SCDU DI CARDIOCHIRURGIA
Università degli Studi di Torino
Ospedale S. Giovanni Battista
Direttore: Prof. Mauro Rinaldi

How to mend a broken heart: transplantation or LVAD?

Massimo Boffini
Mauro Rinaldi

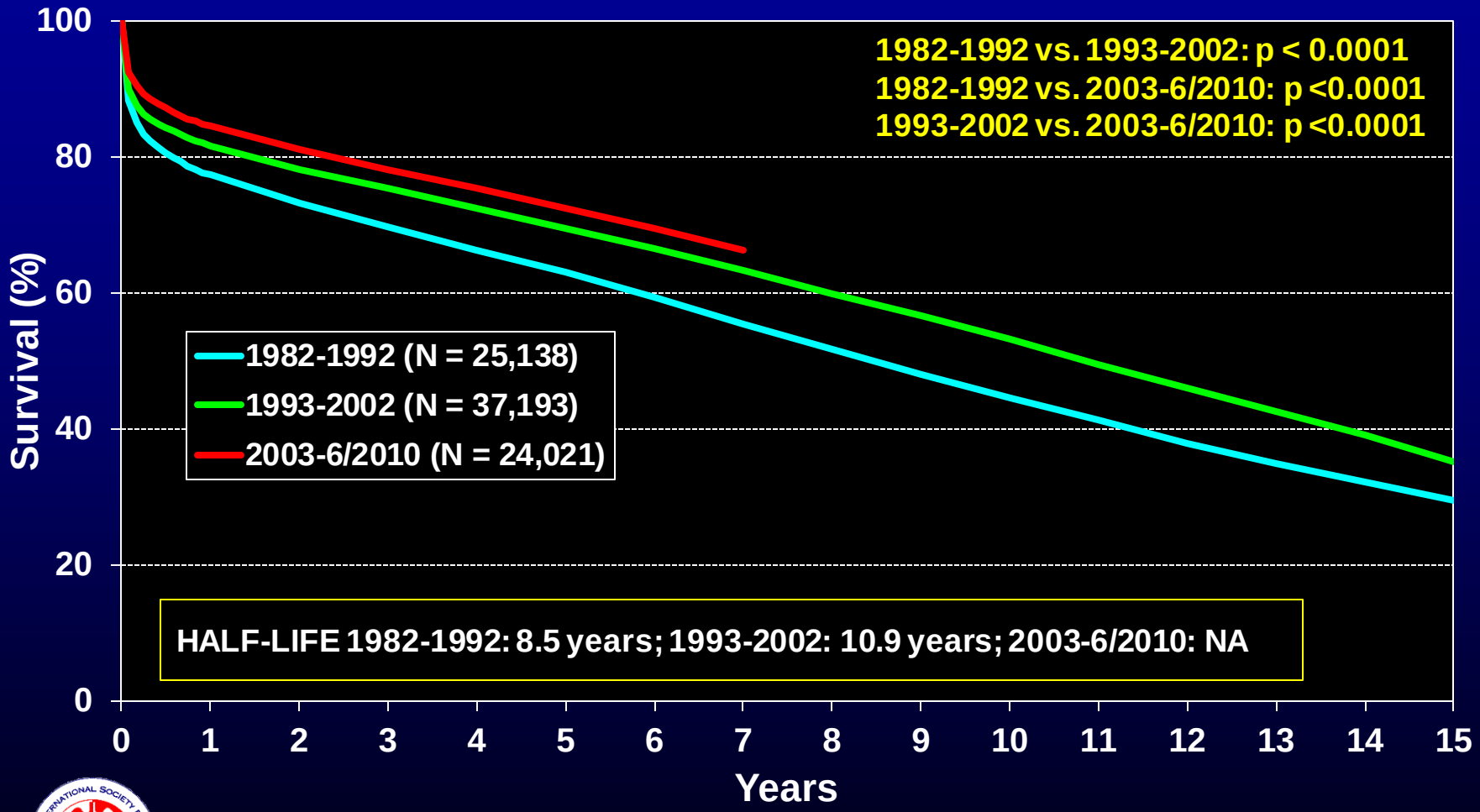
He who would know correctly beforehand those that will recover, and those who will die, and in what cases the disease will be protracted for many days, and in what cases for a shorter time, must be able to form a judgment for having made himself acquainted with all the symptoms, and estimating their powers in comparison with one another.

—Hippocrates

ADULT HEART TRANSPLANTS

Kaplan-Meier Survival by Era

(Transplants: January 1982 - June 2010)



ISHLT

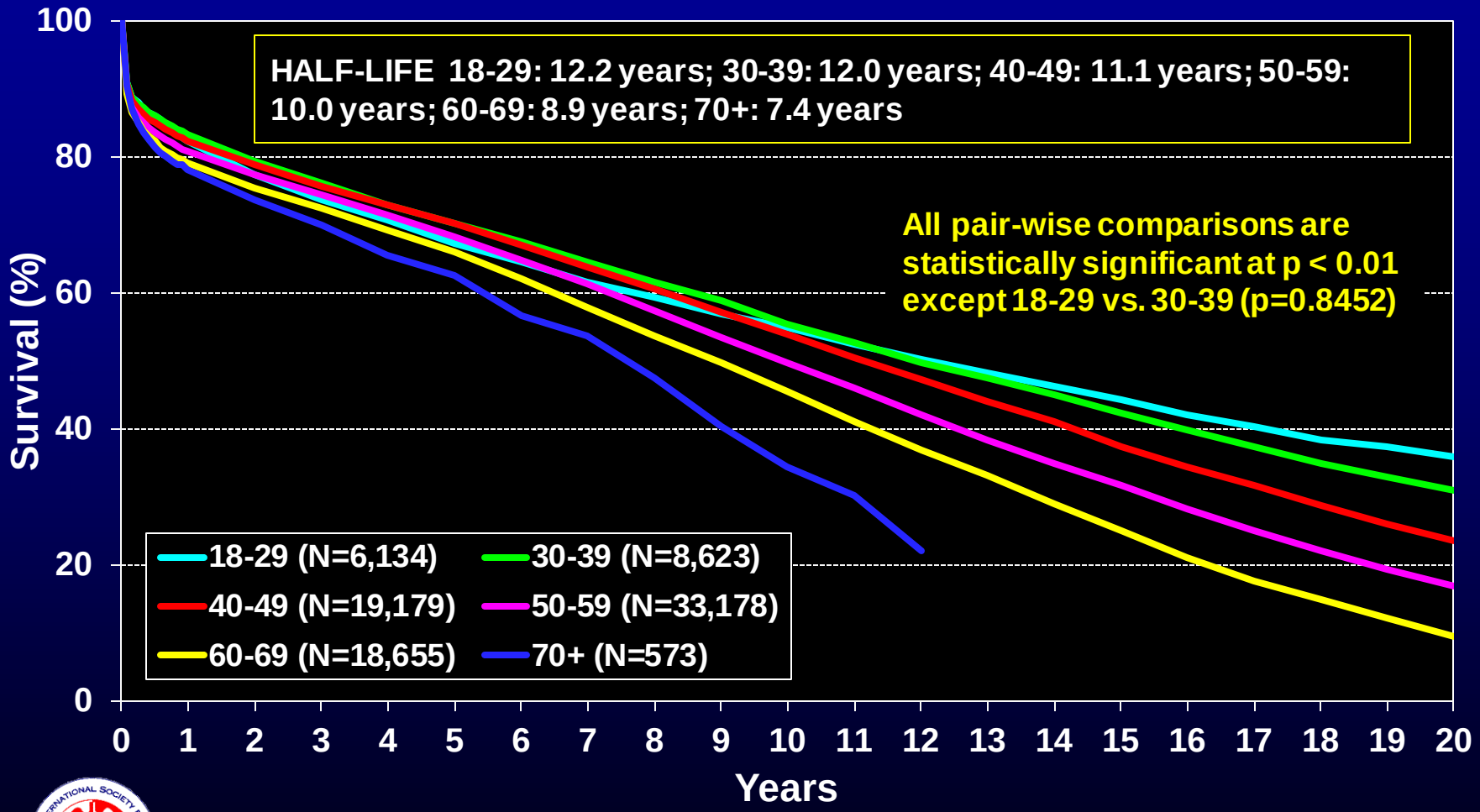
2012

J Heart Lung Transplant. 2012 Oct; 31(10): 1045-1095

ADULT HEART TRANSPLANTS

Kaplan-Meier Survival by Age Group

(Transplants: January 1982 - June 2010)



ISHLT

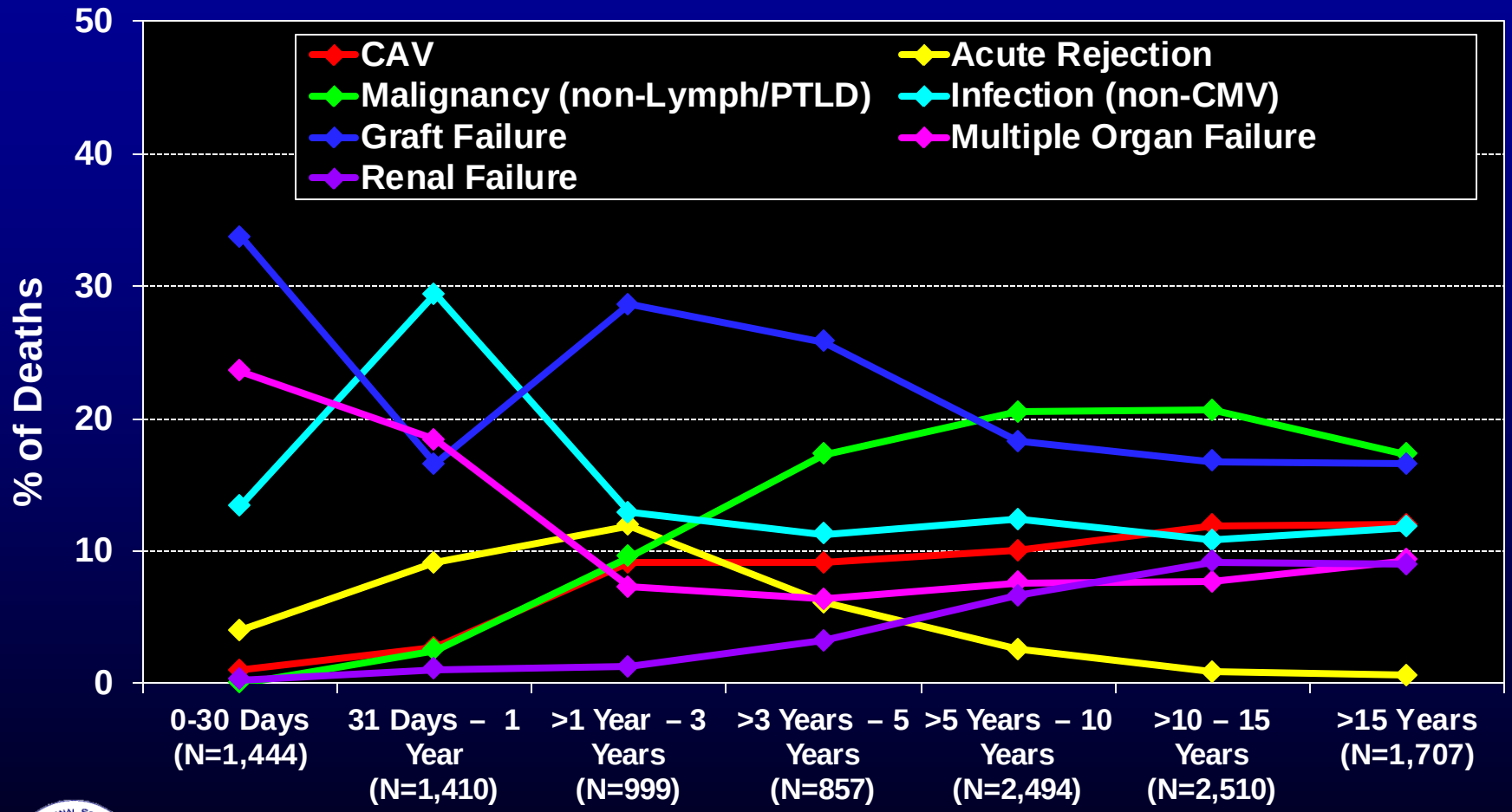
2012

J Heart Lung Transplant. 2012 Oct; 31(10): 1045-1095

ADULT HEART TRANSPLANT RECIPIENTS

Relative Incidence of Leading Causes of Death

(Deaths: January 2004 - June 2011)



ISHLT

2012

J Heart Lung Transplant. 2012 Oct; 31(10): 1045-1095

MALIGNANCY POST-HEART TRANSPLANTATION FOR ADULTS

Cumulative Prevalence in Survivors (Follow-ups: April 1994 - June 2006)

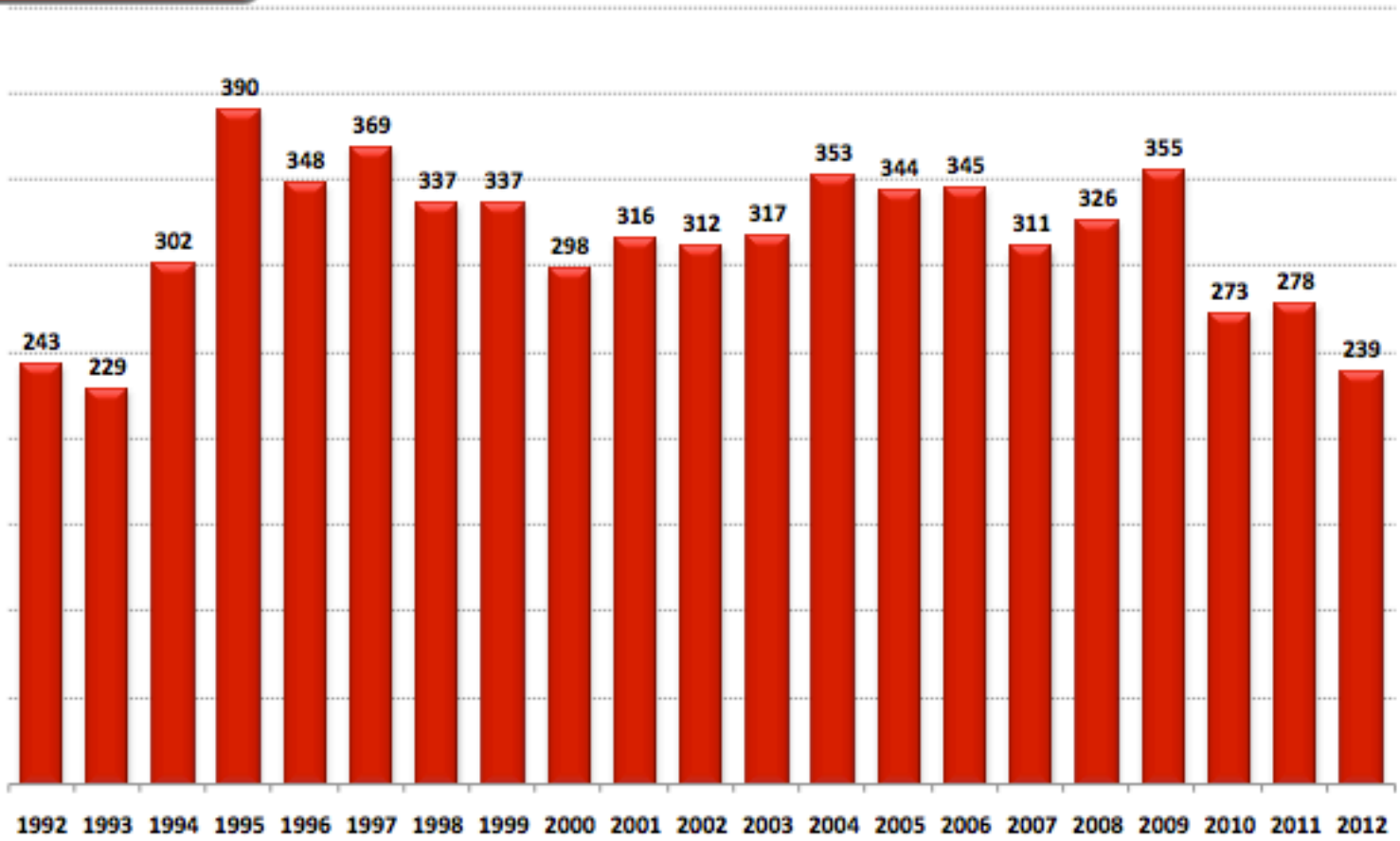
Malignancy/Type		1-Year Survivors	5-Year Survivors	10-Year Survivors
No Malignancy		20441 (97.1%)	7780 (84.9%)	1264 (68.1%)
Malignancy (all types combined)		612 (2.9%)	1389 (15.1%)	592 (31.9%)
Malignancy Type	*Skin*	*282*	*937*	*360*
	Lymph	*142*	*127*	*38*
	Other	*132*	*359*	*108*
	Type Not Reported	*56*	*39*	*126*

"Other" includes: prostate (11, 34, 17), adenocarcinoma (7, 4, 2), lung (5, 4, 1), bladder (4, 5, 4), sarcoma (3, 3, 1), breast (2, 8, 3), cervical (2, 4, 0), colon (2, 3, 1), and renal (2, 7, 2). Numbers in parentheses are those reported within 1 year, 5 years and 10 years, respectively.

ISHLT

Trapianti di CUORE – Anni 1992-2012*

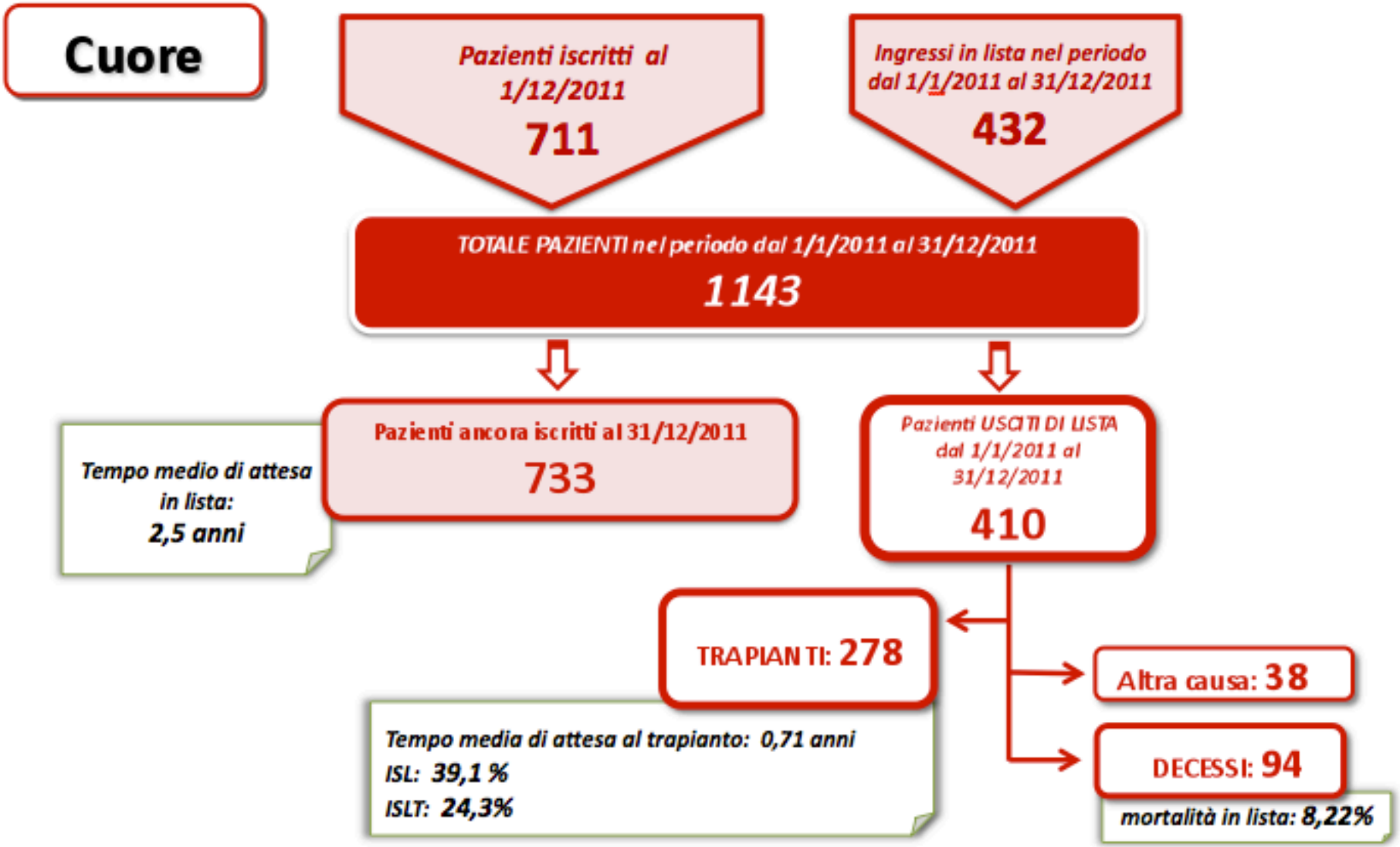
Incluse tutte le combinazioni



FONTE DATI : Reports CIR

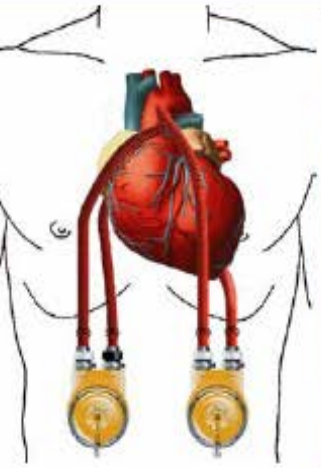
* Dati preliminari al 30 Giugno 2012

Flussi Lista di attesa 1/1/2011 – 31/12/2011



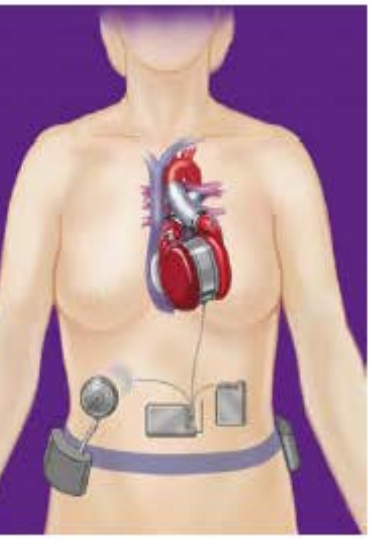
*ISL: numero TX/Numero iscritti inizio anno
**ISLT: numero TX/(Numero iscritti inizio anno+Ingressi)

* Dati SIT al 26 Febbraio 2012

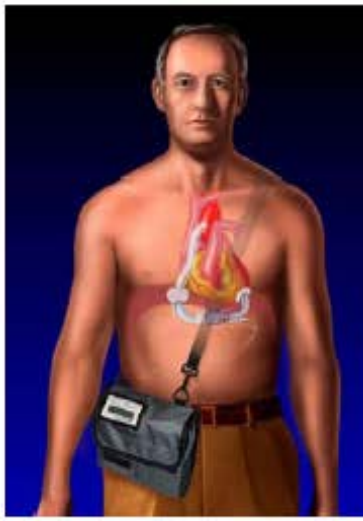















DECISION MAKING PROCESS

- Patient selection
- Time of implant
- Matching patient-disease/device
- Device selection
- Anticoagulation management

CRUCIAL ASPECTS

1. WHICH PATIENT
2. WHEN
3. WHICH DEVICE

CRUCIAL ASPECTS

1. WHICH PATIENT
2. WHEN
3. WHICH DEVICE

CRUCIAL ASPECTS

1. **WHICH PATIENT**
   - Type of heart disease
   - Hemodynamics
2. **WHEN**
3. **WHICH DEVICE**

ITT STRATEGY

- **Bridge to RECOVERY** (AHF due to myocarditis or AMI)
- **Bridge to SURGERY** (mechanical AMI complications)
- **Bridge to DECISION**
- **Bridge to TRANSPLANTATION**
  (End-stage Idiopathic or Ischemic Dilated Cardiomyopathy)
- **DESTINATION THERAPY** (HTx contraindication)

UNDERLYING HEART DISEASE

Long-term VAD

Bridge to TRANSPLANTATION*

DESTINATION THERAPY

Short-term VAD

Bridge to RECOVERY, SURGERY, DECISION*

***BTT** **listed likely moderate unlikely**

VAD Implant Strategy:
Static or Dynamic?

BTT patients always includes 4 categories:

Listed
Likely to be listed
Moderately likely to be listed
Unlikely to be listed

Unknown patients!!

Critical patient is frequently **"unknown patient"**

VAD is a **dynamic** state during which recipients undergo frequent re-evaluation

CRUCIAL ASPECTS

1. IN WHICH PATIENT
2. **WHEN**
3. WHICH DEVICE

INTERMACS: Patient Selection

Patient Profile/Status: INTERMACS Levels

Critical cardiogenic shock (“crash and burn”)

SHORT TERM

Progressive decline (“sliding fast”)

Stable but inotrope dependent (stable but dependent)

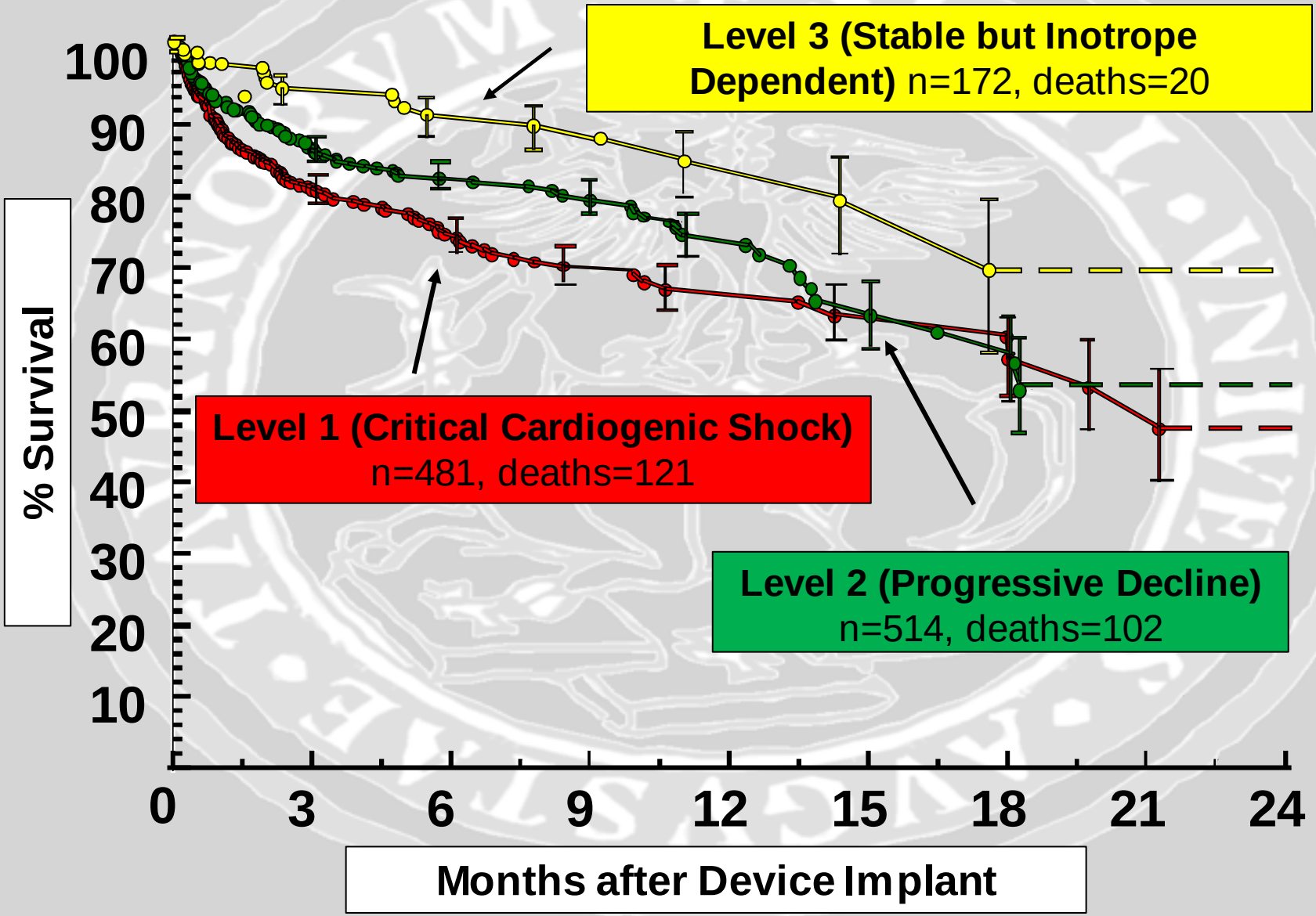
Recurrent advanced HF (“frequent flyer”)

Exertion intolerant

Exertion limited (“walking wounded”)

Advanced NYHA III

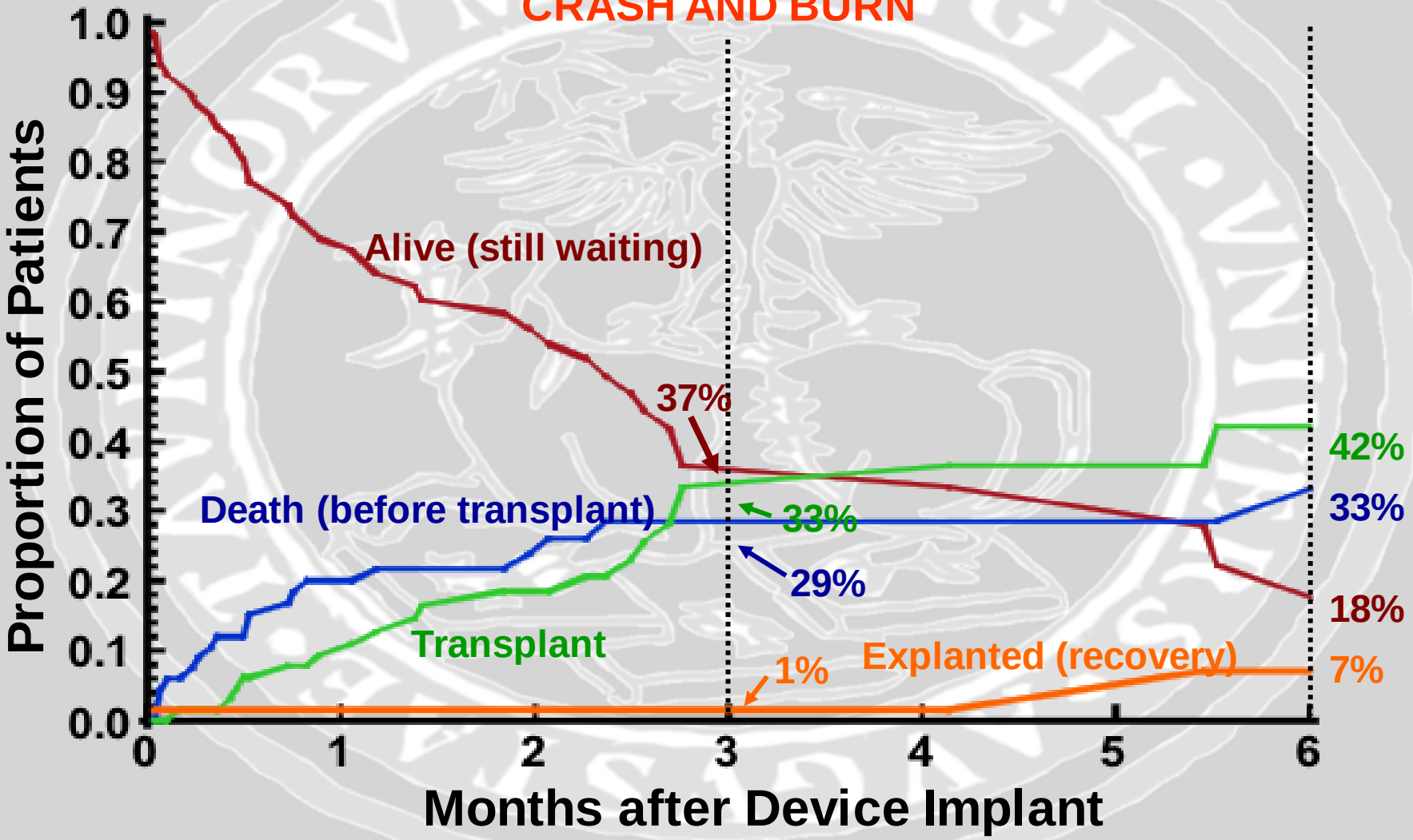
INTER*MACS*: Survival Curves



INTERMACS COMPETING OUTCOMES

Prospective Patients: INTERMACS Level I

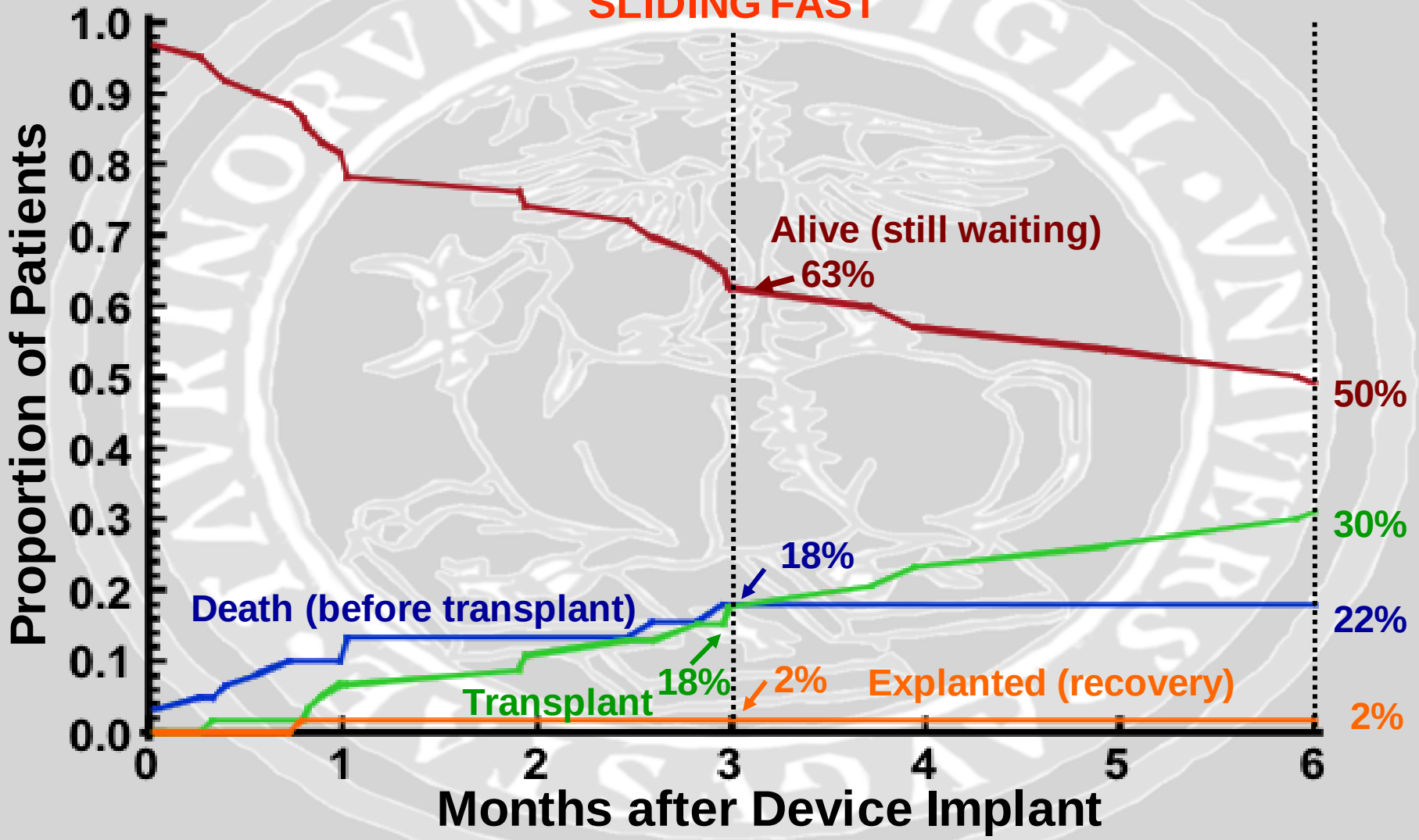
CRASH AND BURN



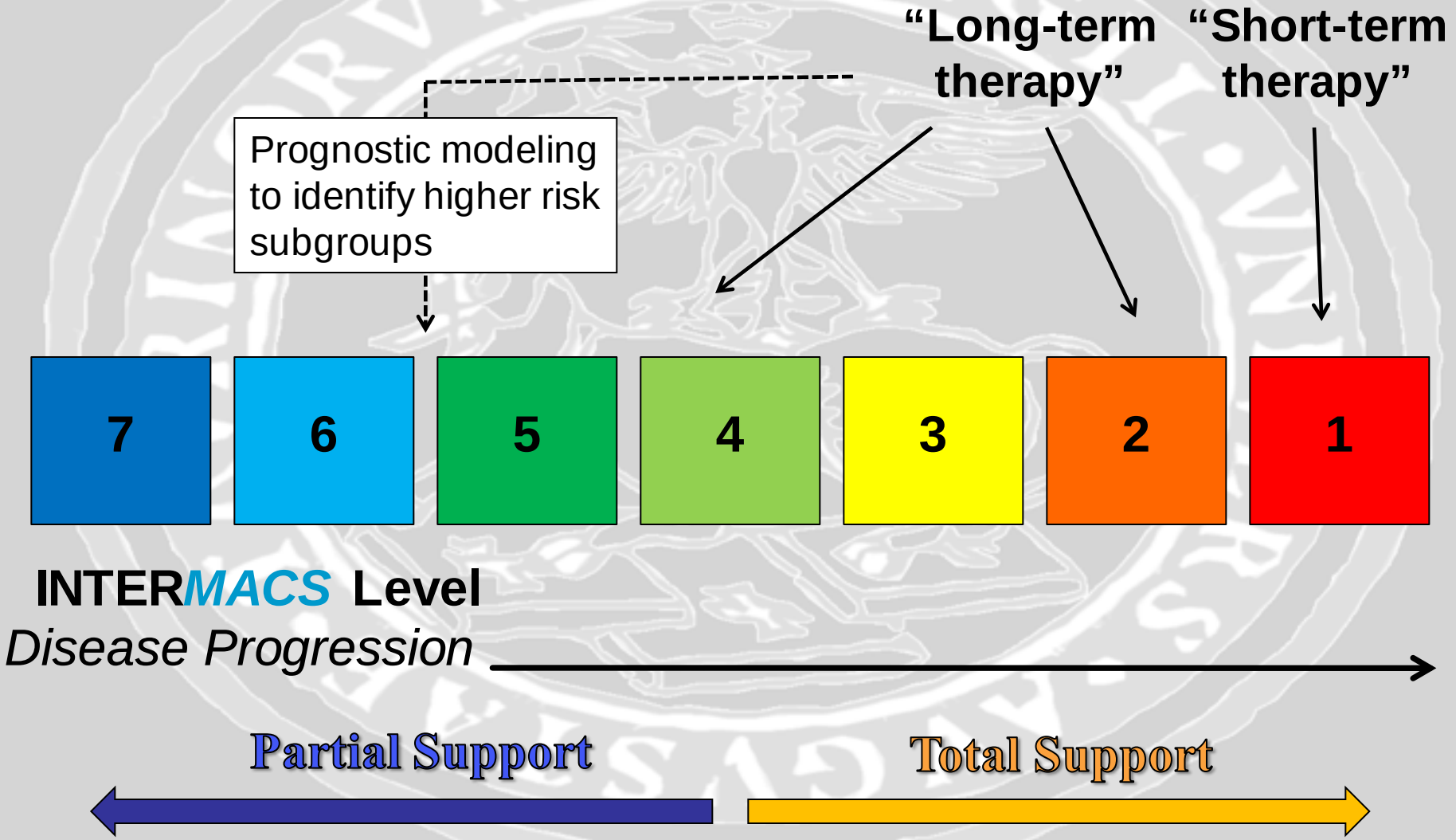
INTERMACS: COMPETING OUTCOMES

Prospective Patients: INTERMACS Level II

SLIDING FAST

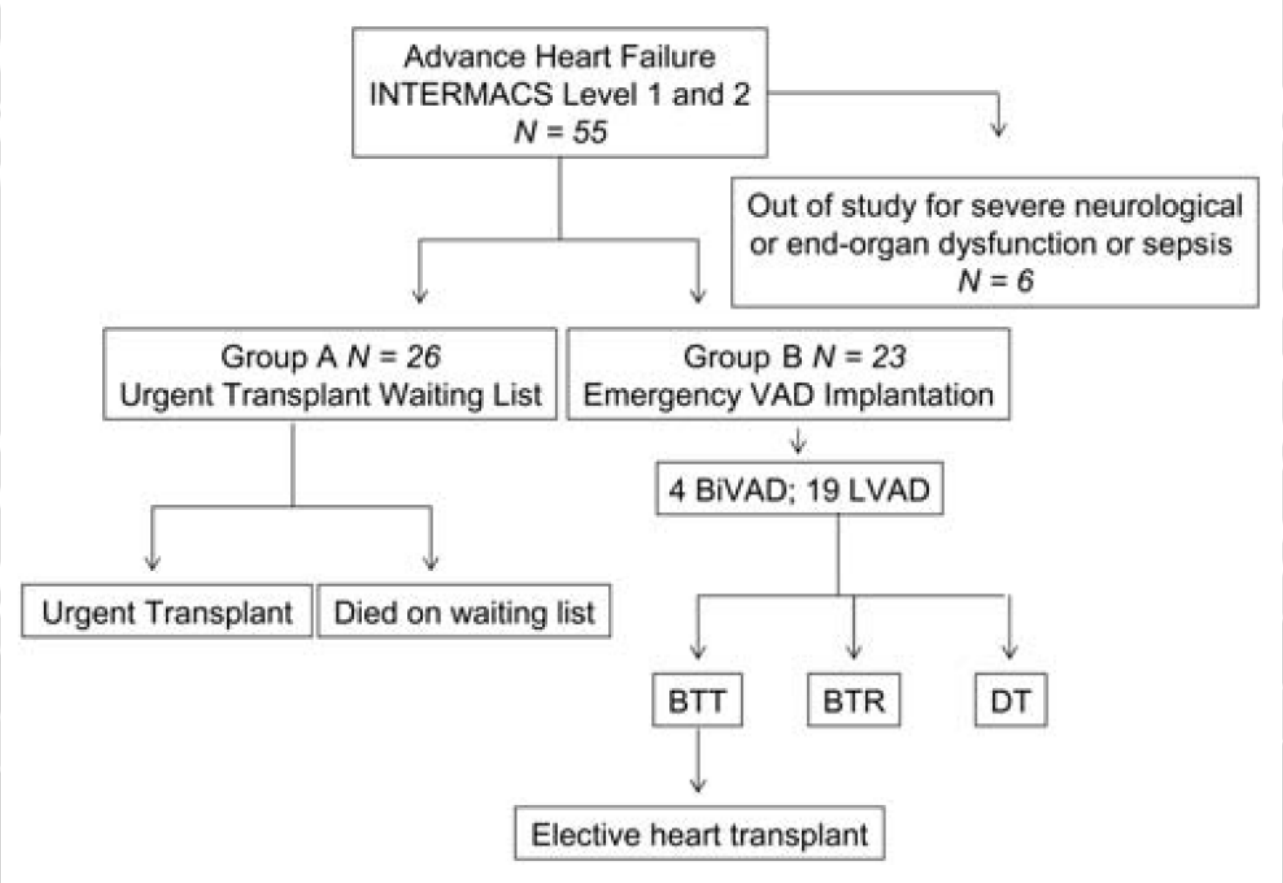


Optimal Time of VAD Implantation



Advanced heart failure in critical patients (INTERMACS 1 and 2 levels): ventricular assist devices or emergency transplantation?†

Matteo Attisani[a,*], Paolo Centofanti[a], Michele La Torre[a], Massimo Boffini[a], Davide Ricci[a,b], Marco Ribezzo[a], Andrea Baronetto[a] and Mauro Rinaldi[a]



Interactive CardioVascular and Thoracic Surgery 15 (2012) 678–684

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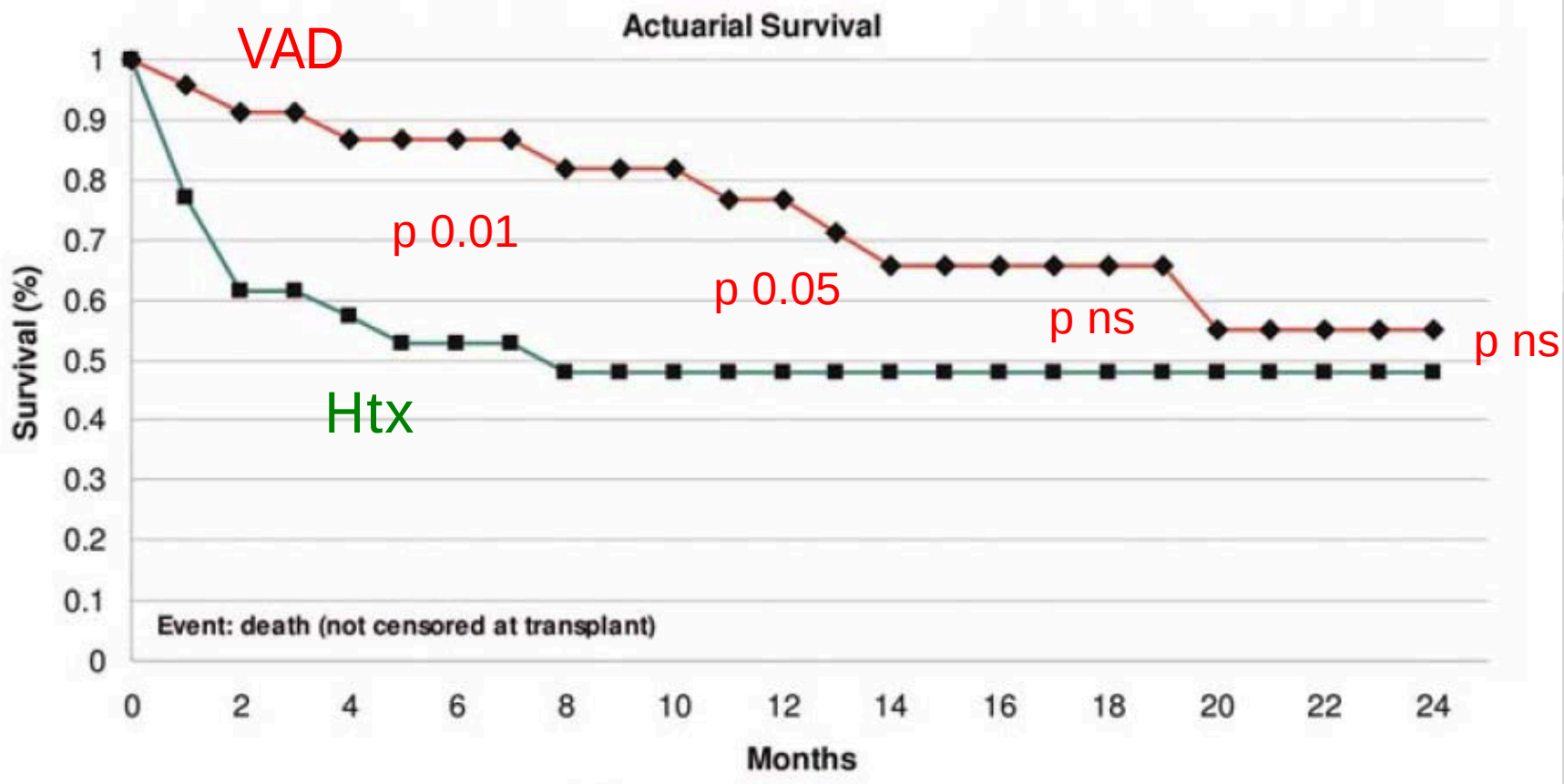

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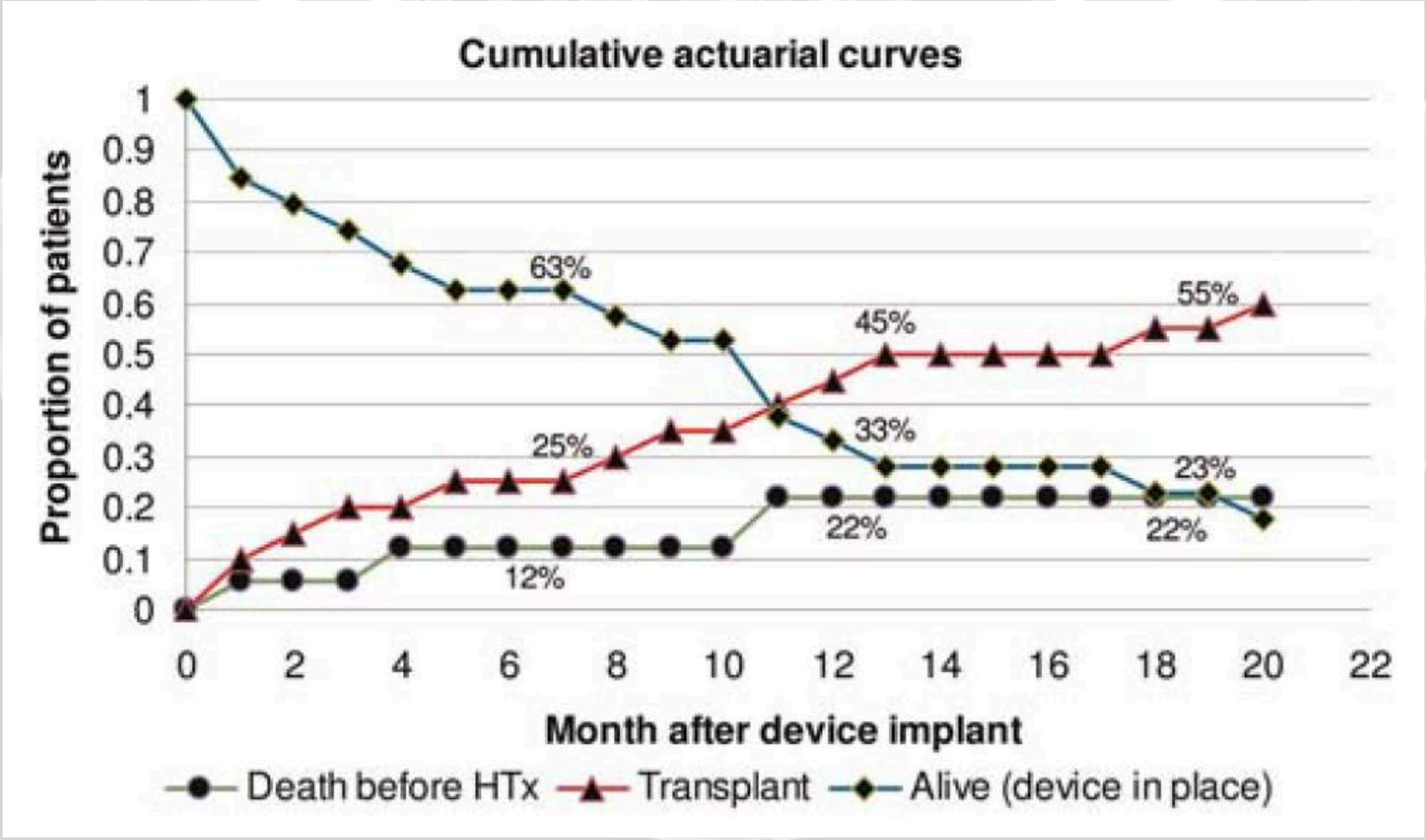


Interactive CardioVascular and Thoracic Surgery 15 (2012) 678–684

Table 1: Preoperative characteristics of patients

Baseline characteristics	Group A (urgent transplant waiting list) (mean ± SD or %)	Group B (urgent VAD implant) (mean ± SD or %)	*P* value
Age (years)	52.6 ± 11.3	50.4 ± 14.0	0.10
Body mass index (kg/m^2)	24.79 ± 4.44	24.84 ± 4.83	0.97
Male	(18/26) 69.2%	(19/23) 82.6%	0.30
INTERMACS level 1	(18/26) 69.2%	(12/23) 52.2%	0.24
Dialysis	(8/26) 30.8%	(4/23) 17.4%	0.30
Mechanical ventilation	(19/26) 73.1%	(14/23) 60.8%	0.38
Haemodynamic profiles			
LVEF (%)	20.71 ± 9.05	15.61 ± 5.39	**0.04**
Cardiac output (l/min)[a]	3.36 ± 0.96	3.46 ± 0.74	0.71
Cardiac index (l/min/m^2)[a]	1.90 ± 0.43	2.03 ± 0.40	0.31
Wedge pressure (mmHg)	18.63 ± 6.34	21.44 ± 5.41	0.13
SVO_2	63.29 ± 12.60	61.22 ± 7.77	0.53
Pulmonary artery pressure (mmHg)			
Systolic	38.11 ± 8.08	37.18 ± 7.89	0.70
Diastolic	22.11 ± 7.54	23.35 ± 5.62	0.55
Mean	28.26 ± 7.01	28.76 ± 5.91	0.80
Pulmonary vascular resistance (Wood's Units)	2.99 ± 1.31	2.25 ± 1.05	**0.05**
Transpulmonary gradient (mmHg)	9.36 ± 3.88	7.29 ± 3.53	0.07
Central venous pressure (mmHg)	14.43 ± 4.90	12.89 ± 3.69	0.26
RVSWI (g m/m^2/beat)	5.20 ± 4.11	7.52 ± 2.01	**0.03**
Tricuspid regurgitation ≥ 3+	(8/26) 30.8%	(5/23) 22.5%	0.73
TAPSE	13.95 ± 3.15	13.72 ± 3.71	0.82
Haemodynamics supported with device			
IABP	(10/26) 38.4%	(8/23) 34.8%	0.80
ECMO	(12/26) 46.1%	(5/23) 21.7%	0.08
Albumin serum (g/dl)	2.76 ± 0.42	2.87 ± 0.47	0.41
AST	448.73 ± 832.75	150.17 ± 220.81	0.14
ALT	395.77 ± 718.76	293.22 ± 525.64	0.6
Total bilirubin (mg/dl)	2.96 ± 3.17	1.73 ± 0.94	0.12
BUN (mg/dl)	106.00 ± 68.11	76.11 ± 38.80	0.10
Creatinine serum (mg/dl)	2.19 ± 1.48	1.46 ± 0.60	**0.05**
INR	1.73 ± 0.81	1.46 ± 0.33	0.19
LDH (mg/dl)	1979.64 ± 2206.64	974.83 ± 556.32	0.07
Haemoglobin (g/dl)	10.75 ± 1.83	10.74 ± 1.92	0.99
Haematocrit (%)	32.50 ± 5.69	33.21 ± 6.19	0.69
Leukocytes (×1000)/ml	12.90 ± 4.74	13.32 ± 3.98	0.76
Platelets (×1000/ml)	156.50 ± 119.59	160.72 ± 117.65	0.91

ALT: alanine aminotransferase; AST: aspartate aminotransferase; BUN: blood urea nitrogen; ECMO: extracorporeal membrane oxygenation; IABP: intra-aortic balloon pump; INR: international normalized ratio; LDH: lactate dehydrogenase; LVEF: left ventricular ejection fraction; RVSWI: right ventricular stroke work index; SVO2: oxygen venous mixed saturation; TAPSE: tricuspid annular plane systolic excursion; VAD: ventricular assist device.

CRUCIAL ASPECTS

1. WHICH PATIENT
2. WHEN
3. **WHICH DEVICE**

PATIENT/DEVICE MATCHING

- Reversibility of heart dysfunction
- Degree of left and right dysfunction
- Expected duration of support
- Type of support
- Patient syze
- Age
- Severity of comorbidities

LONG-TERM VADS

5° Generation

4° Generation

3° Generation

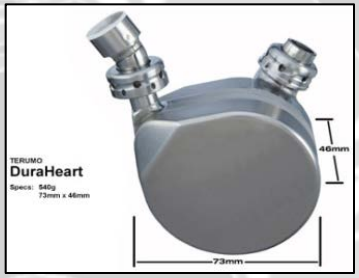
2° Generation

1° Generation

92 gr

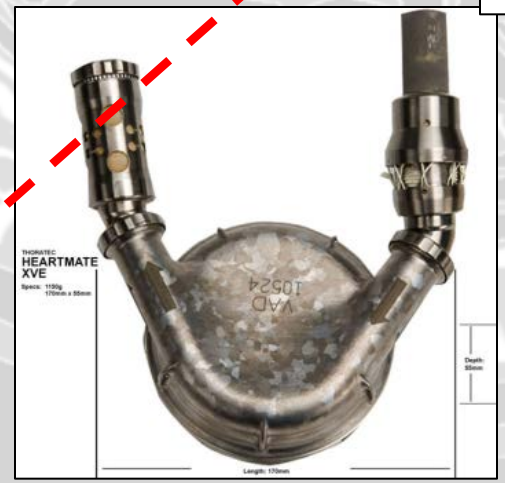
100 gr

500 gr



300 gr

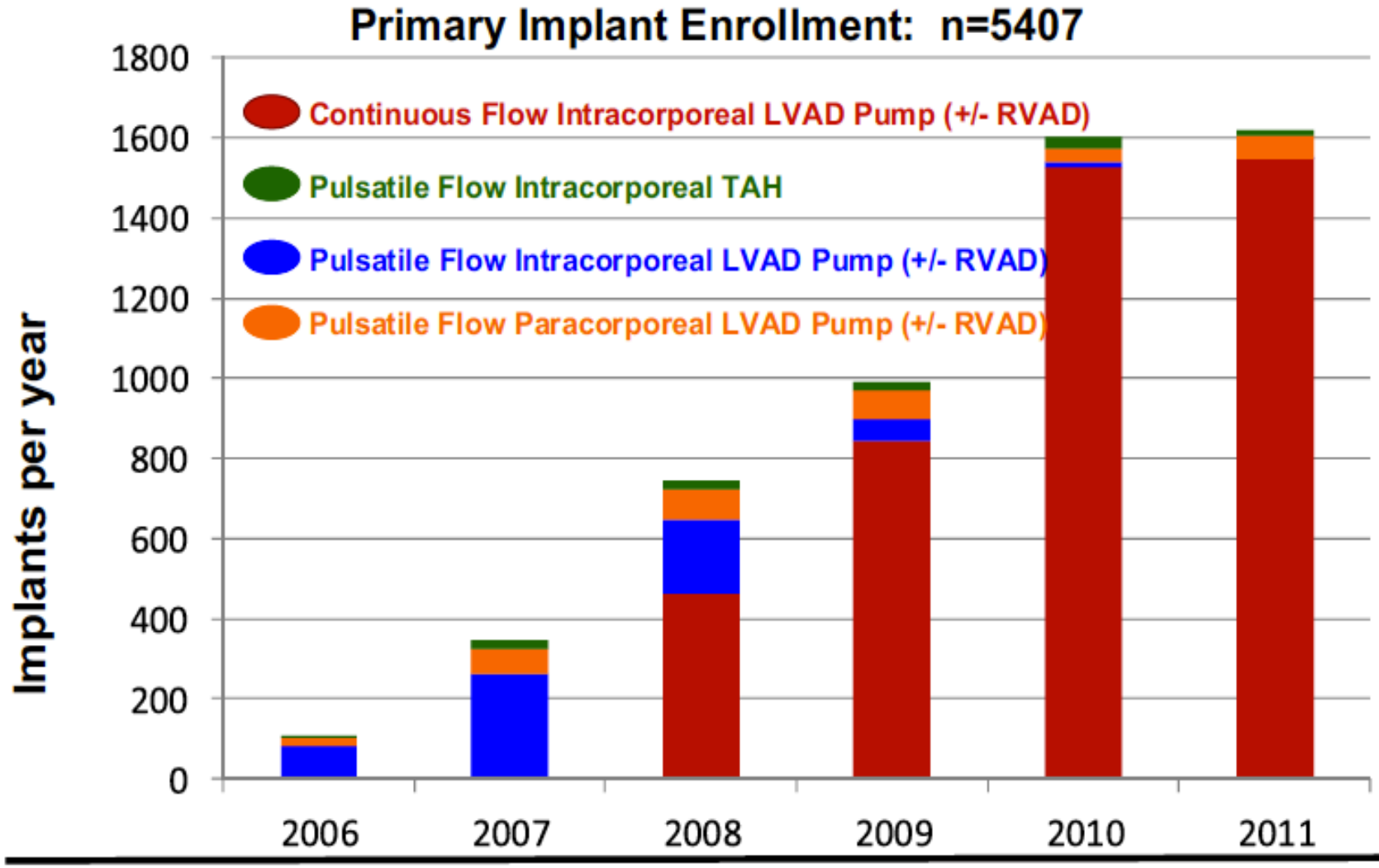
100 gr



750 grammi

1000 grammi

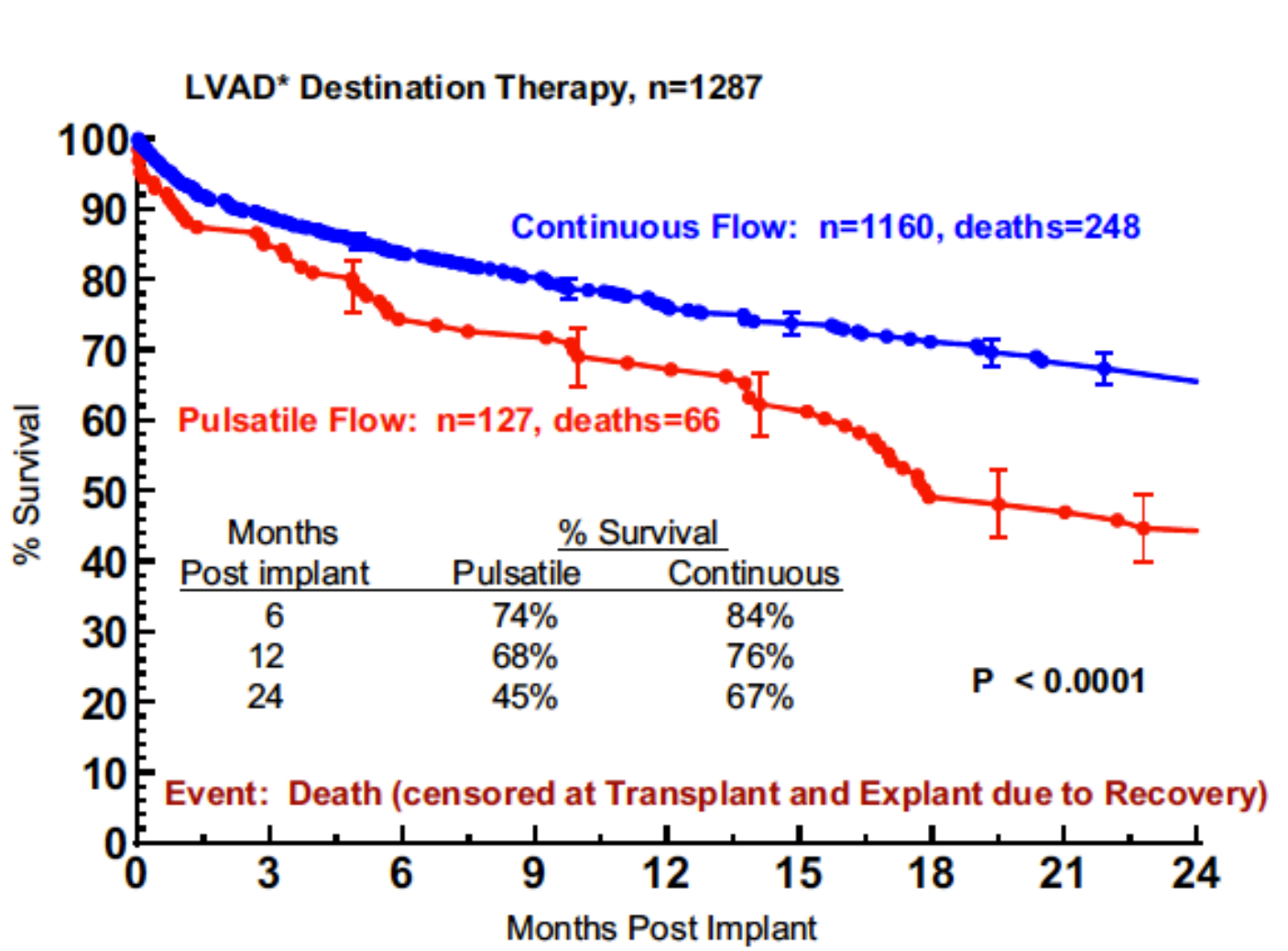
INTER*MACS*



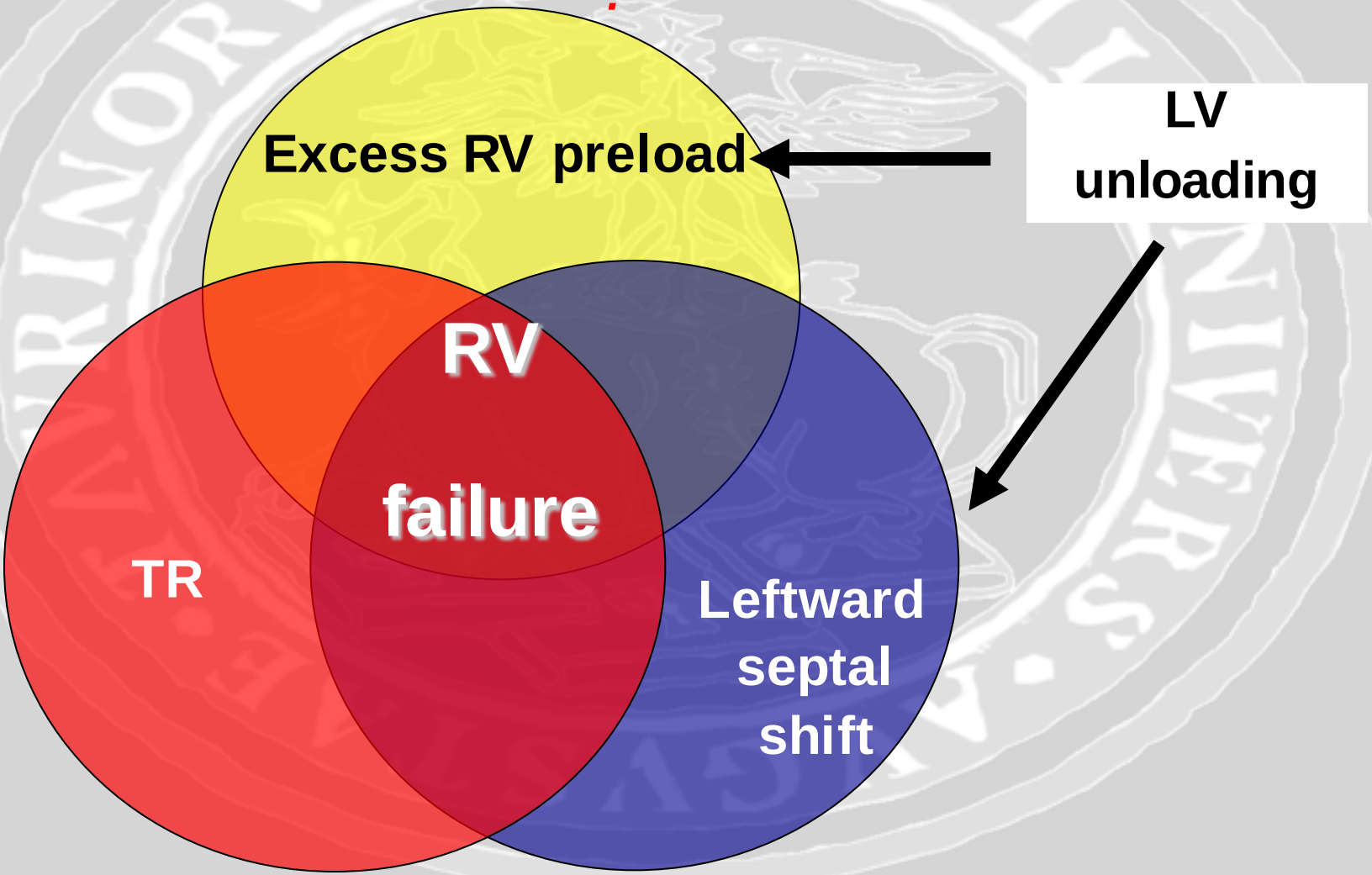
	2006	2007	2008	2009	2010	2011
Cont Intra Pump	1	1	464	843	1526	1548
Puls Intra TAH	2	22	22	24	27	15
Puls Intra Pump	82	263	183	55	12	2
Puls Para Pump	18	61	74	71	36	55

INTER*MACS*

CONTINUOUS VS PULSATILE FLOW



VENTRICULAR INTERDEPENDANCE: the vicious cycle



The Right Ventricular Failure Risk Score

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

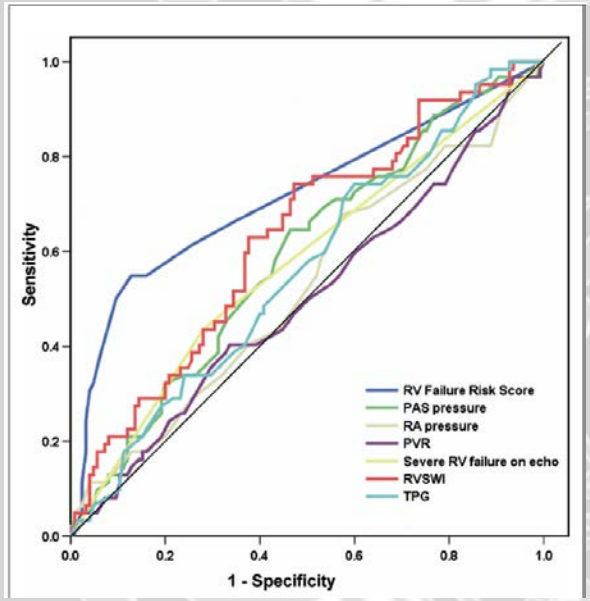
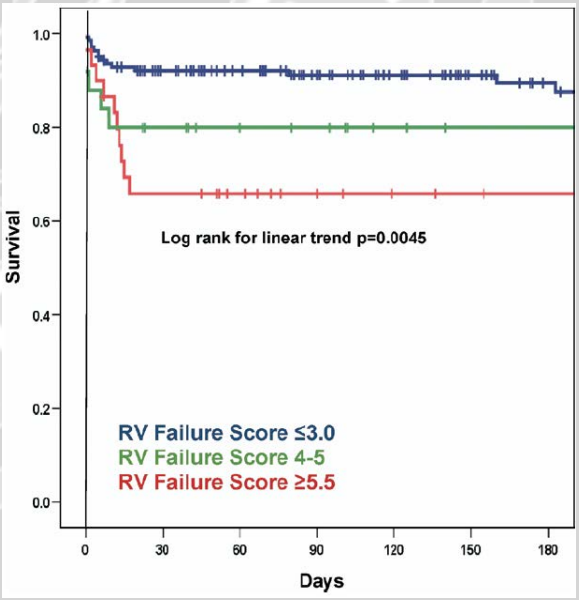


Table 6 Right Ventricular Failure Risk Score and Likelihood of RV Failure by Score Strata

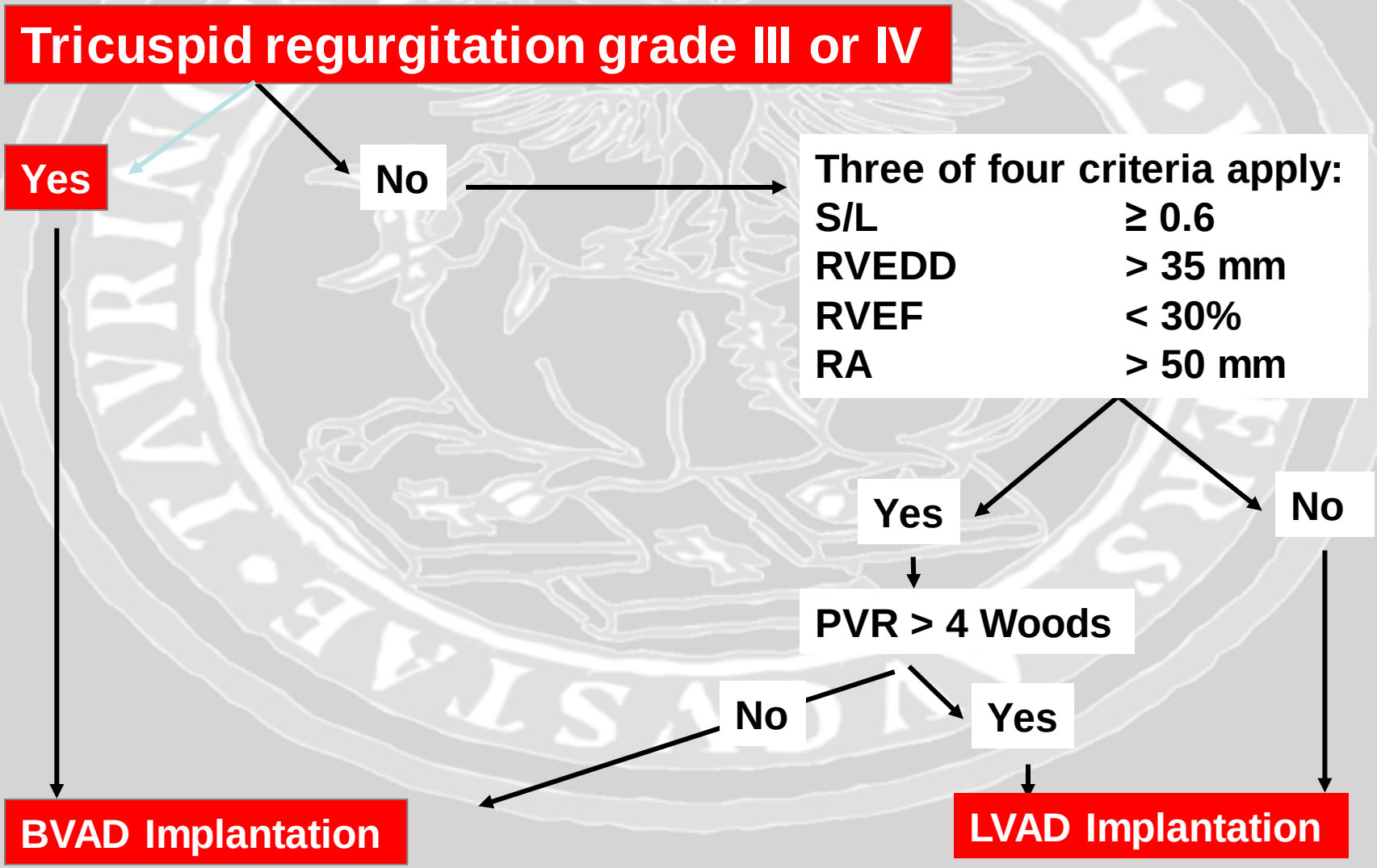
Risk Score	n	RV Failure (n)	No RV Failure (n)	Likelihood Ratio (95% CI)
≤3.0	142	29	113	0.49 (0.37–0.64)
4.0–5.0	25	15	10	2.8 (1.4–5.9)
≥5.5	30	24	6	7.6 (3.4–17.1)

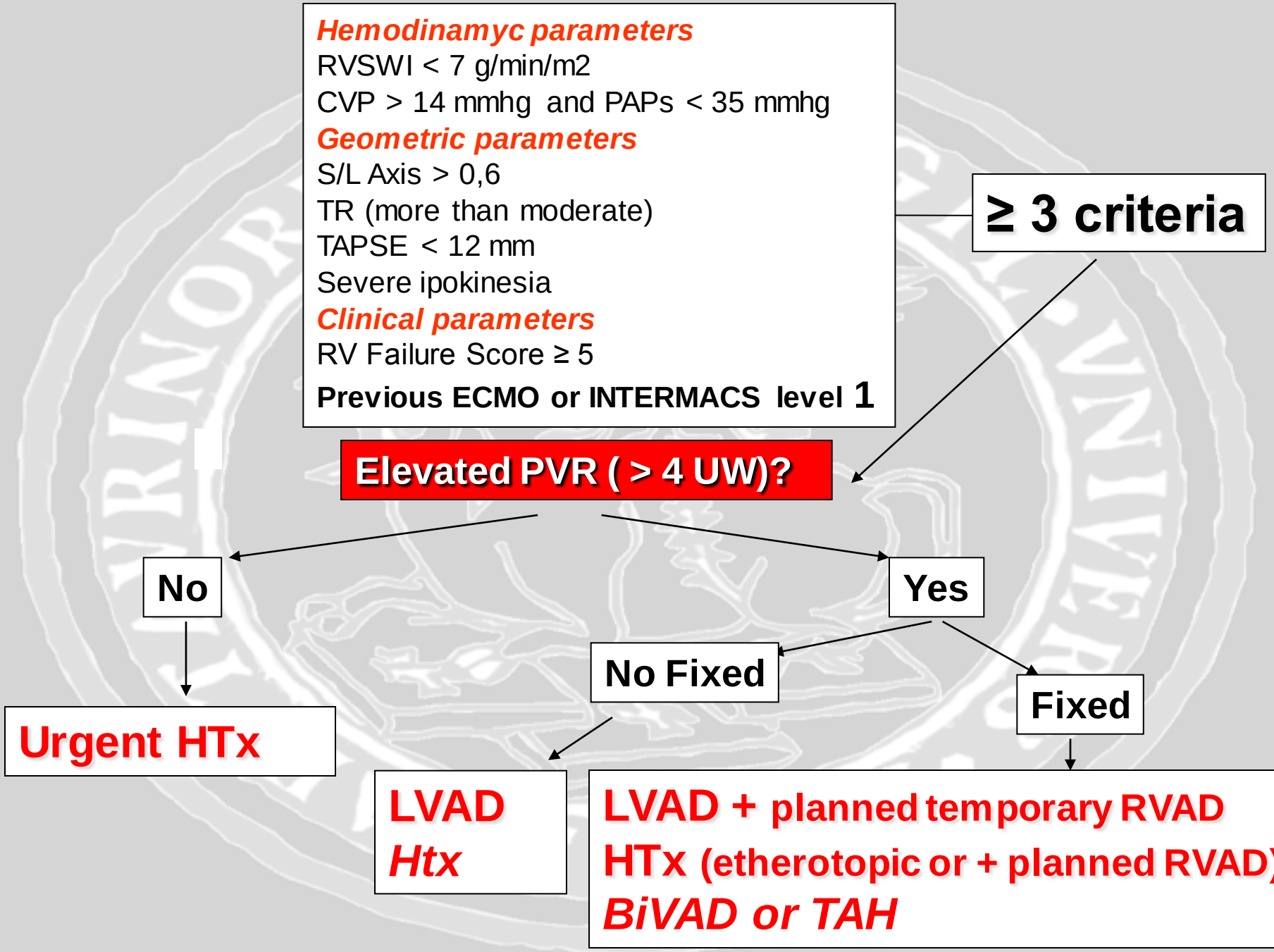
Pre-implant Vasopressor	**4**	**points**
AST > 80 IU/l	**2**	**points**
Bilirubin > 2 mg/dl	**2,5**	**points**
Creatinine > 2,3 mg/dl	**3**	**points**



Tricuspid Incompetence and Geometry of the Right Ventricle as Predictors of Right Ventricular Function After Implantation of a Left Ventricular Assist Device

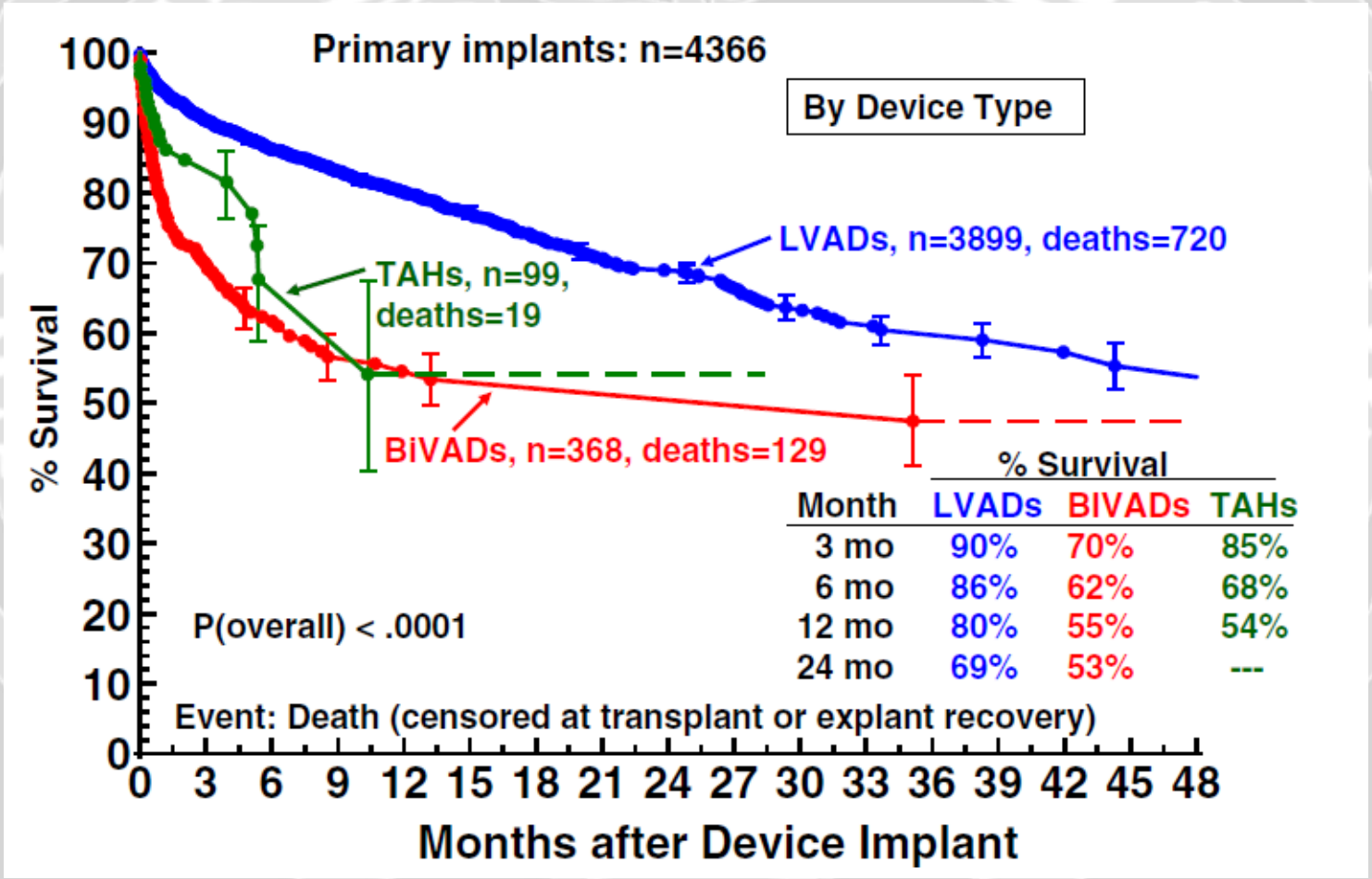
Evgenij V. Potapov, MD,[a] Alexander Stepanenko, MD,[a] Michael Dandel, MD, PhD,[a] Marian Kukucka, MD,[b] Hans B. Lehmkuhl, MD,[a] Yuguo Weng, MD, PhD,[a] Felix Hennig, MD,[a] Thomas Krabatsch, MD, PhD,[a] and Roland Hetzer, MD, PhD[a]




Hemodinamyc parameters
RVSWI < 7 g/min/m2
CVP > 14 mmhg and PAPs < 35 mmhg
Geometric parameters
S/L Axis > 0,6
TR (more than moderate)
TAPSE < 12 mm
Severe ipokinesia
Clinical parameters
RV Failure Score ≥ 5
Previous ECMO or INTERMACS level 1
≥ 3 criteria
Elevated PVR (> 4 UW)?
No
Yes
Urgent HTx
No Fixed
Fixed
LVAD
Htx
LVAD + planned temporary RVAD
HTx (etherotopic or + planned RVAD)
BiVAD or TAH

INTER*MACS*

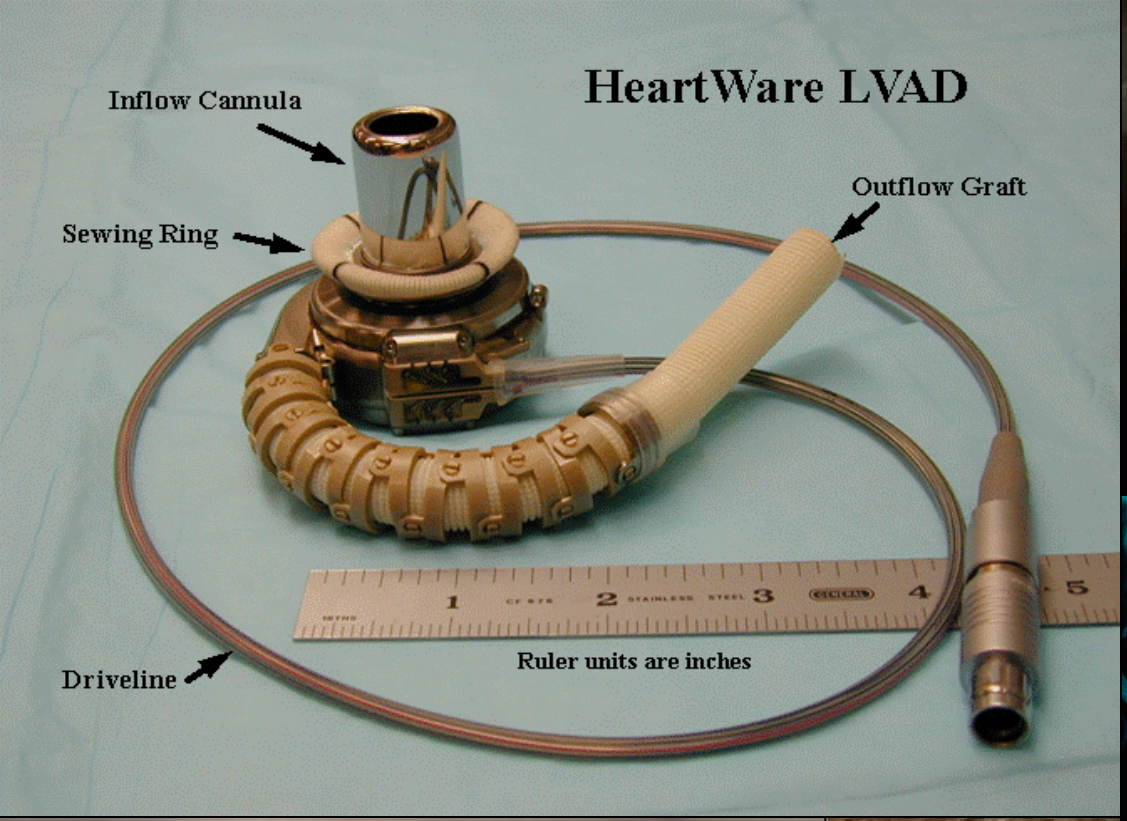
LVAD vs BIVAD

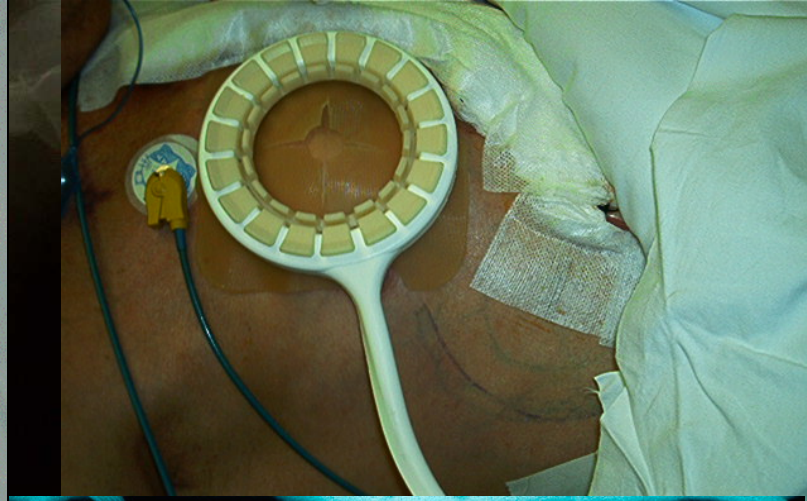


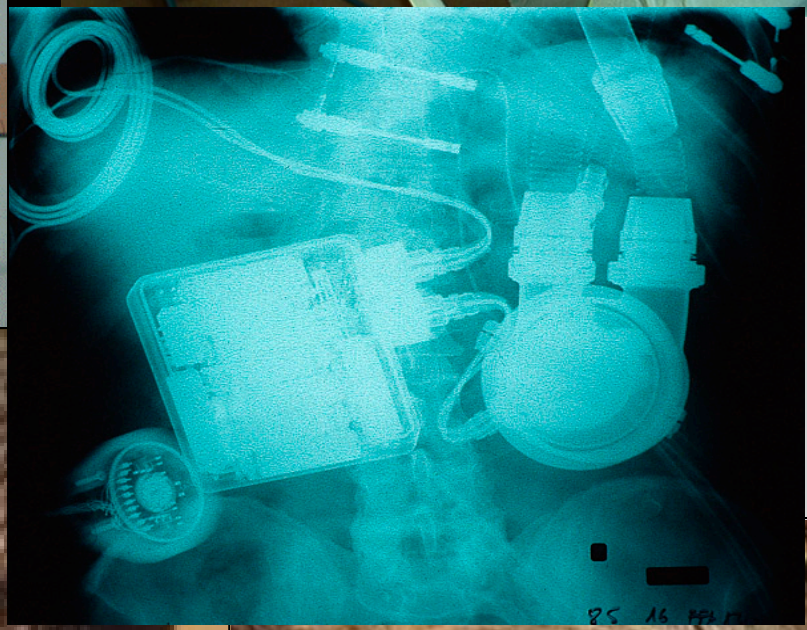
INTERMACS: June 23, 2006 – September 30, 2008

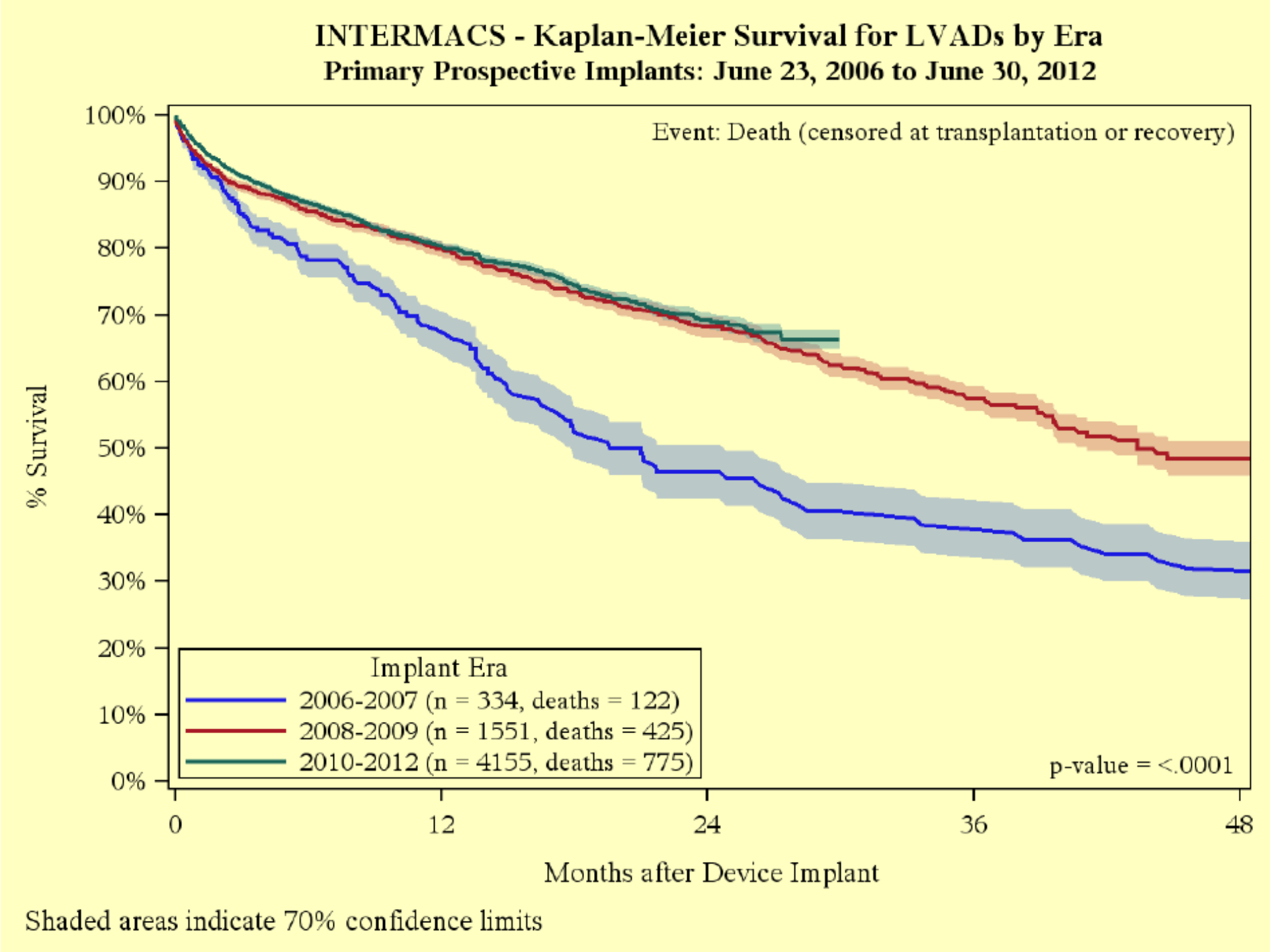
LVAD: Total Patients (n=712)

Adverse Events	Episodes (Pts)	< 30 days (pt)	≥ 30 days (pt)
Device Malfunction	116 (83)	19 (15)	97 (68)
Bleeding	652 (250)	377 (205)	264 (35)
Cardiac/Vascular			
Right Heart Failure	74 (71)	57 (57)	15 (12)
Myocardial Infarction	3 (3)	3 (3)	0 (0)
Cardiac Arrhythmia	232 (142)	169 (112)	62 (29)
Pericardial Drainage	59 (48)	49 (41)	8 (5)
Hypertension	138 (88)	40 (36)	98 (52)
Arterial Non-CNS Thromb	12 (11)	8 (8)	4 (3)
Venous Thromb Event	59 (48)	41 (35)	13 (8)
Hemolysis	19 (18)	4 (4)	15 (14)
Infection	687 (241)	262 (155)	424 (85)
Neurological Dysfunction	135 (105)	68 (60)	67 (45)
Renal Dysfunction	100 (78)	75 (60)	17 (11)
Hepatic Dysfunction	46 (39)	23 (23)	23 (16)
Respiratory Failure	190 (135)	133 (100)	42 (26)
Other			
Wound Dehiscence	20 (16)	9 (8)	10 (7)
Psychiatric Episode	85 (72)	34 (33)	51 (39)
Other AEs	328 (191)	111 (74)	217 (117)
Total AEs (prospective)	2955 (503)		

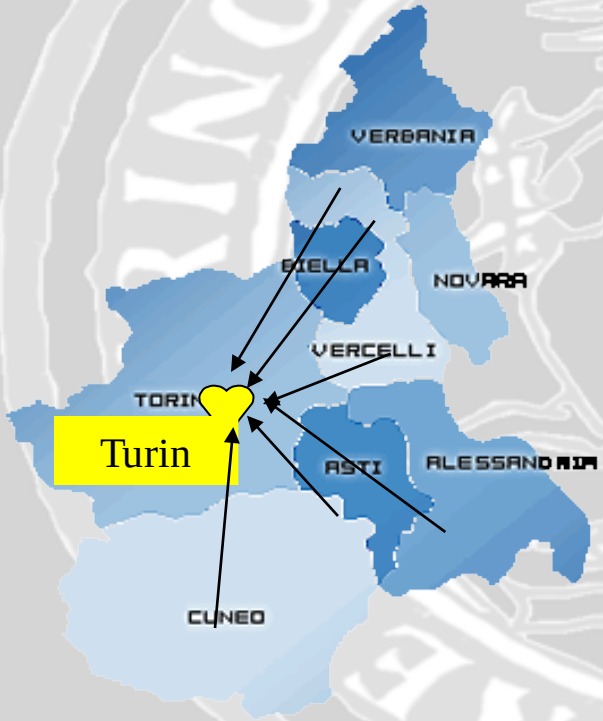

HeartWare LVAD
Inflow Cannula
Outflow Graft
Sewing Ring
Driveline
Ruler units are inches






INTERMACS - Kaplan-Meier Survival for LVADs by Era
Primary Prospective Implants: June 23, 2006 to June 30, 2012
Event: Death (censored at transplantation or recovery)
% Survival
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
12
24
36
48
Months after Device Implant
Implant Era
2006-2007 (n = 334, deaths = 122)
2008-2009 (n = 1551, deaths = 425)
2010-2012 (n = 4155, deaths = 775)
p-value = <.0001
Shaded areas indicate 70% confidence limits

REGIONAL NETWORK

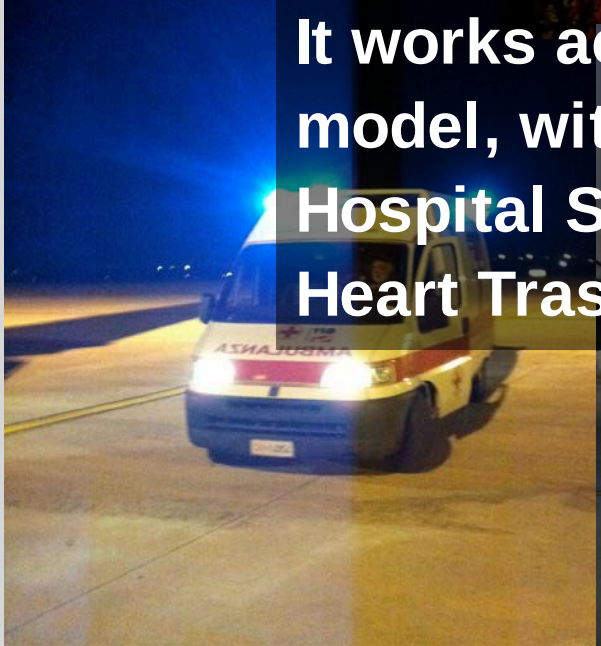


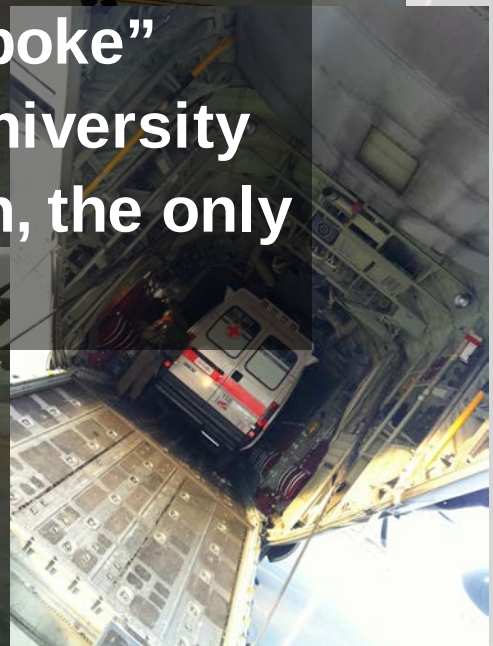
The Ventricular Assist Device program has been instituted in Turin in **2006**.

It is integrated with the **Heart Transplant Program** and it was conceived as an answer to the increasing demand of chronic and acute heart failure therapy

“Hub and Spoke” model

It works according to an “hub and spoke” model, with the hub located at the University Hospital S. Giovanni Battista in Turin, the only Heart Trasplant Center of our region





SPOKE Center

I Level

ICU

Trombolisi + IABP

II Level

ICU +
Cath + Surg

IABP + Angiography
PTCA / CABG / ECMO

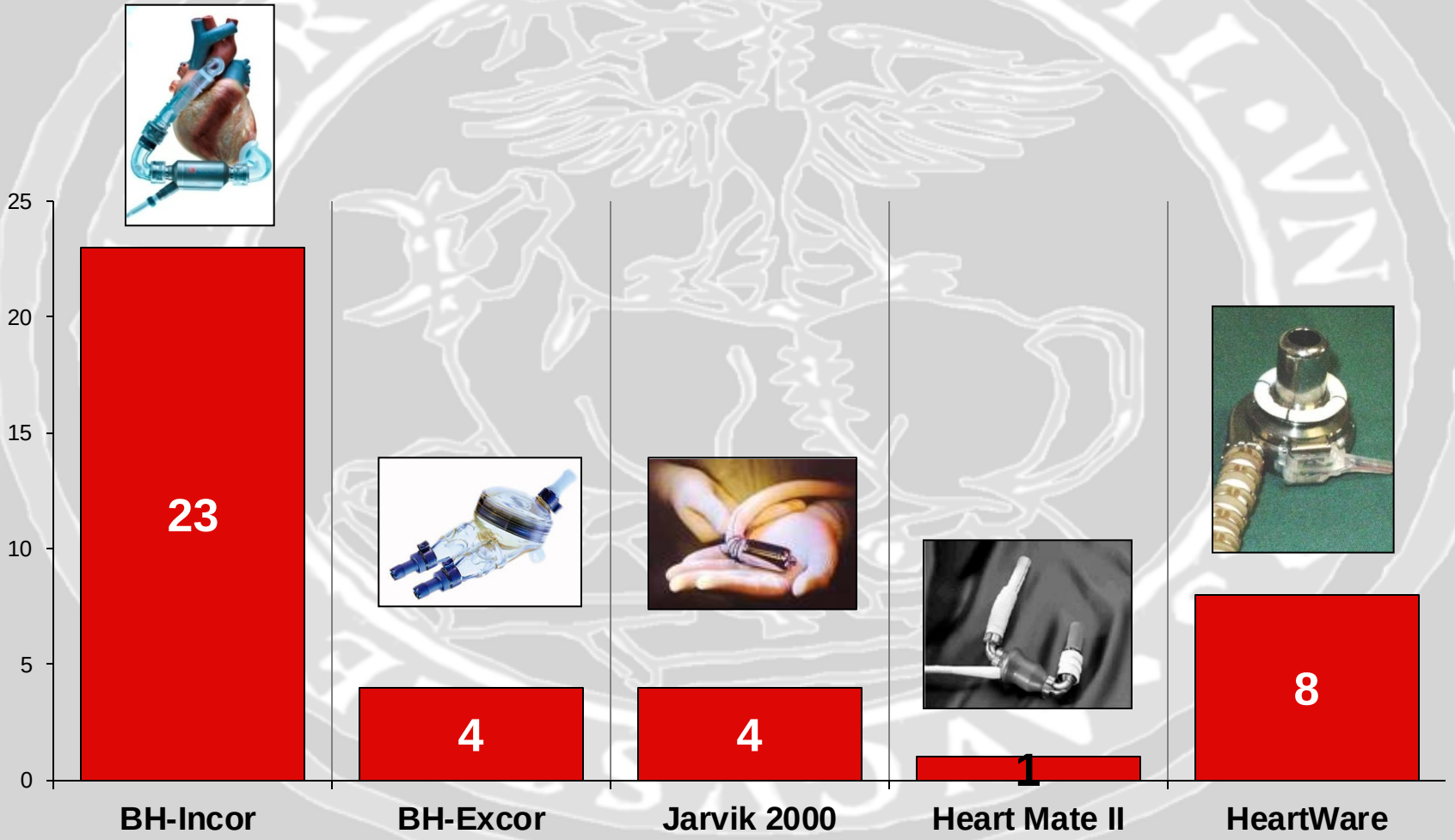
HUB Center

III Level

ICU +
Cath/Surg
VAD/HTx

ECMO / VAD / HTx

TURIN EXPERIENCE
VAD implants: 2006-2012



CONCLUSIONS

- HTx remains the gold standard for ESHF
- VAD implantation seems to be an effective **alternative to urgent list**
- **Hemodynamic stabilization** of critically ill patients can lead to an **elective HTx**
- Biventricular dysfunction management still remains a debated topic: BIVAD, TAH, HTx.

"Eventually, as cardiac support or replacement devices become smaller, more durable, and less obstrusive, they may become as conventional and common place as pacemaker are today"

Frazier OH, 2000


Massimo Boffini
Paolo Centofanti
Michele La Torre
Matteo Attisani
Davide Ricci
Marco Ribezzo
Roger Devotini
Andrea Baronetto