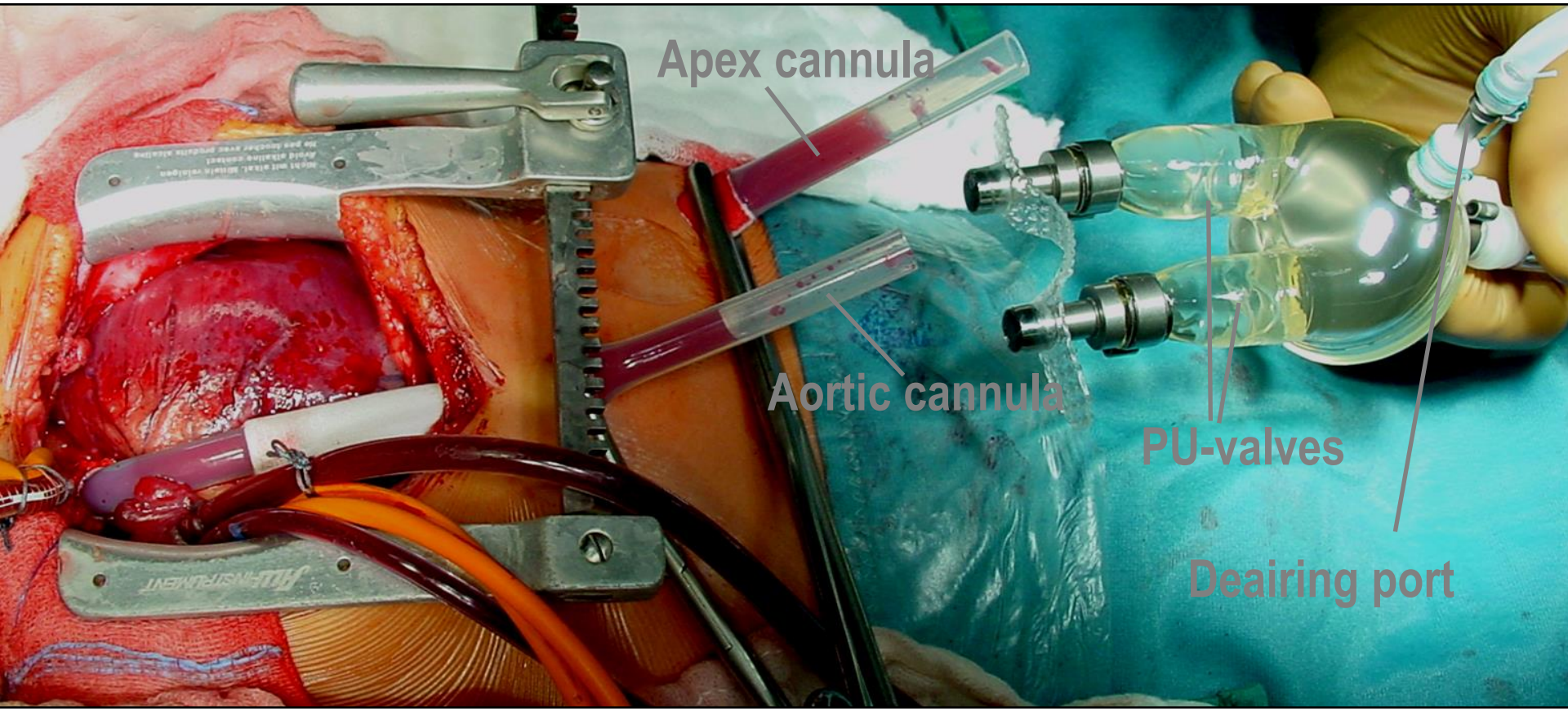


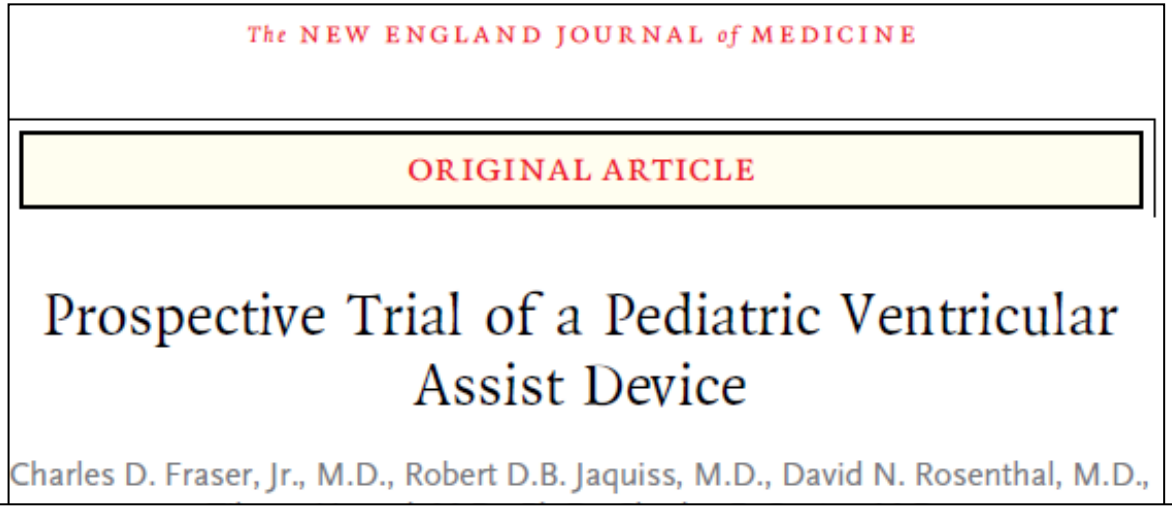
Prof. E. S. Bücherl



Prof. R. Hetzer

Connection Pump to Cannulae





- 48 children from 17 Centers with severe heart failure received a BERLIN HEART EXCOR VAD:
  - Cohorte 1: young children (med. age 1 year) **…Survival 88 %**
  - Cohorte 2: older children (med. age 9 years) **...Survival 92 %**

- *What did the Europeans made wrong before ??*
- Very strong participant selection: 2-Ventricle circulation, must be on the waiting list for HTx, Previous ECMO treatment excluded
- Compared with survival of a matched historical ECMO gro

Serious adverse events, including infection, stroke, and bleeding, occurred in a majority of study participants.

Fraser CD Jr et al. N Engl J Med 2012;367:532-541

Berlin Heart EXCOR Pediatric Ventricular Assist Device for Bridge to Heart Transplantation in US Children

Christopher S. Almond, MD, MPH*; David L. Morales, MD*; ... MD;
Mark W. Turrentine, MD; Michiaki ... Sc;
Lori C. Jordan, MD; ... MD;
... S;
... en, MD;
... MD;

- The NEJM published trial was an highly selected cohort.
- In the same centers, at the same time interval only 1:4 met the criteria.
- Not 68, but 204 children were supported with the EXCOR Berlin Heart
  - **Transplantation in 67 %**
  - **Weaning 6 %**
  - **Death 26 %**
  - **Neurological dysfunction in 29 %**

Bac ... assist device is superior to ... are limited to 1 in 4 children ... S children who received the ... ors for mortality to facilitate ...

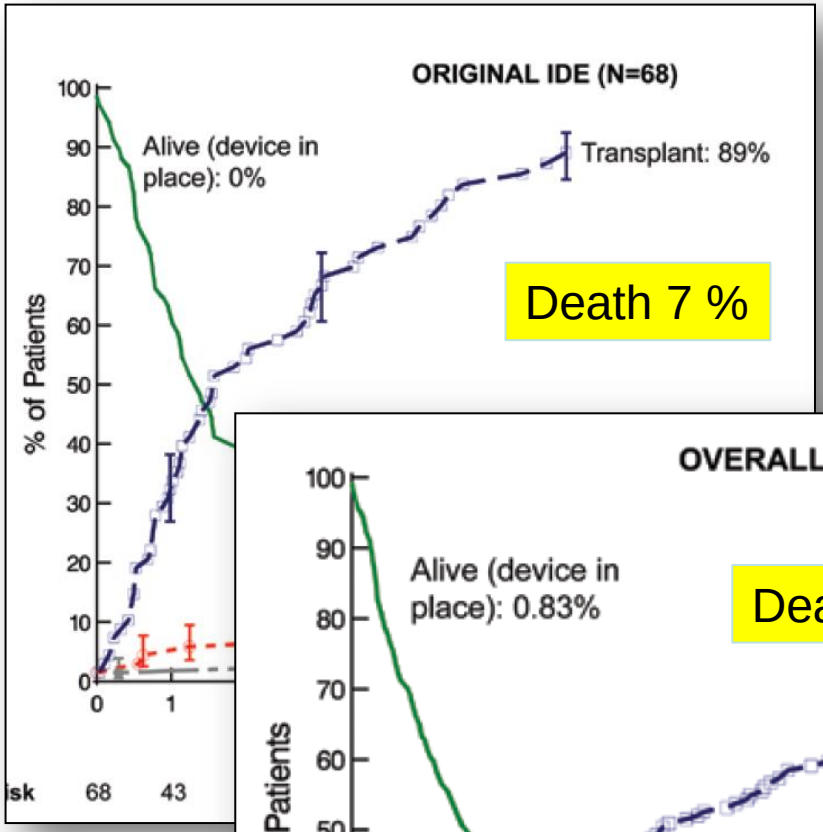
Meth ... who reached transplant ... device. Multivariable analysis identified lower weight, bivent ... factors for early mortality and bilirubin extremes and renal d ... dysfunction occurred in 29% and was the leading cause of dea ...

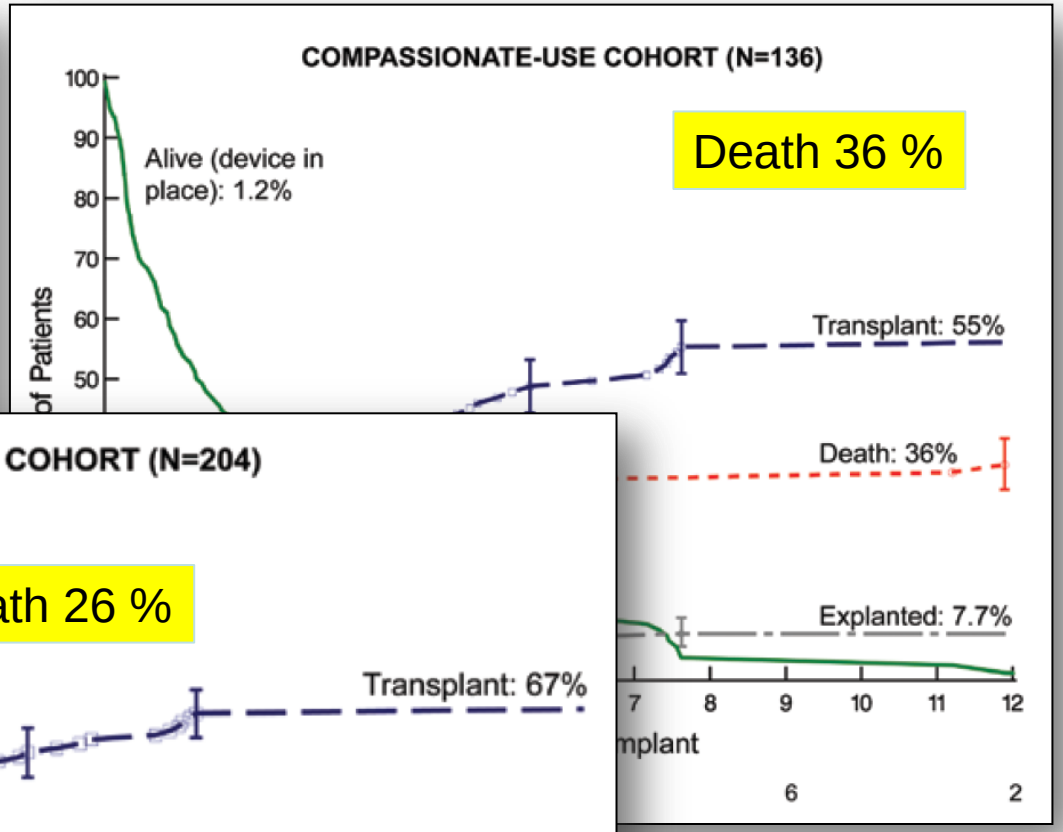
Conclusions—Use of the Berlin Heart EXCOR has risen drama ... a new treatment standard in the United States for pediatric bri ... to transplantation or recovery; an important fraction experien ... dysfunction, hepatic dysfunction, and biventricular assist device ... membrane oxygenation before implantation and congenital he ...

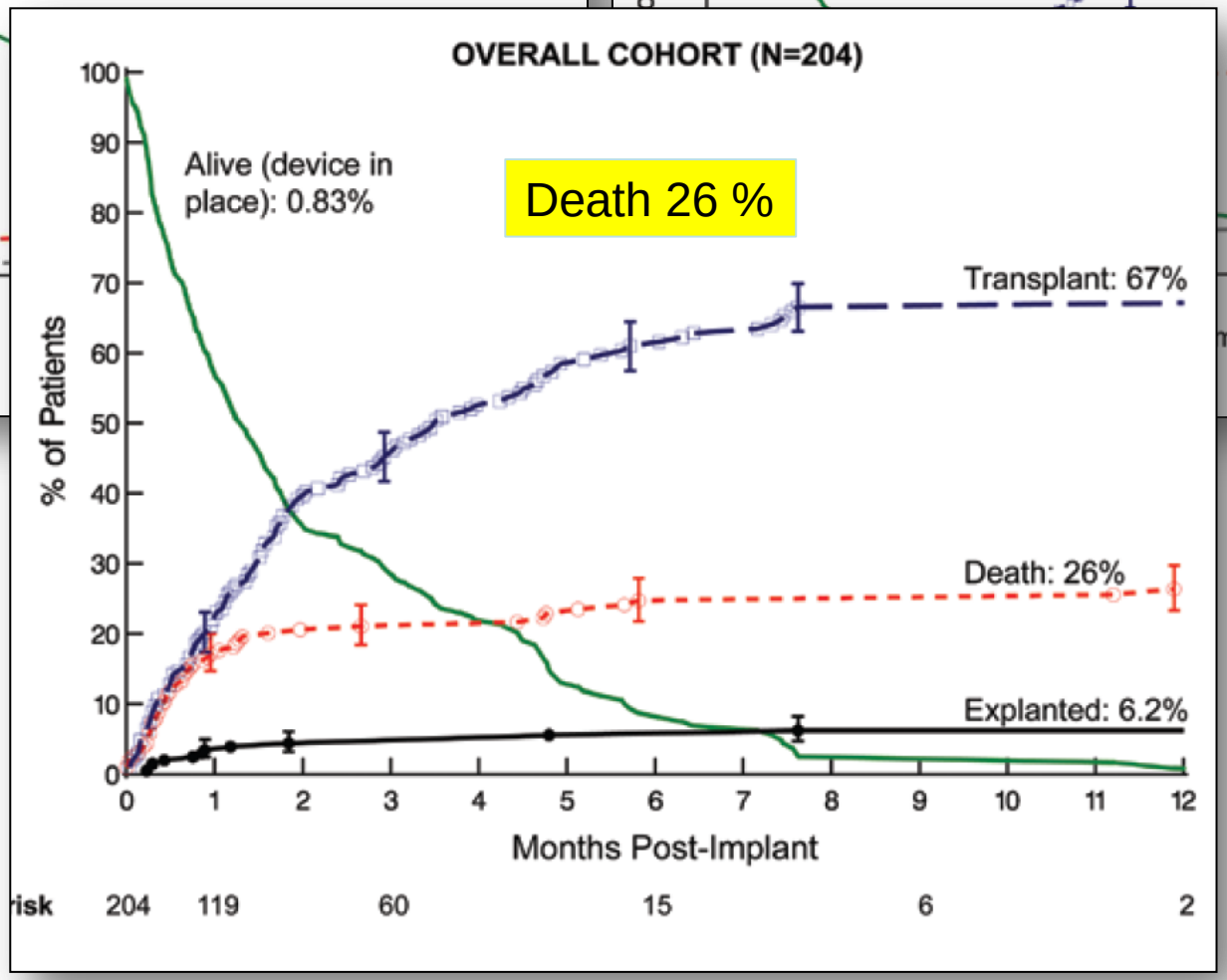
Multivariate risks for mortality:

BVAD
lower BW
Bili elevated
renal dysfunction

Neurological dysfunction
in 29 % as leading cause of death


ORIGINAL IDE (N=68)
Alive (device in place): 0%
Transplant: 89%
Death 7 %
% of Patients
100
90
80
70
60
50
40
30
20
10
0
0
1
isk 68 43


COMPASSIONATE-USE COHORT (N=136)
Alive (device in place): 1.2%
Death 36 %
Transplant: 55%
Death: 36%
Explanted: 7.7%
of Patients
100
90
80
70
60
50
7
8
9
10
11
12
mplant
6
2


OVERALL COHORT (N=204)
Alive (device in place): 0.83%
Death 26 %
Transplant: 67%
Death: 26%
Explanted: 6.2%
% of Patients
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
12
Months Post-Implant
risk 204 119 60 15 6 2

The use of the Berlin Heart EXCOR in pat[illegible]with functional single ventricle

Samuel Weinstein, MD, MBA,[a] Ricard[illegible] Chr[illegible]
Francis Fynn-Thompson, MD,[c] James H[illegible] Gulesse[illegible]
Christine Tjossem, BS,[g] Robert Kroslow[illegible]nn,[a] and Robert [illegible]

Introduction: The frequency and suc[illegible]entricular assist devices (VADs) as a br[illegible] cardiac transplantation have been steadily increasing since 2003, but the experience in patients with complex congenital heart disease has not been well described. Using a large prospectively collected dataset of children supported with the Berlin Heart EXC[illegible]wed the experience in children with single ventricular anatomy or physiology (SV), and [illegible]h those supported with biventricular circulation (BV) over the same time period.

Methods: The EXCOR Investigation [illegible]tudy database was retrospectively reviewed. VAD implants under the primary cohort and [illegible]ohort between May 2007 and December 2011 were included in this review.

Results: T[illegible] tients [illegible] VAD w[illegible] SV. T[illegible]mmon diagnosis was hypoplast[illegible] (15 [illegible] were [illegible]al palliative surgery (Blalock-[illegible]), 12 [illegible]pulm[illegible]PC), and 5 after total cavopulm[illegible]PC). [illegible]iven [illegible]after stage I surgery and 1 aft[illegible] wer[illegible]ian ti[illegible]e, 1-363 days) versus 39 days (ran[illegible]ge, 0-455 days) for BV (P = .01). The ability to be bridged to transplant or recovery in SV patients is lower than for BV patients (11 of 26 [42.3%] vs 185 of 255 [72.5%]; P = .001). Three of 5 patients with TCPC were success[illegible]ant a[illegible]h 1 V[illegible]ts with SCPC were bridged to tr[illegible] 9 pa[illegible] stag[illegible].

Conclusions [illegible]c VA[illegible]e to t[illegible]vith SV anatomy or physiology, a[illegible] than[illegible]n this[illegible]re better in patients with SCPC and TCPC. VAD support for patients with shunted sources of pulmonary blood flow should be applied with caution. (J Thorac Cardiovasc Surg 2014;147:697-705)

survival until HTx or recovery: SV vs BV: 42 % vs 73 %

26 / 255
SV / BV

15 / 26
HLHS

Stage 1
Shunt
9

Stage 2
SCPC
12

Stage 3
TCPC
5

1 (11%)
Survival until HTx

7 (58 %)
Survival until HTx

3 (60 %)
Survival until HTx

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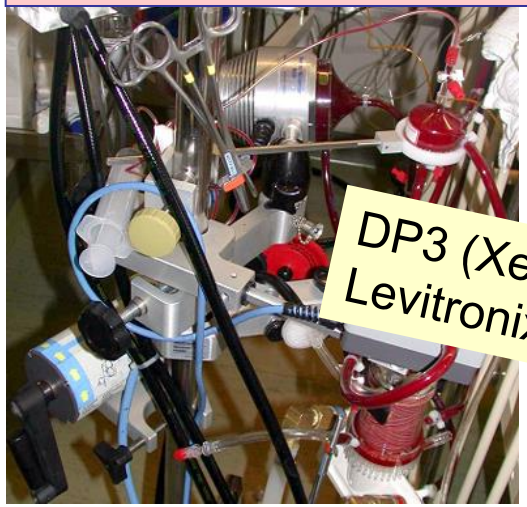

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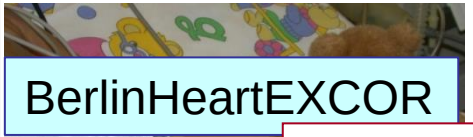

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Centrif. Pump

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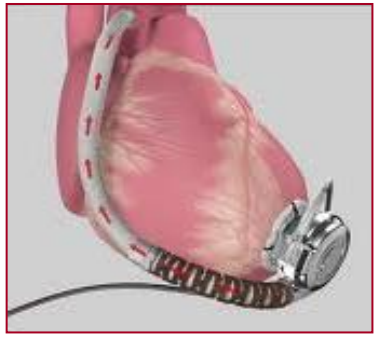
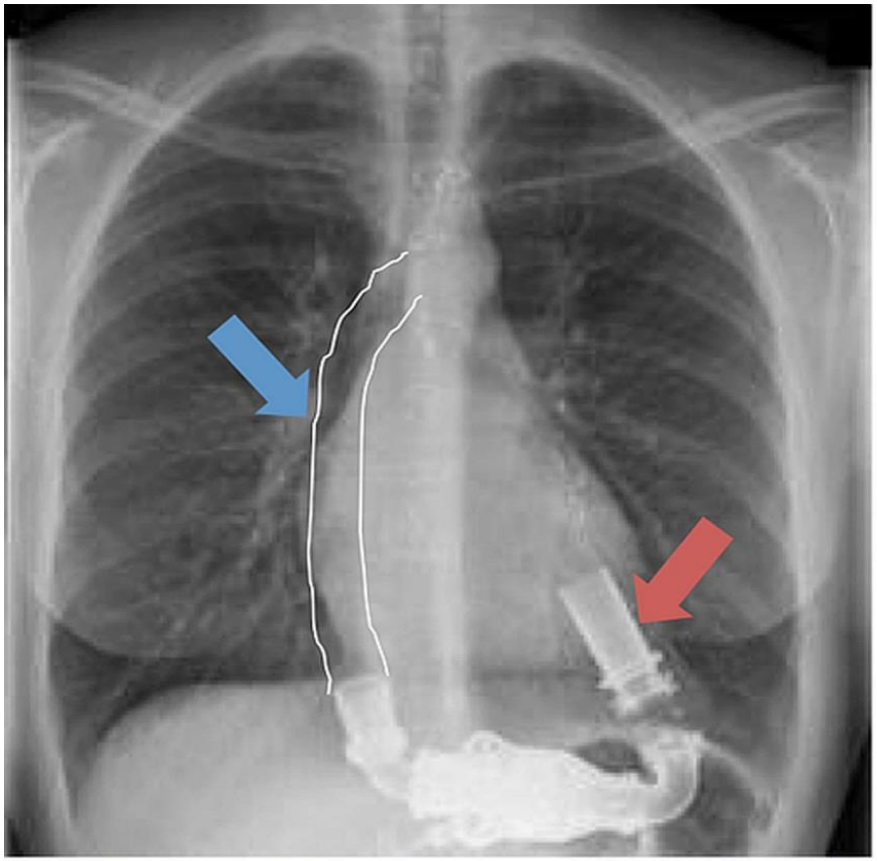


Heartware
Heart mate II

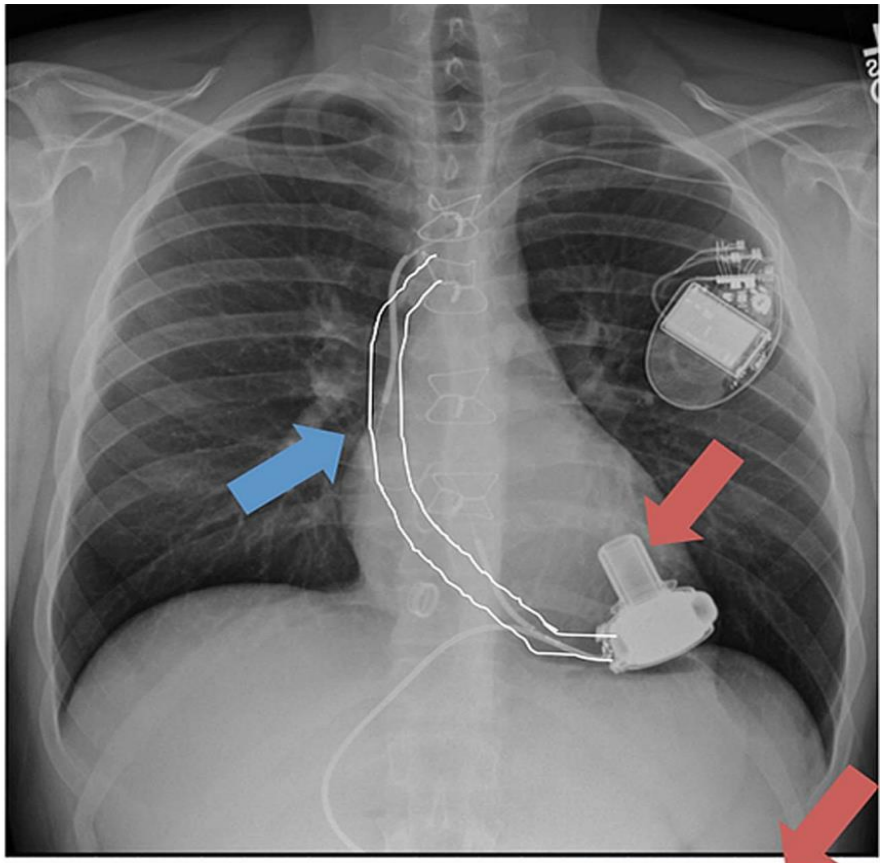
Chances:

- intracorporeal setting
- long term cardiac support
- higher mobility
- chance to sent home (?)

Heartmate II, axial flow device



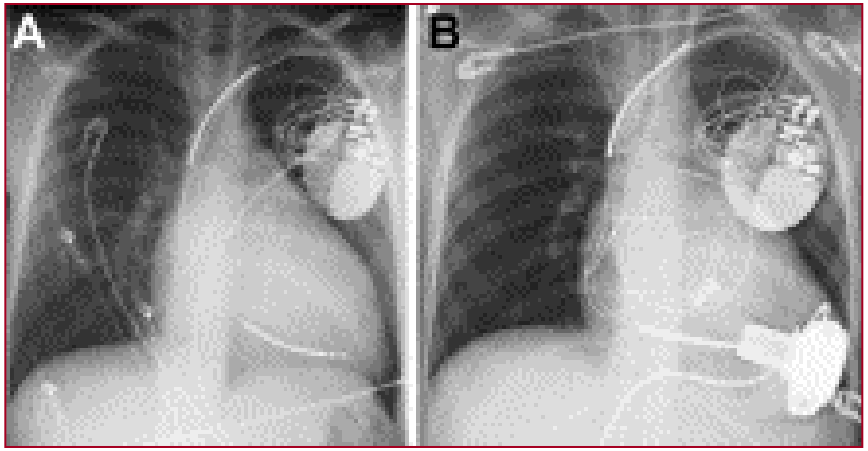
Heartware centrifugal flow device



Kirkpatrick JN, et al. Heart 2015

HeartWare (HeartWare Inc,Miami Lakes, FL)

- Small (pump weight 140 g)
- LVAD only
- Centrifugal continuous-flow pump with a hybrid magnetic bearing.
- It is implanted within the pericardial space and connected to the external power and control panel via the driveline that is externalized through the abdominal wall.

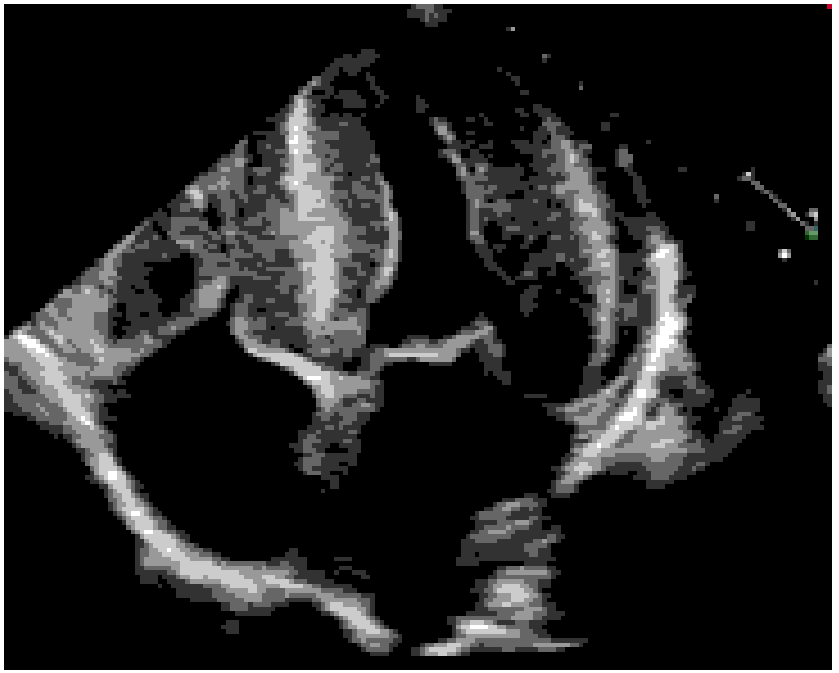


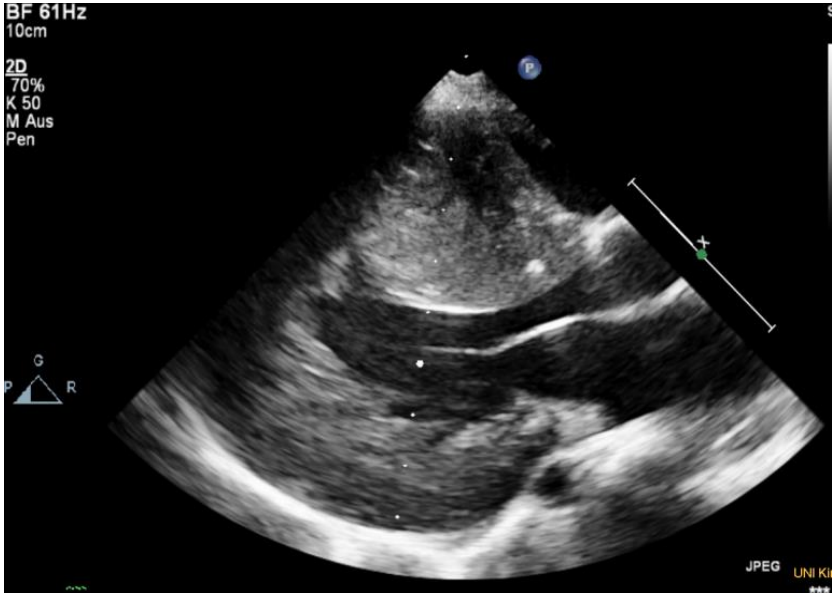
Case: 6-year old boy

Hypertrophic cardiomyopathy

- VT and cardiac arrest during sports
- CPR and defibrillation (ROSC within 10 min.)
- Referred to our PCICU

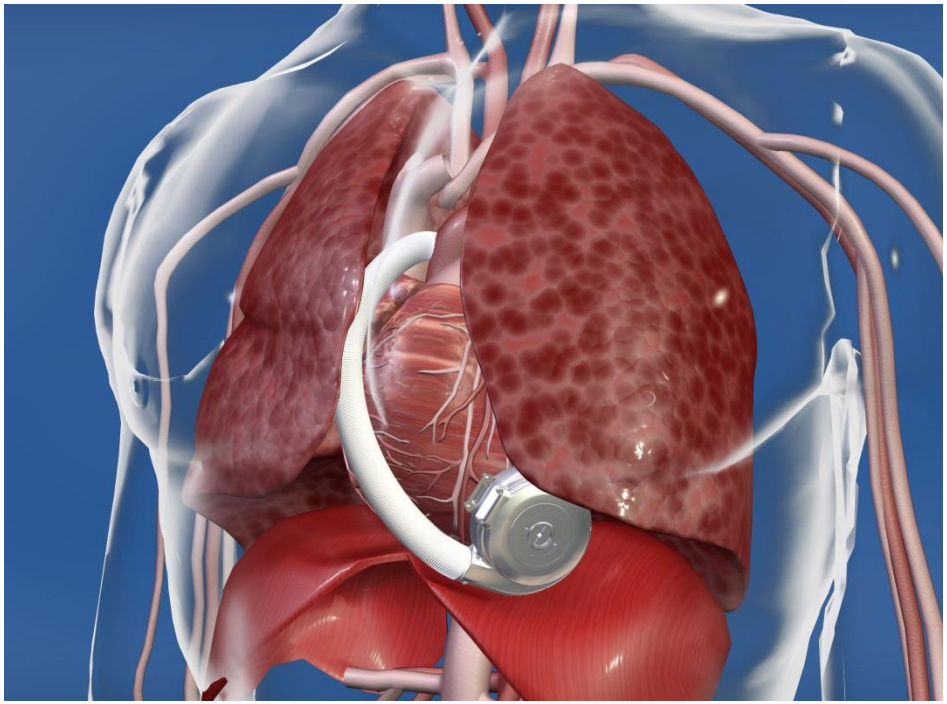
- Implantation of an AICD
- 1 week later **sustained VT** under full medical treatment (amiodarone, ß-blocker)

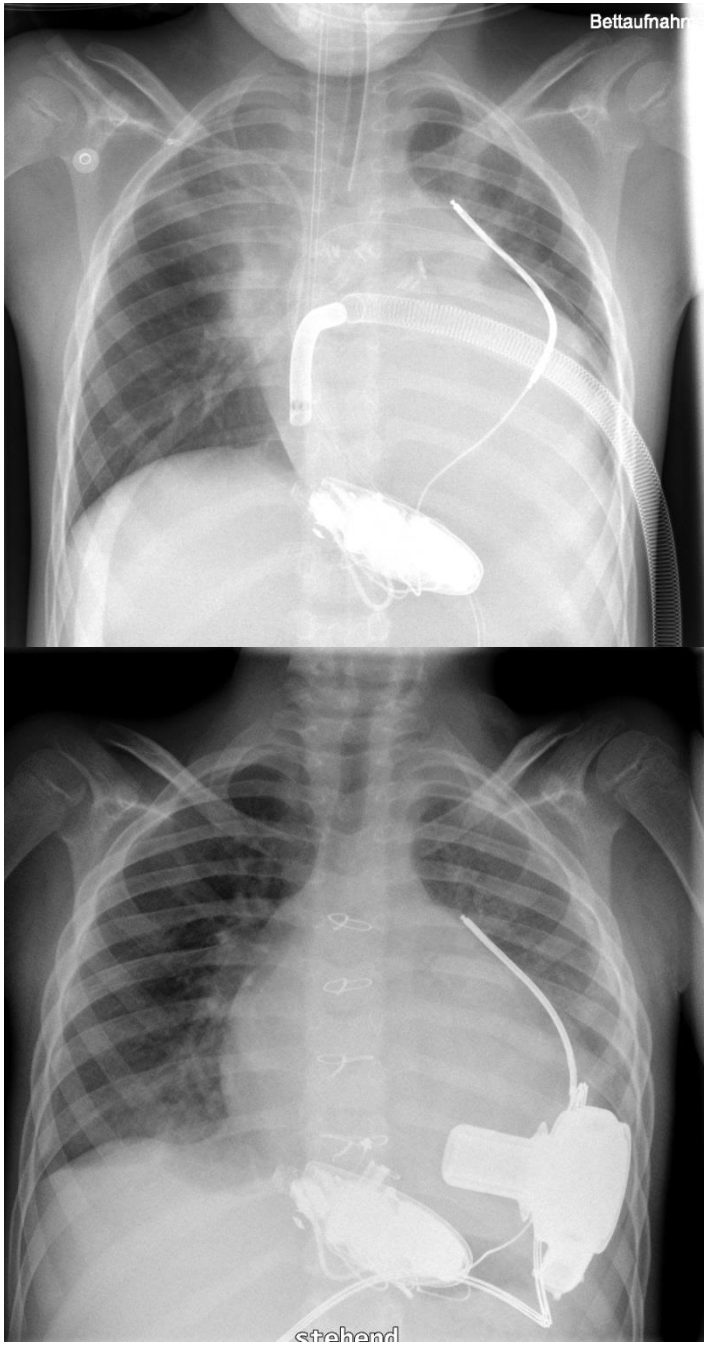


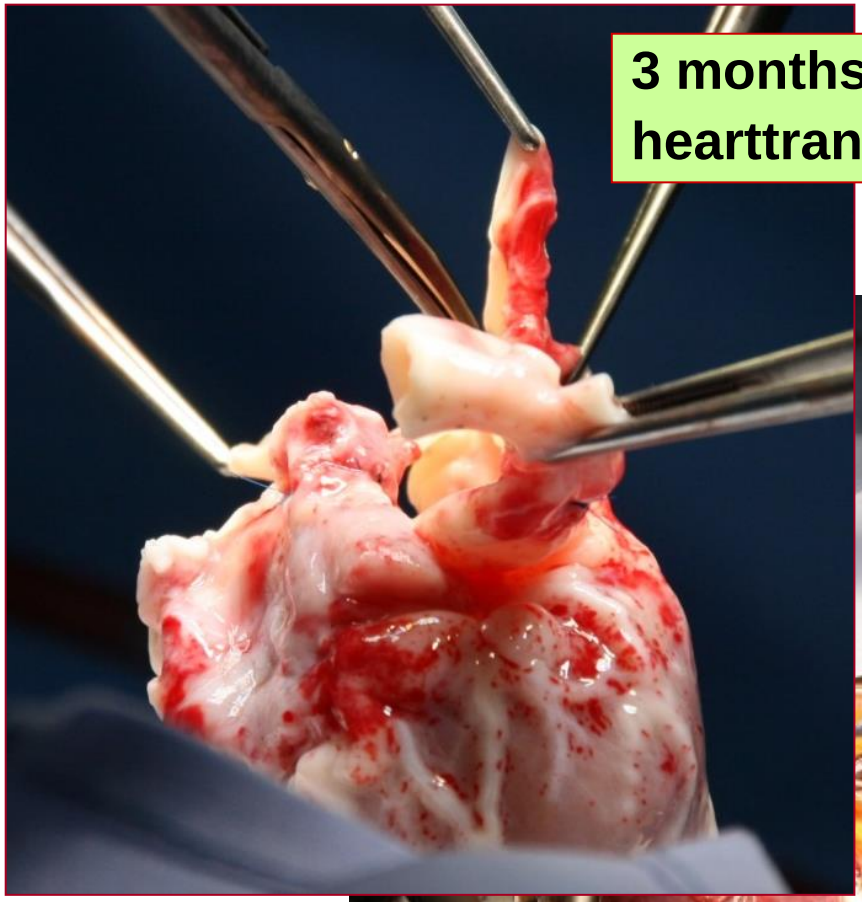


Case: 6-year old boy

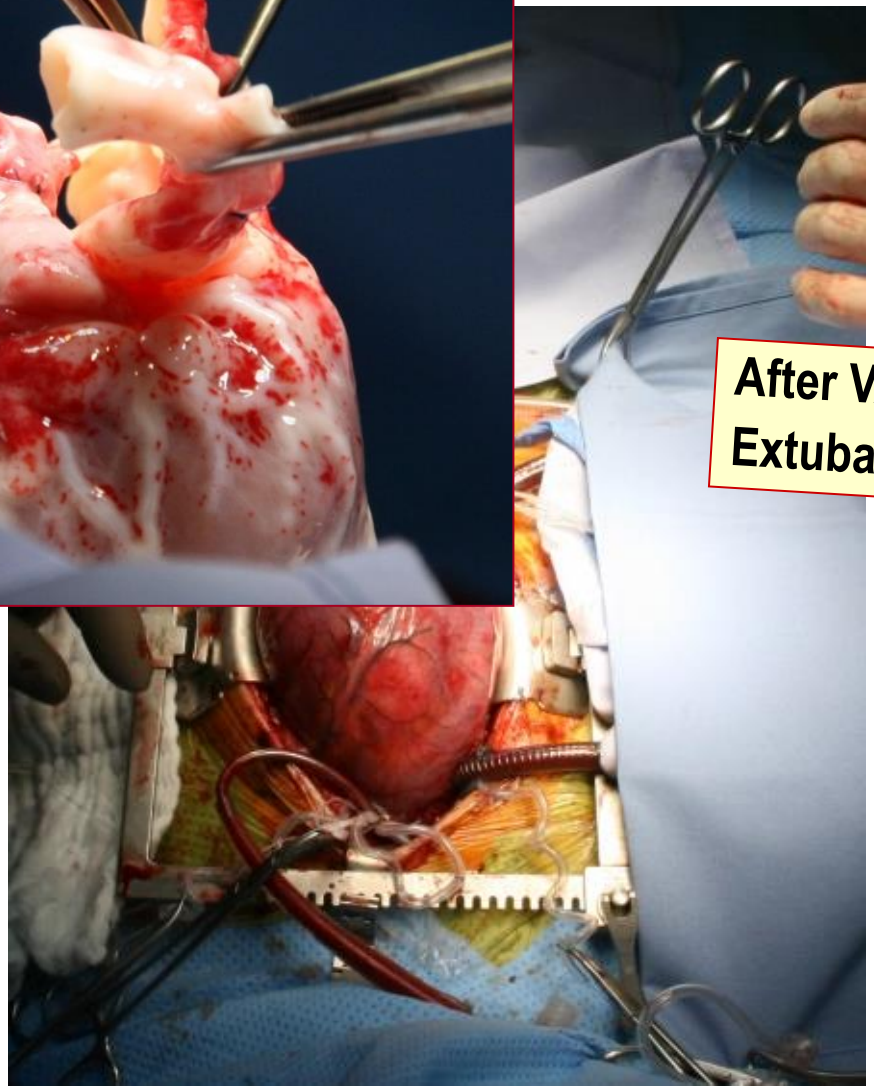
- **ECLS** implantation
- **After 3 days ECLS switch to LVAD (Heart Ware)**
- Listed for heart transplantation

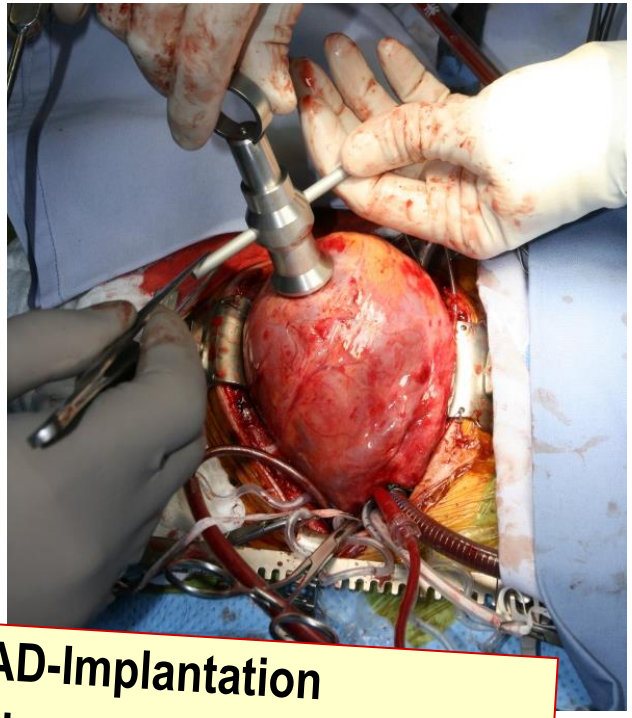




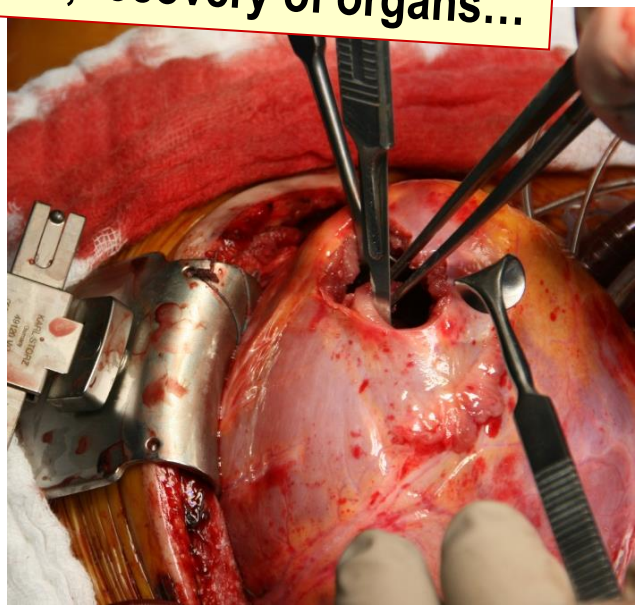


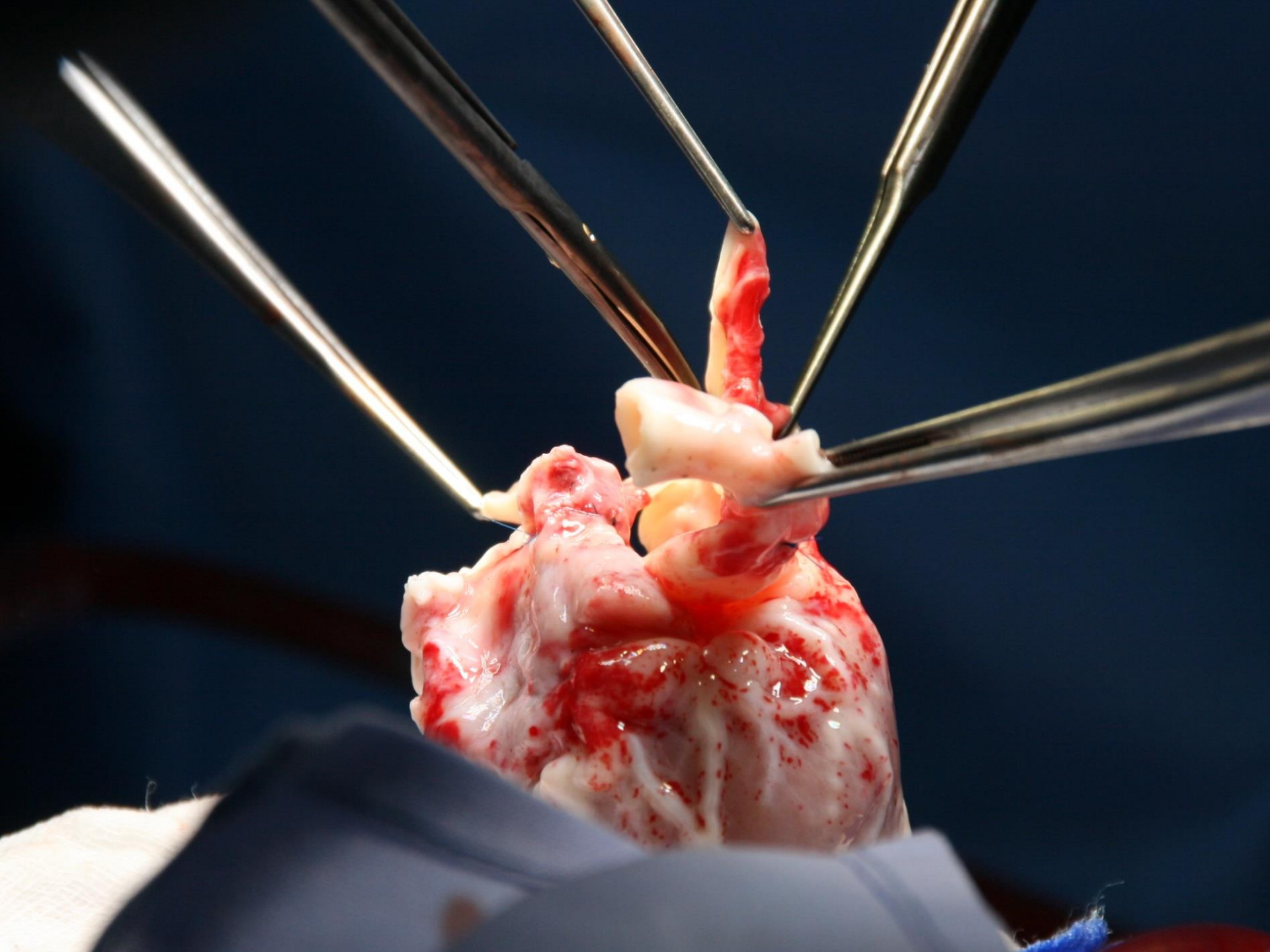
3 months later:
hearttransplantation





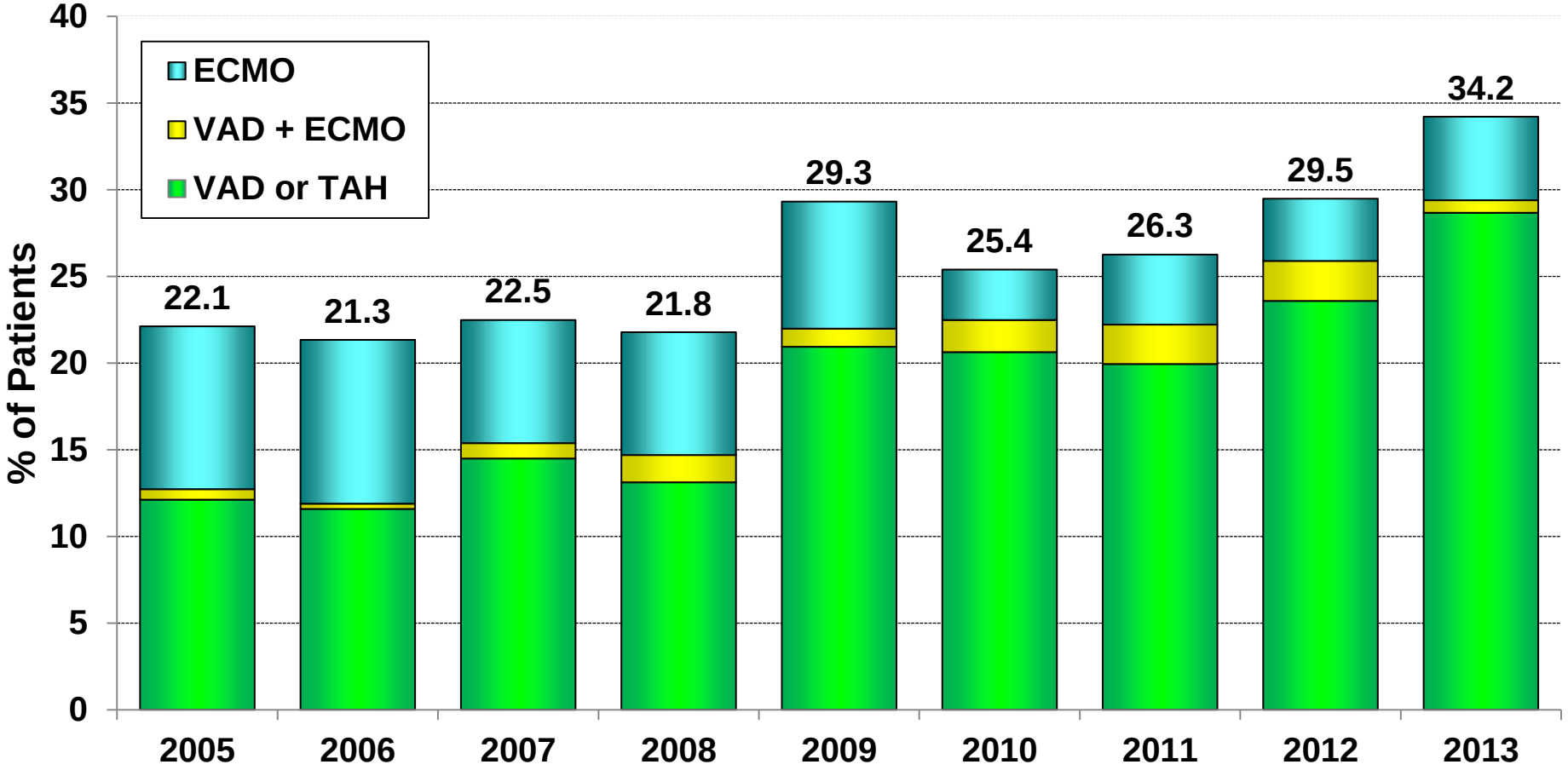
After VAD-Implantation
Extubation, recovery of organs…





Pediatric Heart Transplants

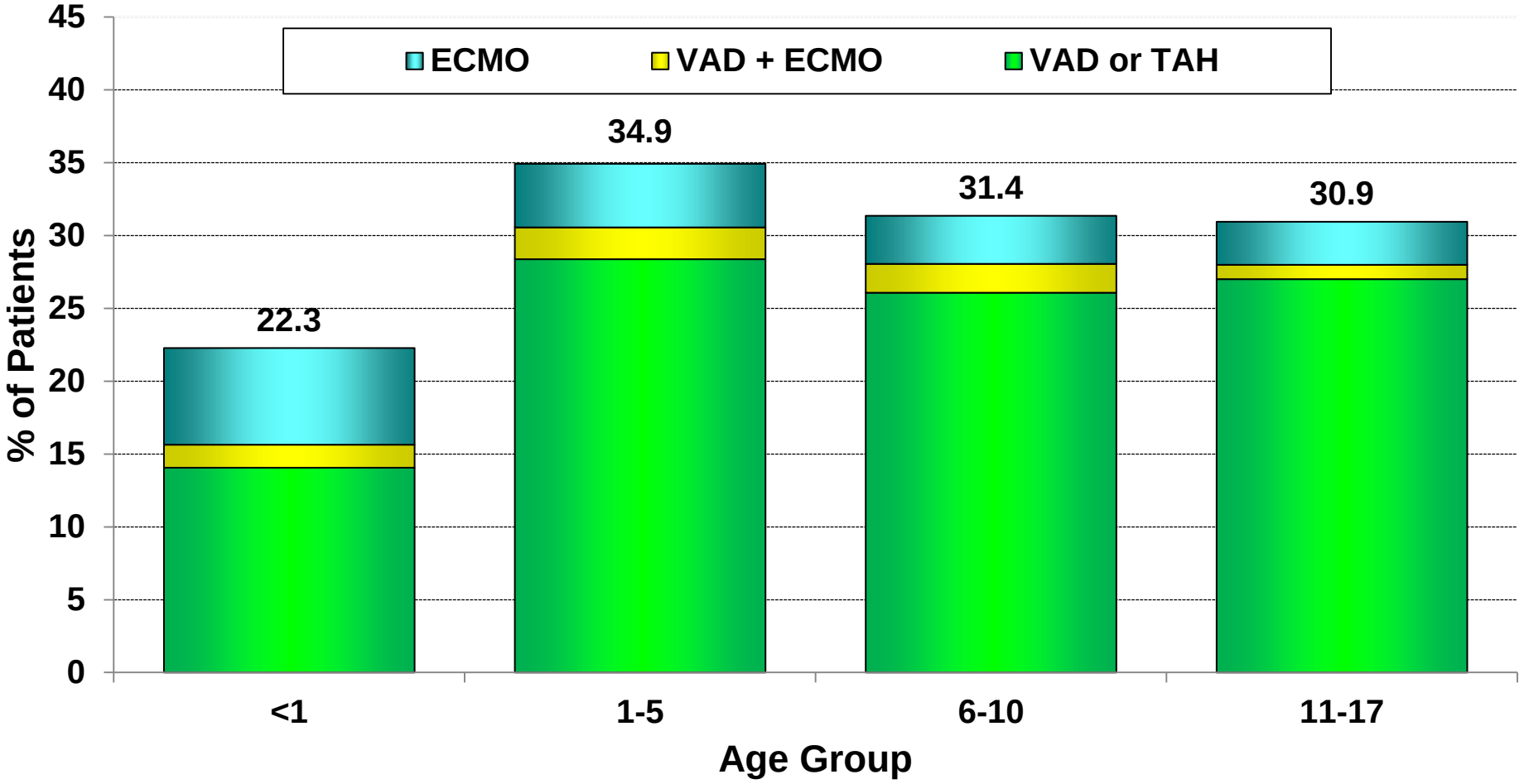
% of Patients Bridged with Mechanical Circulatory Support* by Year (Transplants: January 2005 – December 2013)



*

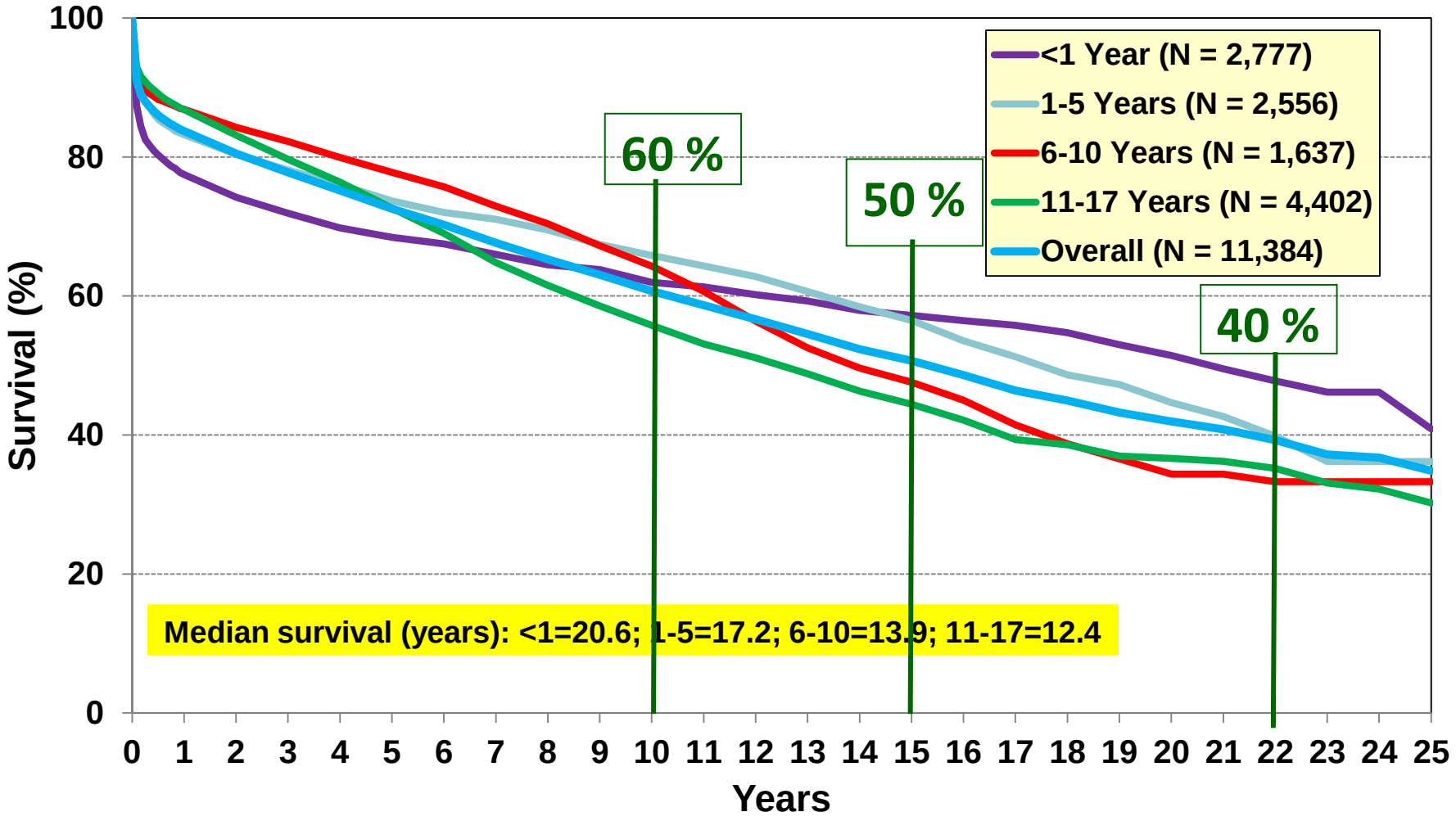
Pediatric Heart Transplants

% of Patients Bridged with Mechanical Circulatory Support* by Age Group (Transplants: January 2009 – June 2014)



Longterm survival of „all“pediatric transplants ?

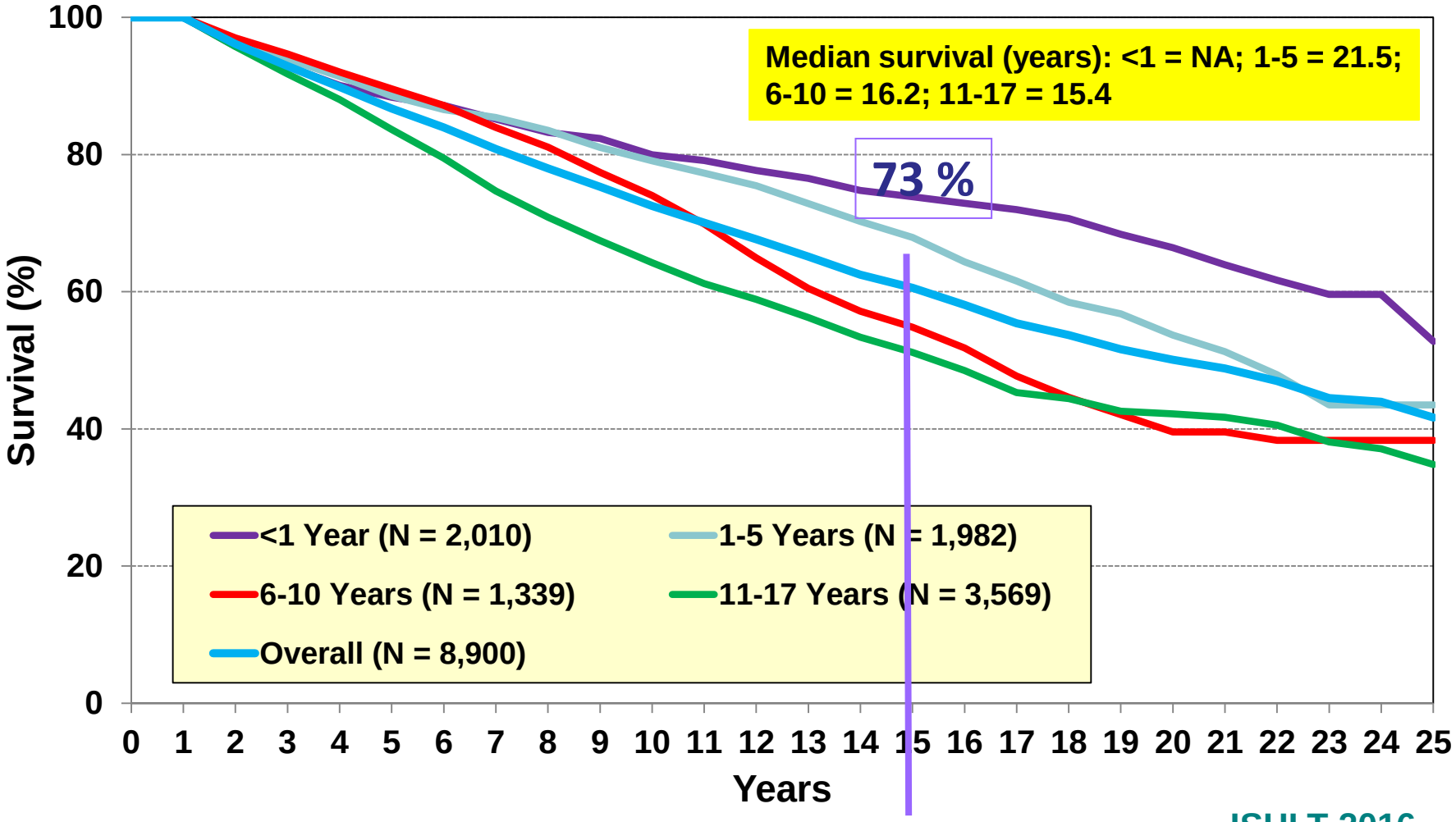
Transplanted between 1982-2013, ISHLT



ISHLT 2016

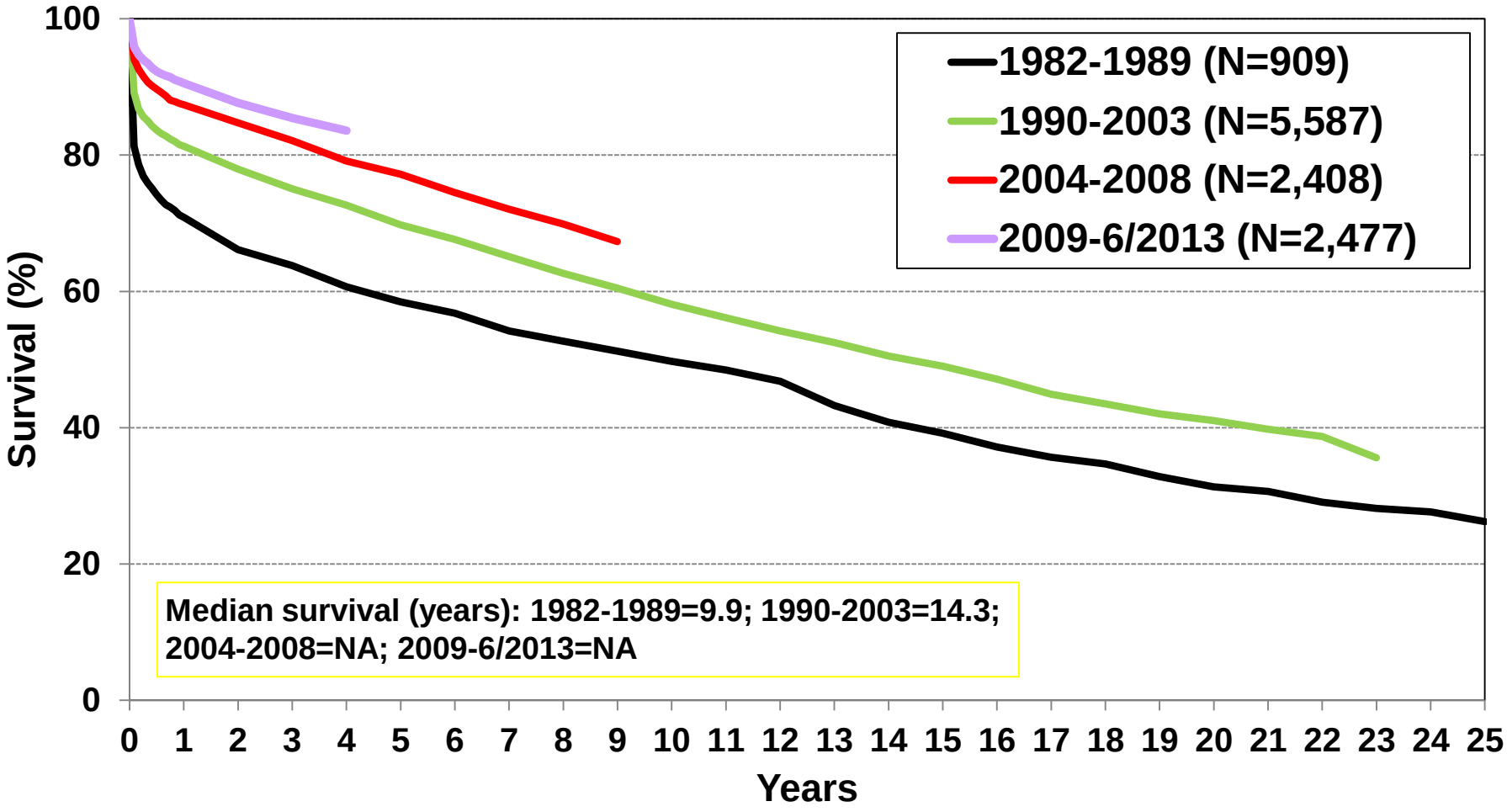
Longterm-survival of those who survived the first year after transplantation?

HTx 1982-2009 ISHLT



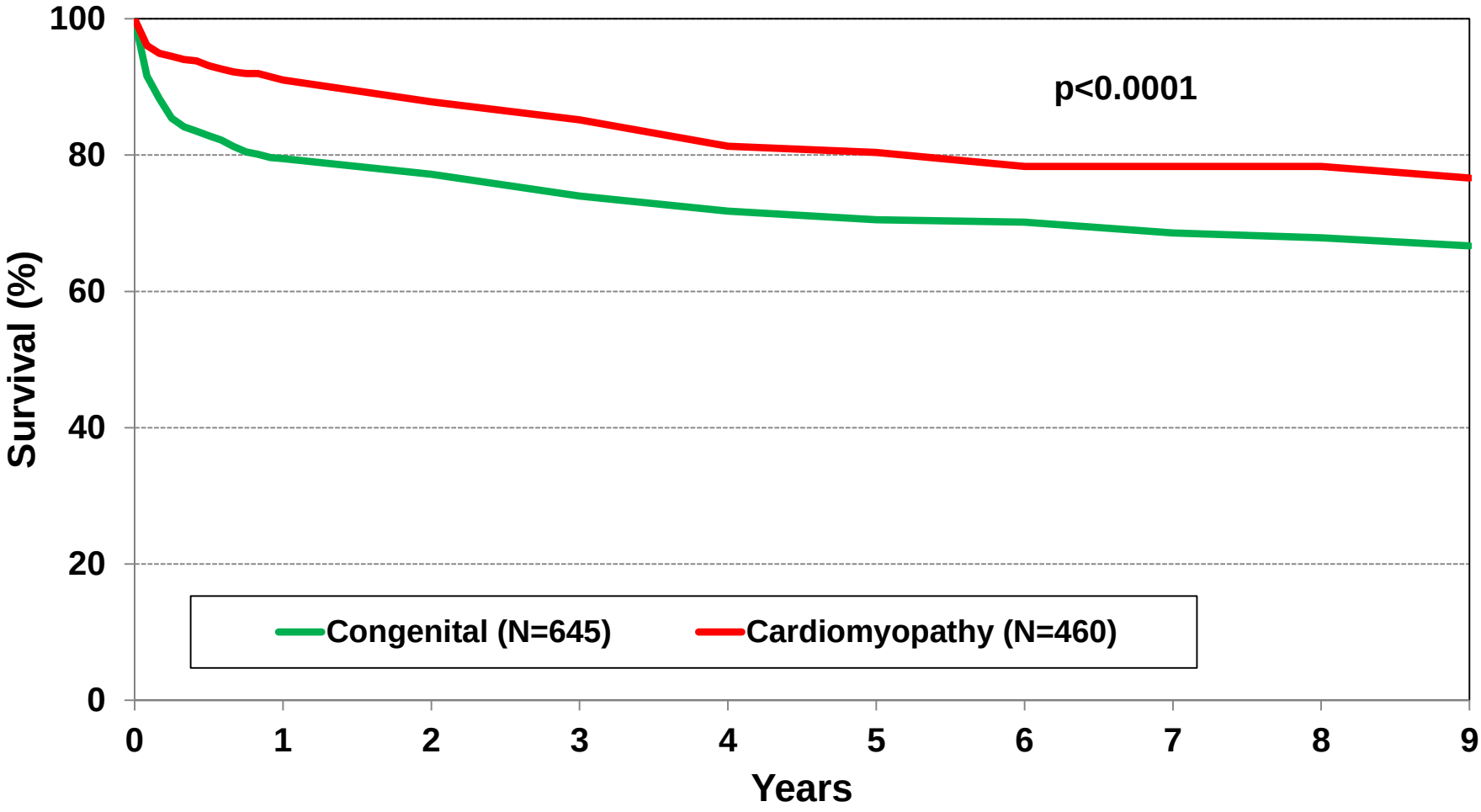
ISHLT 2016

Pediatric Heart Transplants
Kaplan-Meier Survival by Era
(Transplants: January 1982 – June 2013)



ISHLT 2016

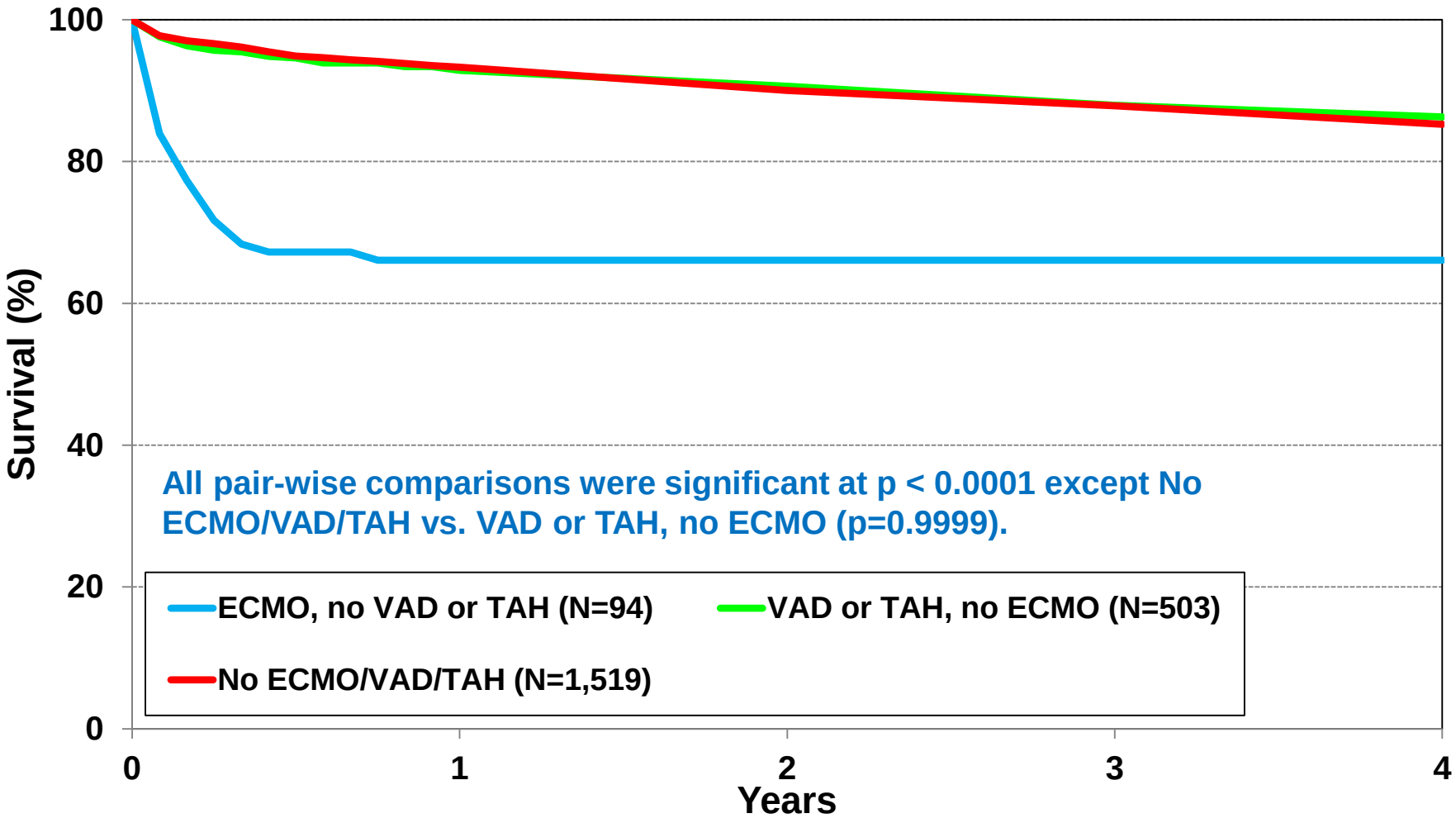
Pediatric Heart Transplants
Kaplan-Meier Survival by Diagnosis
Age: < 1 Year (Transplants: January 2004 – June 2013)



Pediatric Heart Transplants

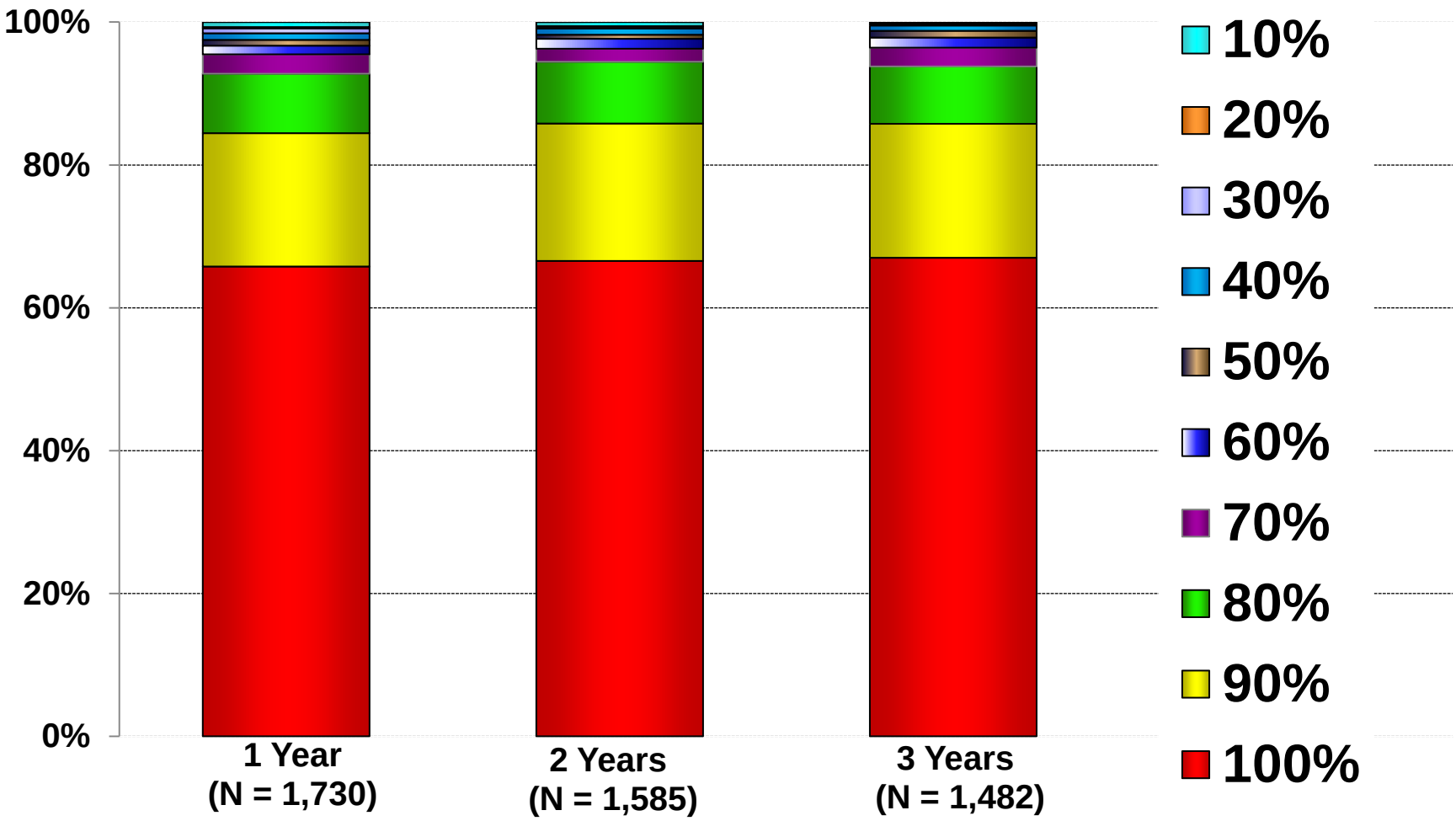
Kaplan-Meier Survival by Mechanical Circulatory Support Usage*

(Transplants: January 2009 – June 2013)



* LVAD, RVAD, TAH, ECMO

Pediatric Heart Transplants
Functional Status of Surviving Recipients
(Follow-ups: January 2009 – June 2014)



Conclusions

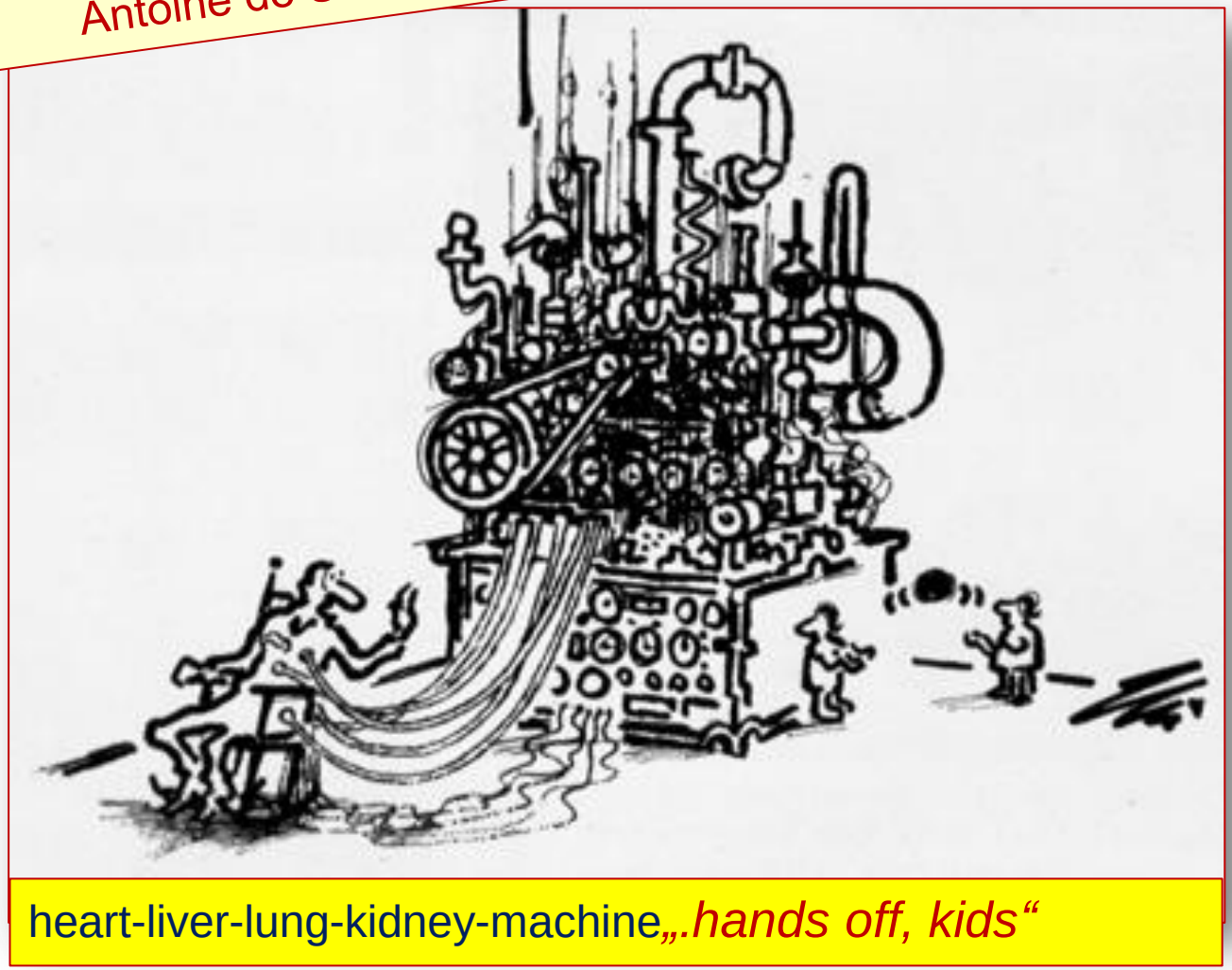
- Actually the Berlin Heart is the onliest long term VAD for infants
- Survival rate strongly depends on indication
- Bleeding and clotting are still severe problems
- Pediatric heart tranplantation is an option even for the smallest
- Long term survival after HTx in young children is better than in adults

MCS is teamwork!

“Whether you think you can or think you can't - you are right.”
(Henry Ford)

Perfection is achieved,
not when there is nothing more to add,
but when there is nothing left to take away.

Antoine de Saint-Exupéry



heart-liver-lung-kidney-machine*„.hands off, kids“*