

HUMANITAS

RESEARCH HOSPITAL

SCOMPENSO CARDIACO, INSUFFICIENZA
CARDIACA TERMINALE, TRAPIANTO
CARDIACO

Il trapianto cardiaco
ed il
cuore artificiale
oggi



IX CONGRESSO NAZIONALE IX CONGRESSO NAZIONALE IX CONGRESSO NAZIONALE IX CONGRES
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**IX CONGRESSO NAZIONALE
ECOCARDIOCHIRURGIA 2017**

MILANO, 27 - 28 - 29 MARZO 2017

DIRETTORI
ANTONIO MANTERO
GIUSEPPE TARELLI

COORDINATORI
ESECUITIVI
FRANCESCO ALAMANNI
EMANUELE CATENA
GIOVANNI CORRADO
CORRADO LETTIERI

PROGRAMMA
FINALE


Centro Congressi
Palazzo delle Stelline
Corso Magenta, 61
20123 Milano

HUMANITAS

Dr. Alessandro BARBONE
UO di Cardiochirurgia

THU WEEK

#HistoryofMedicine

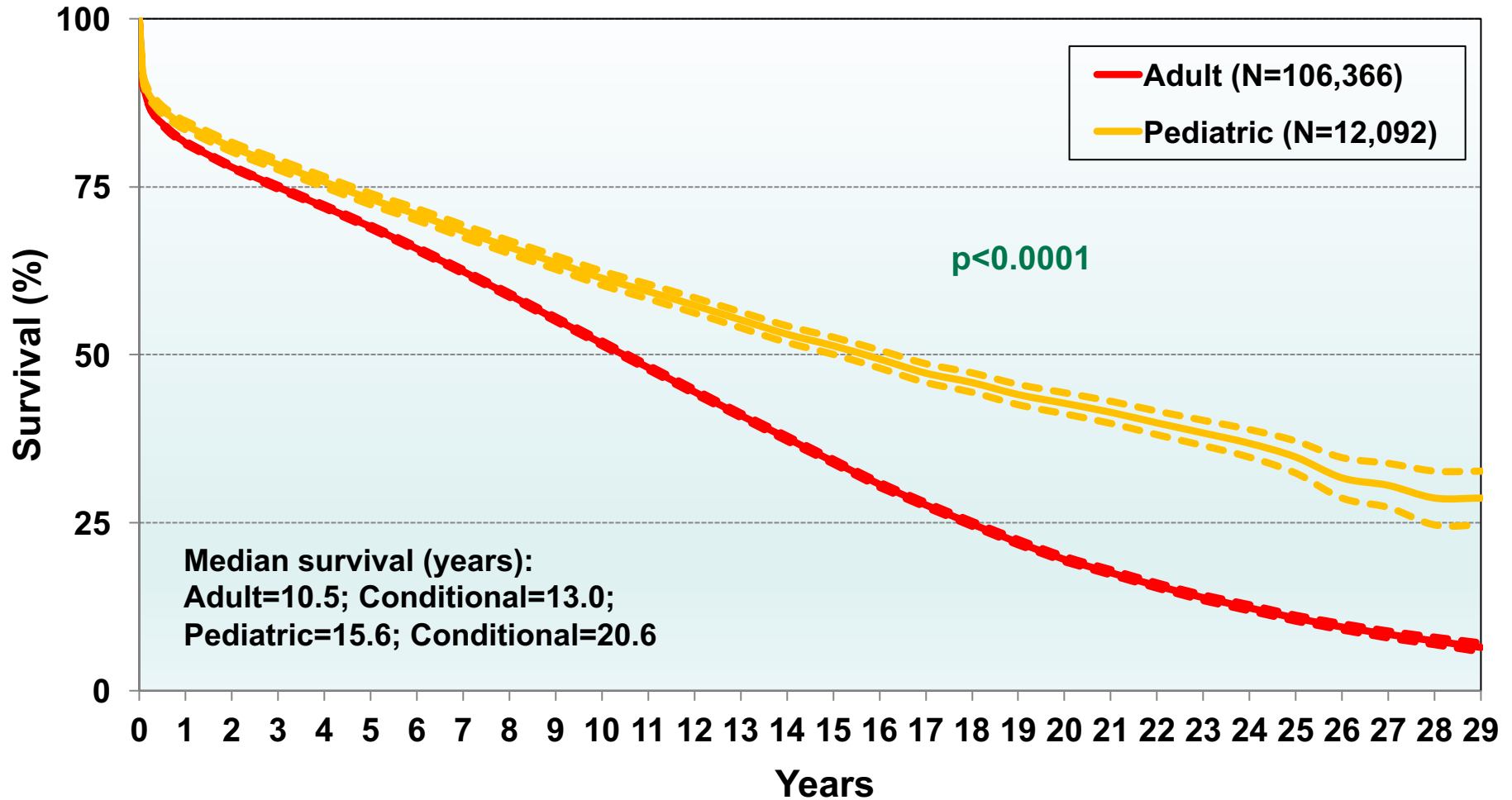
 **ColumbiaDoctors**
Department of Surgery

June 9, 1984
First Successful Pediatric Heart Transplant

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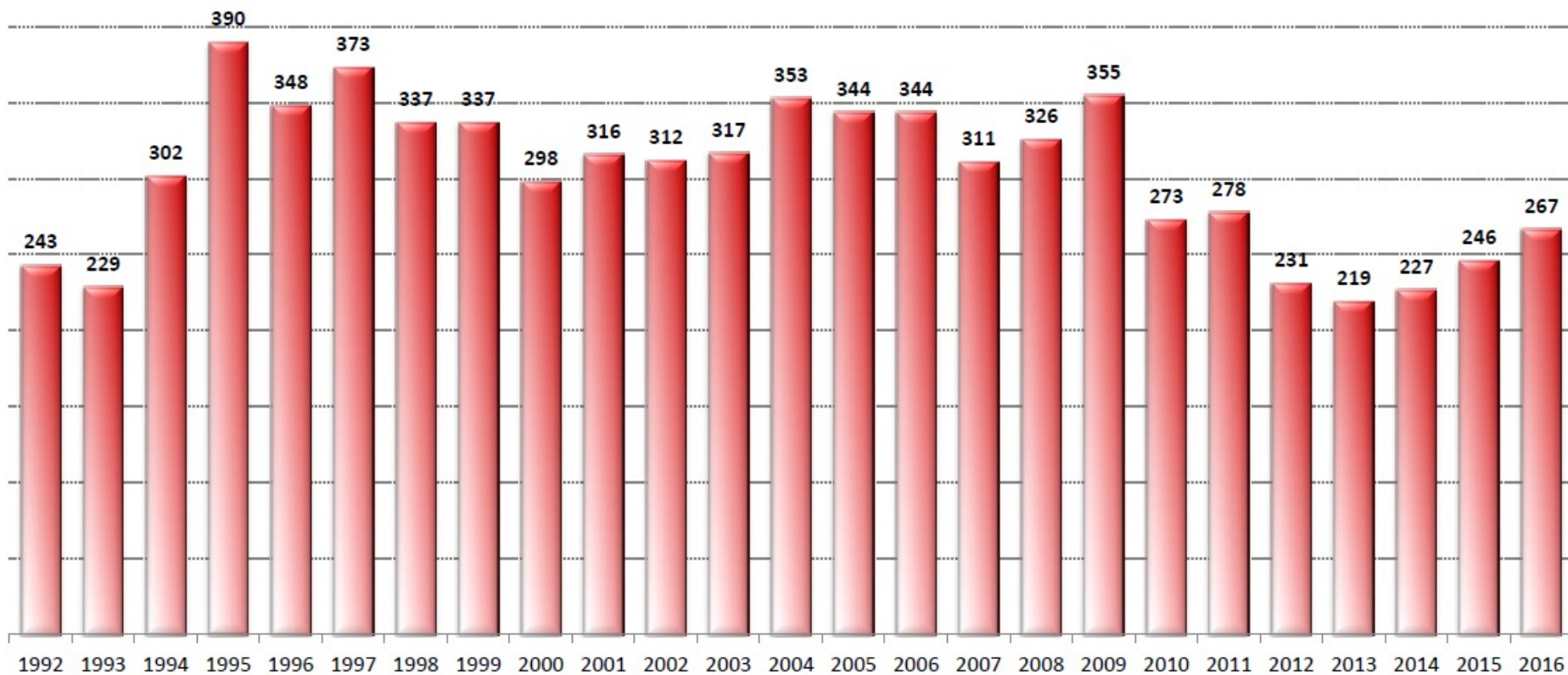
Adult and Pediatric Heart Transplants Kaplan-Meier Survival by Age Group

(Transplants: January 1982 – June 2015)



Trapianti di CUORE – Anni 1992-2016*

*Incluse tutte le
combinazioni*





Liste di Attesa al 31 Dicembre 2016*

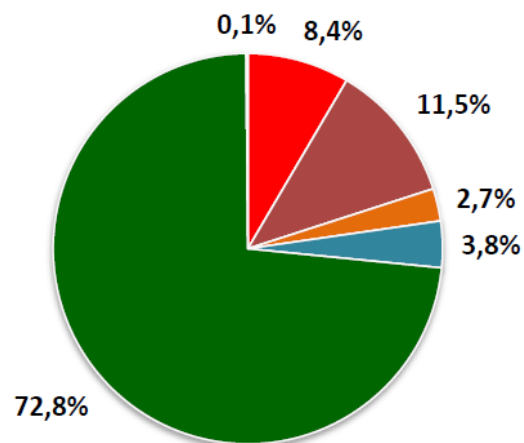
PAZIENTI in lista d'attesa in ITALIA al 31/12/2016 :

8856

| | |
|-----------|--------|
| Rene | 6598** |
| Fegato | 1041 |
| Cuore | 742 |
| Polmone | 346 |
| Pancreas | 248 |
| Intestino | 13 |

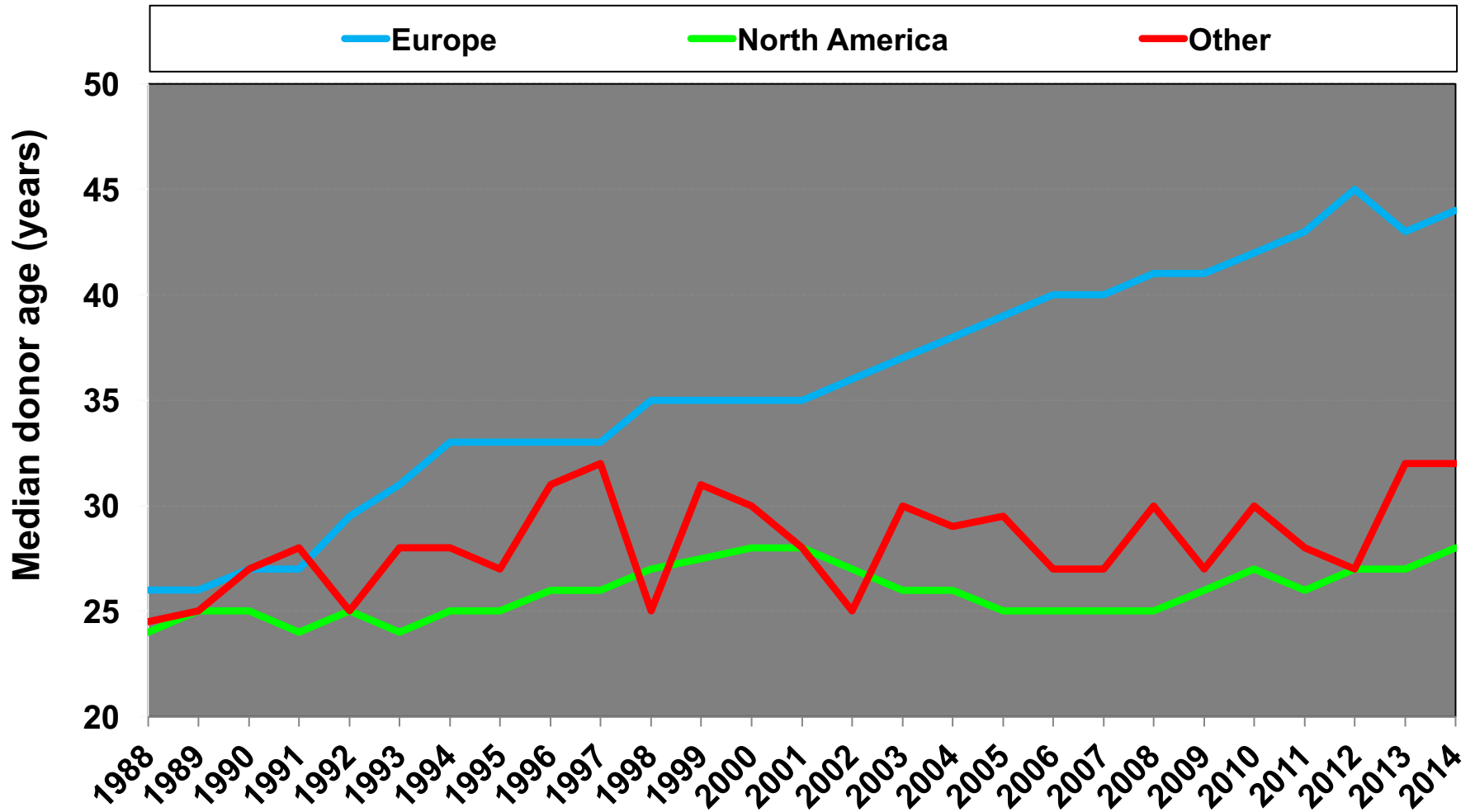
Iscrizioni rene
8077**

** Per il rene ogni paziente può avere più di una iscrizione



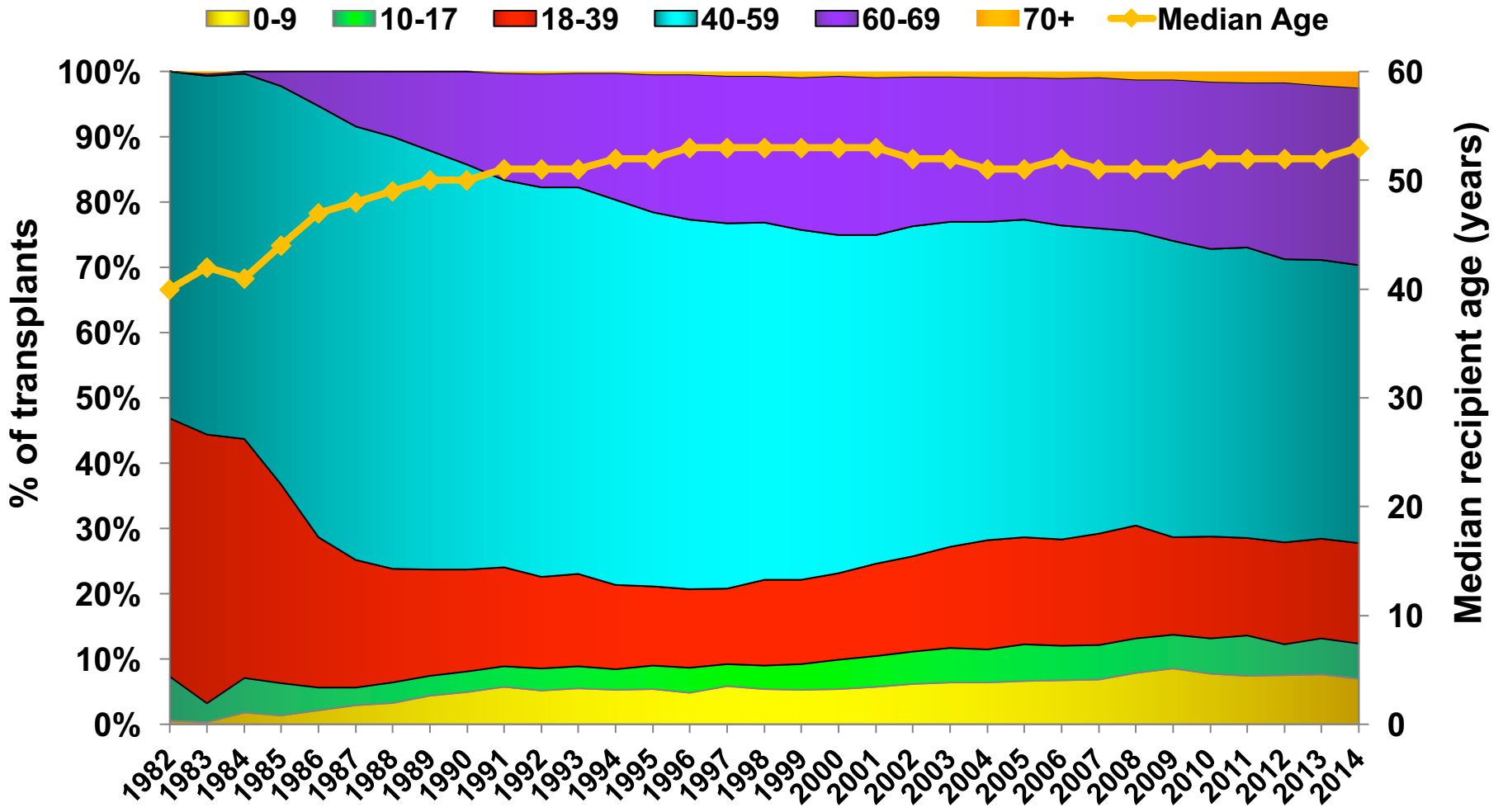
■ CUORE ■ FEGATO ■ PANCREAS ■ POLMONE ■ RENE ■ INTESTINO

Adult and Pediatric Heart Transplants Median Donor Age by Location



Adult and Pediatric Heart Transplants

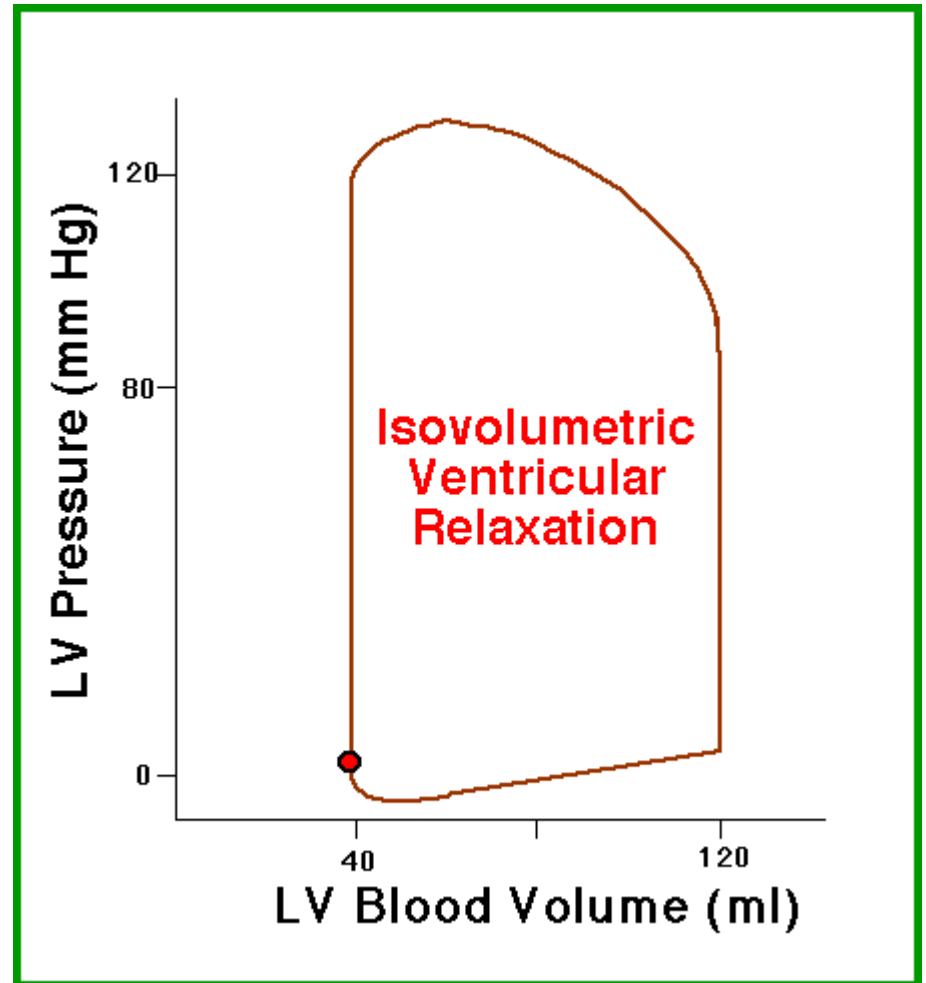
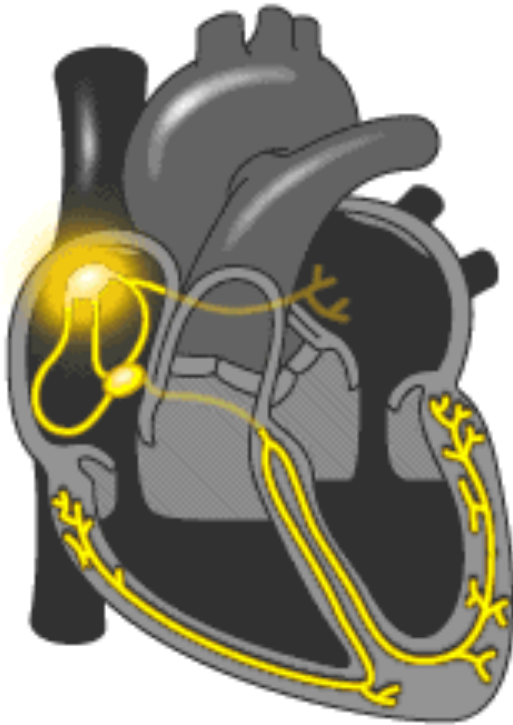
Recipient Age by Year of Transplant



Ministero della Salute

- Oltre i 65 anni lo scompenso cardiaco rappresenta la prima causa di ricovero in ospedale; anche per questo è considerato un problema di salute pubblica di enorme rilievo. A soffrire di scompenso cardiaco in Italia sono circa 600.000 persone e si stima che la sua frequenza raddoppi a ogni decade di età
 - (dopo i 65 anni arriva al 10% circa).

Ciclo Cardiaco



The Washington Post

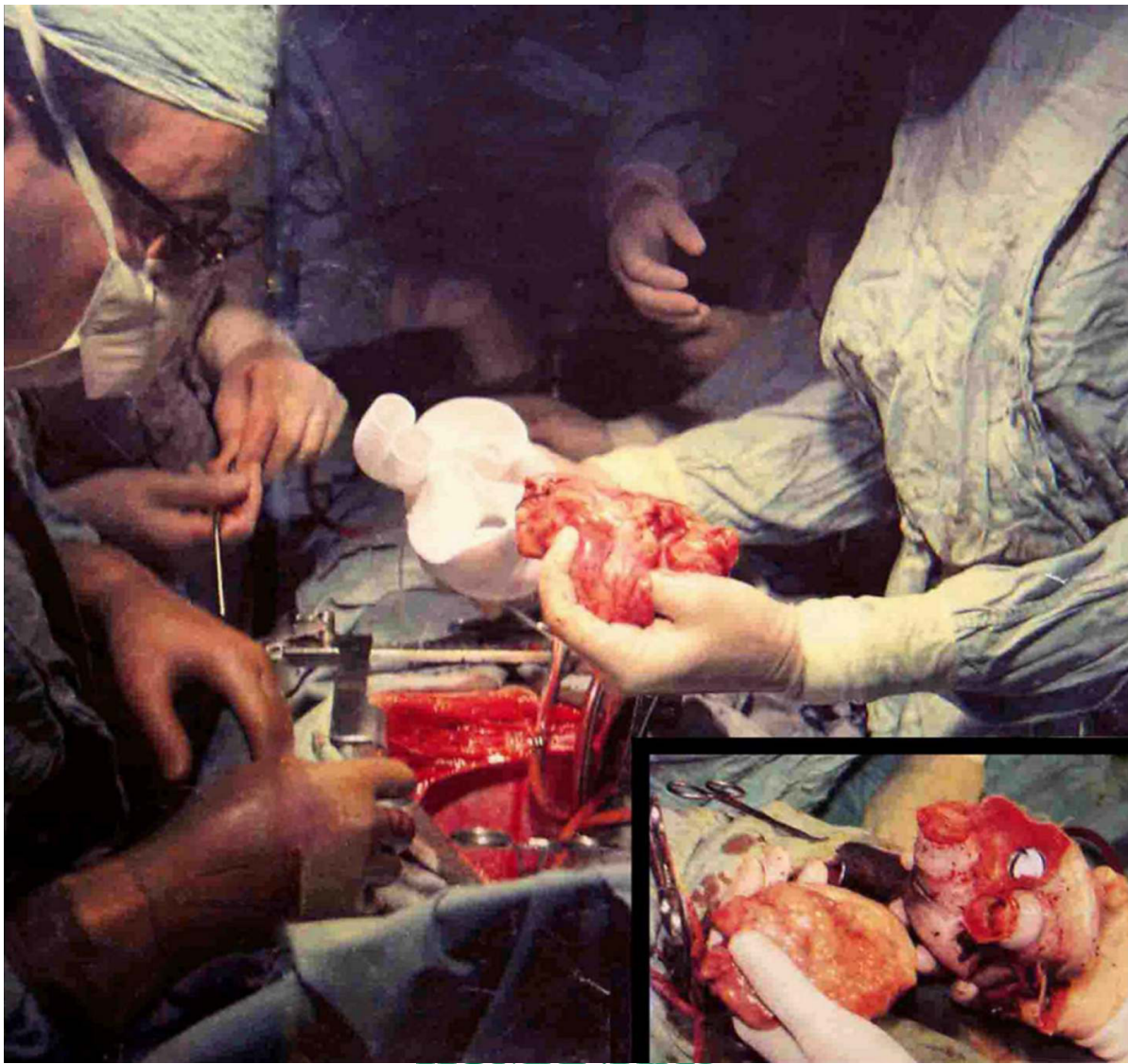
April 5th 1969

On April 4th, 1969, Haskell Karp became the first human being to have his natural heart removed and replaced with an artificial one. Surgeon Denton Cooley, known as "the man with the golden hands," performed the historic operation.

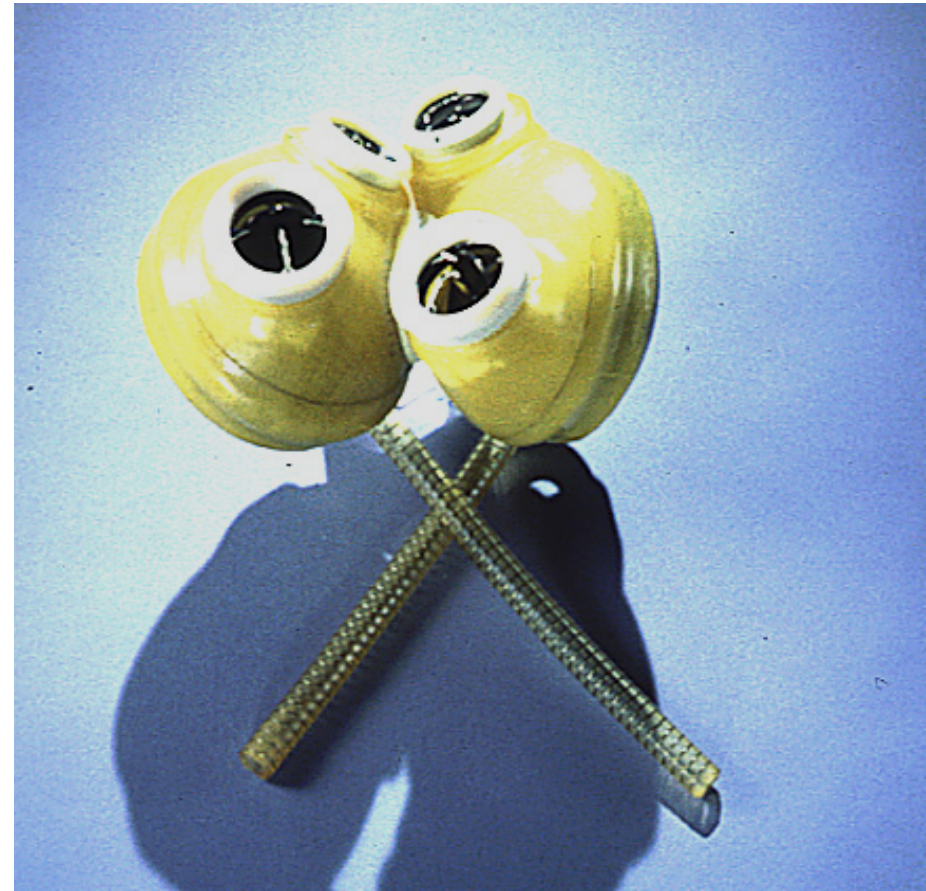
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The Liotta TAH





Jarvik 7 – CardioWest® - Syncardia



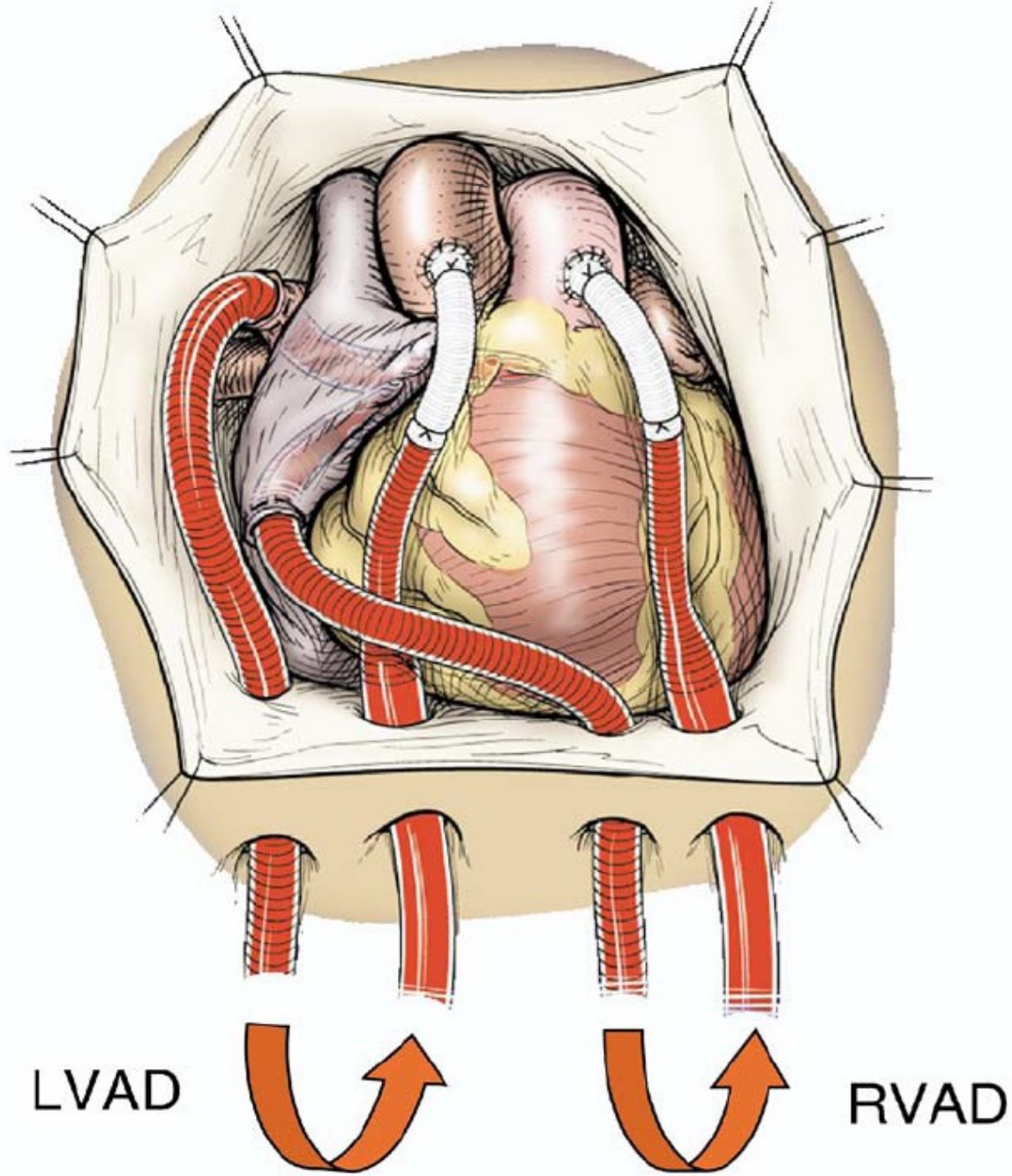
MANTAS

AbioCor™ Total Artificial Heart

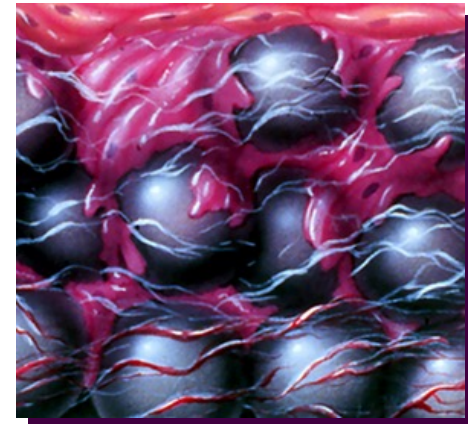




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The HeartMate I Left Ventricular Assist System



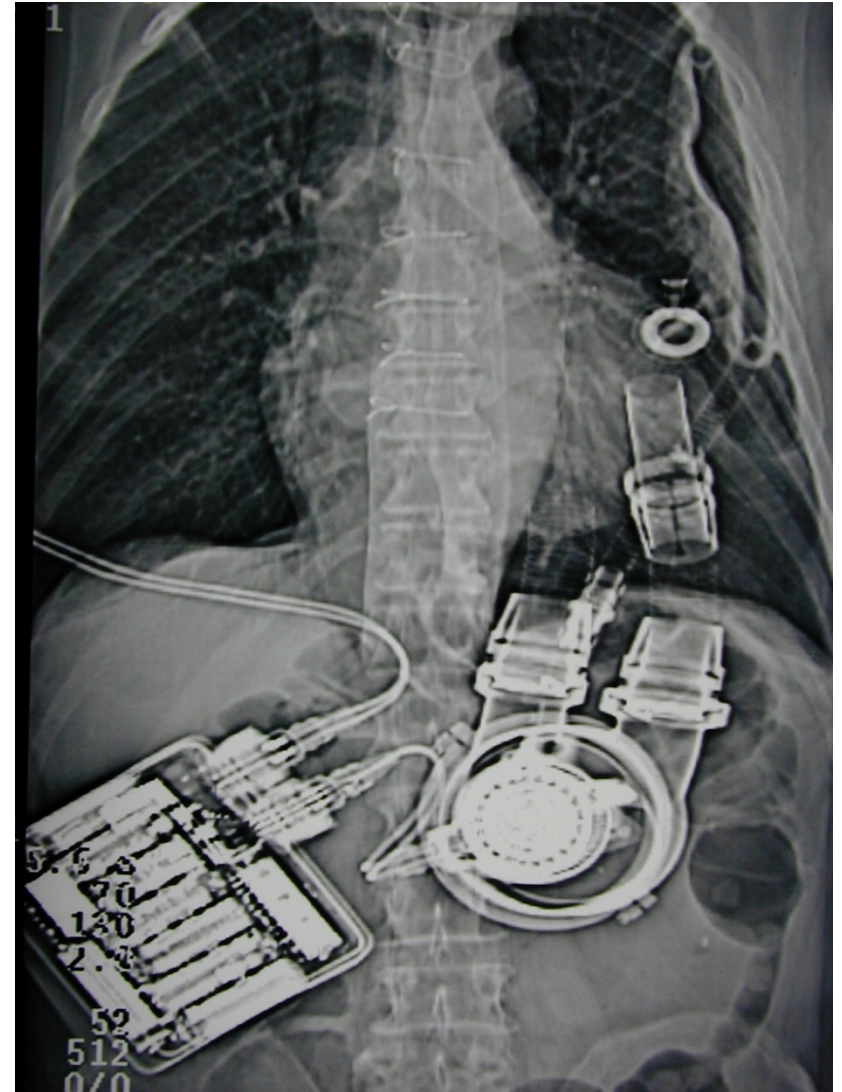
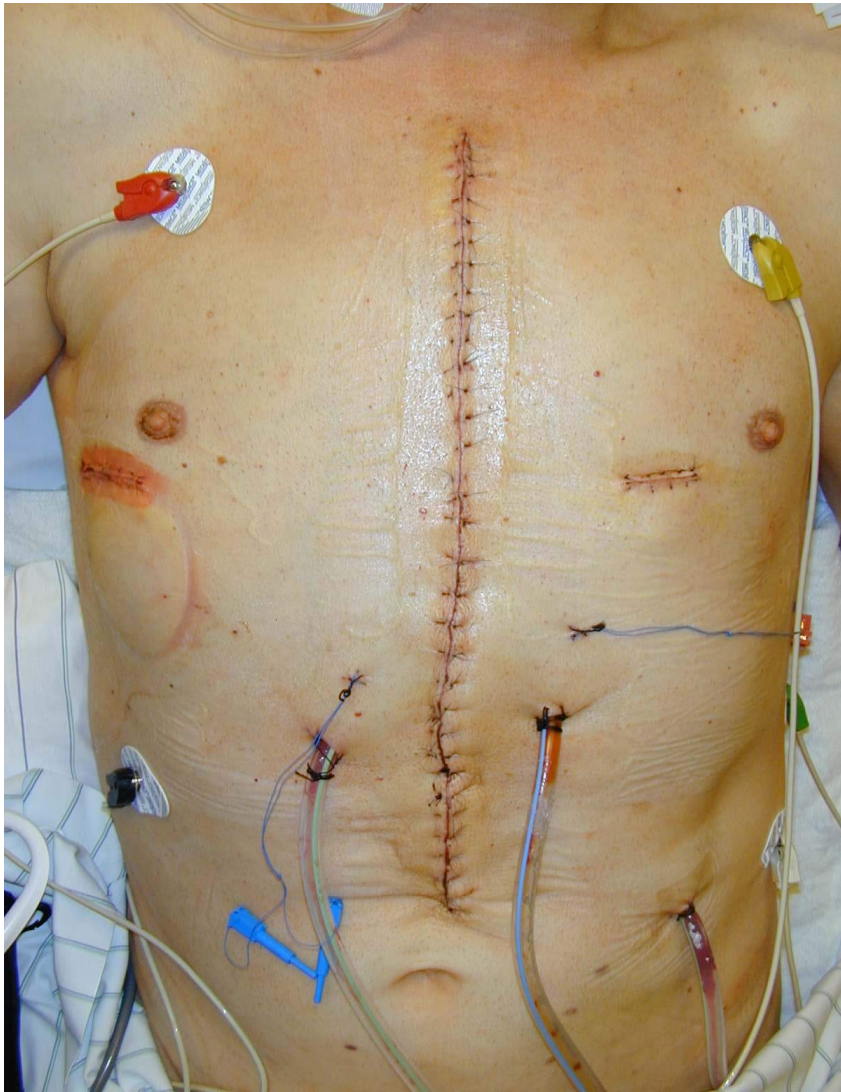
HUM

LionHeart™

Arrow LionHeart™ Left Ventricular Assist System (LVAS)

- Totally Implantable
- No “drive” & venting
- Transcutaneous Energy Transmission System (TET)
- 20’ Free of Plug Autonomy

AS

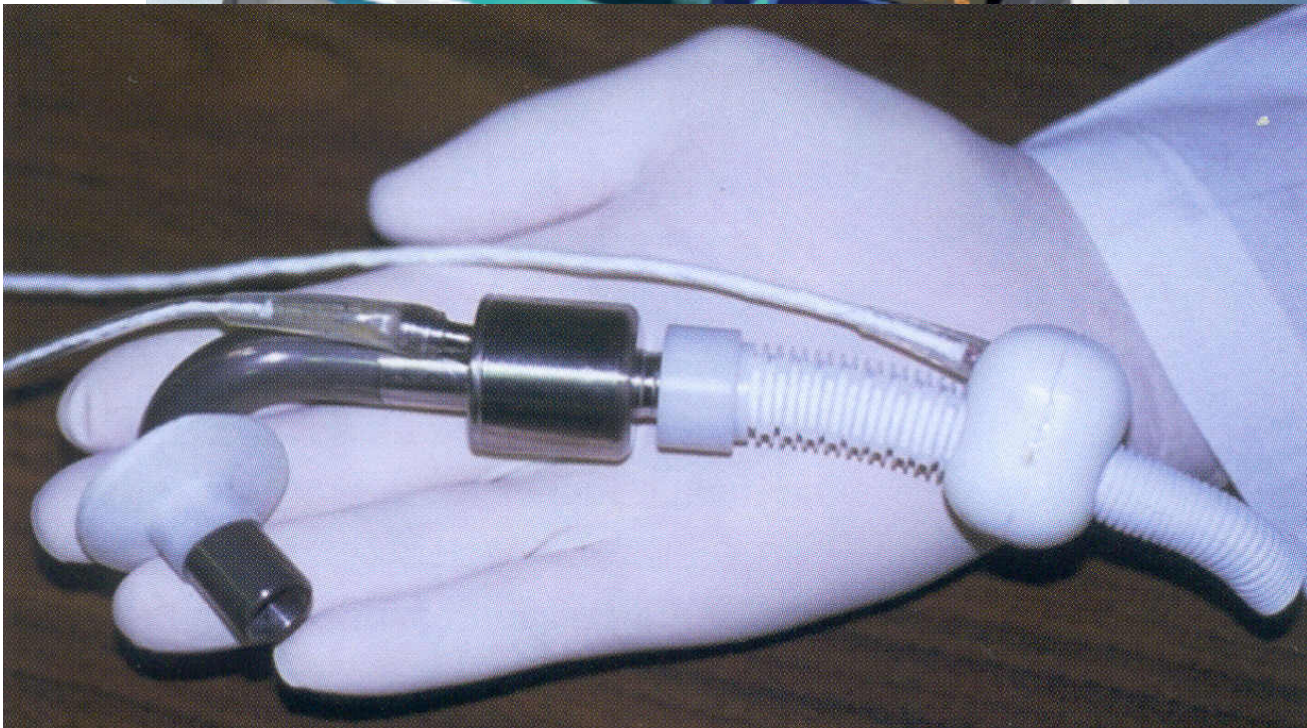
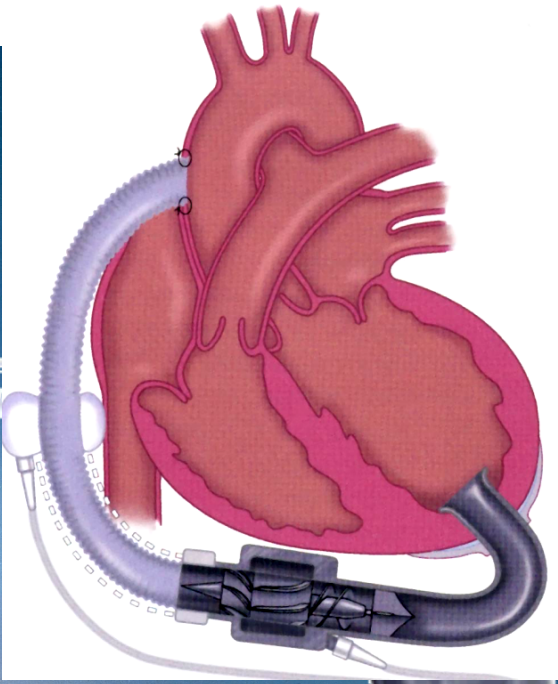
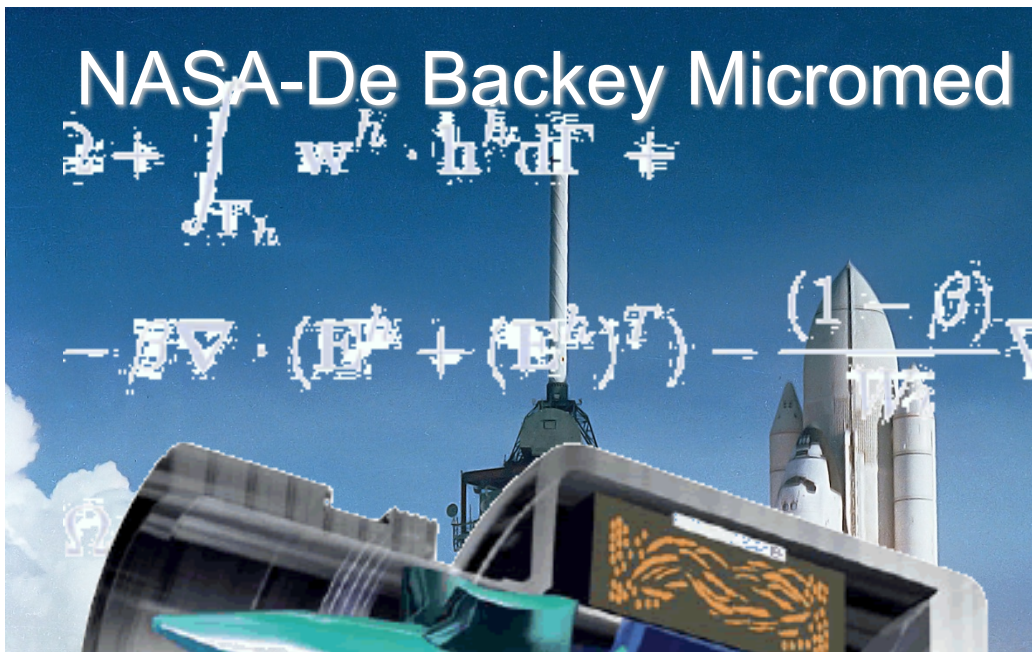


LionHeart LVAD **HUMANTAS**

NASA-De Backey Micromed

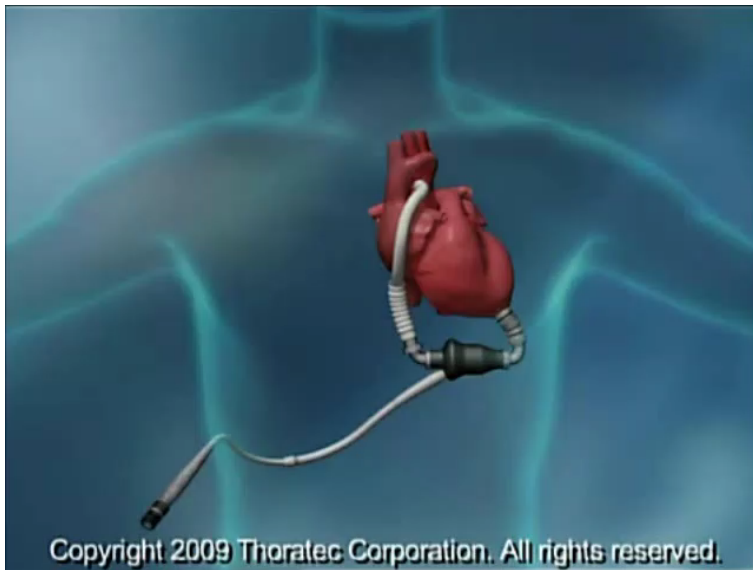
$$2 + \int w^h \cdot h \cdot d\Gamma + \#$$

$$- \nabla \cdot (\mathbf{E}^h + (\mathbf{E}^h)^T) - (1 - \beta) \nabla$$

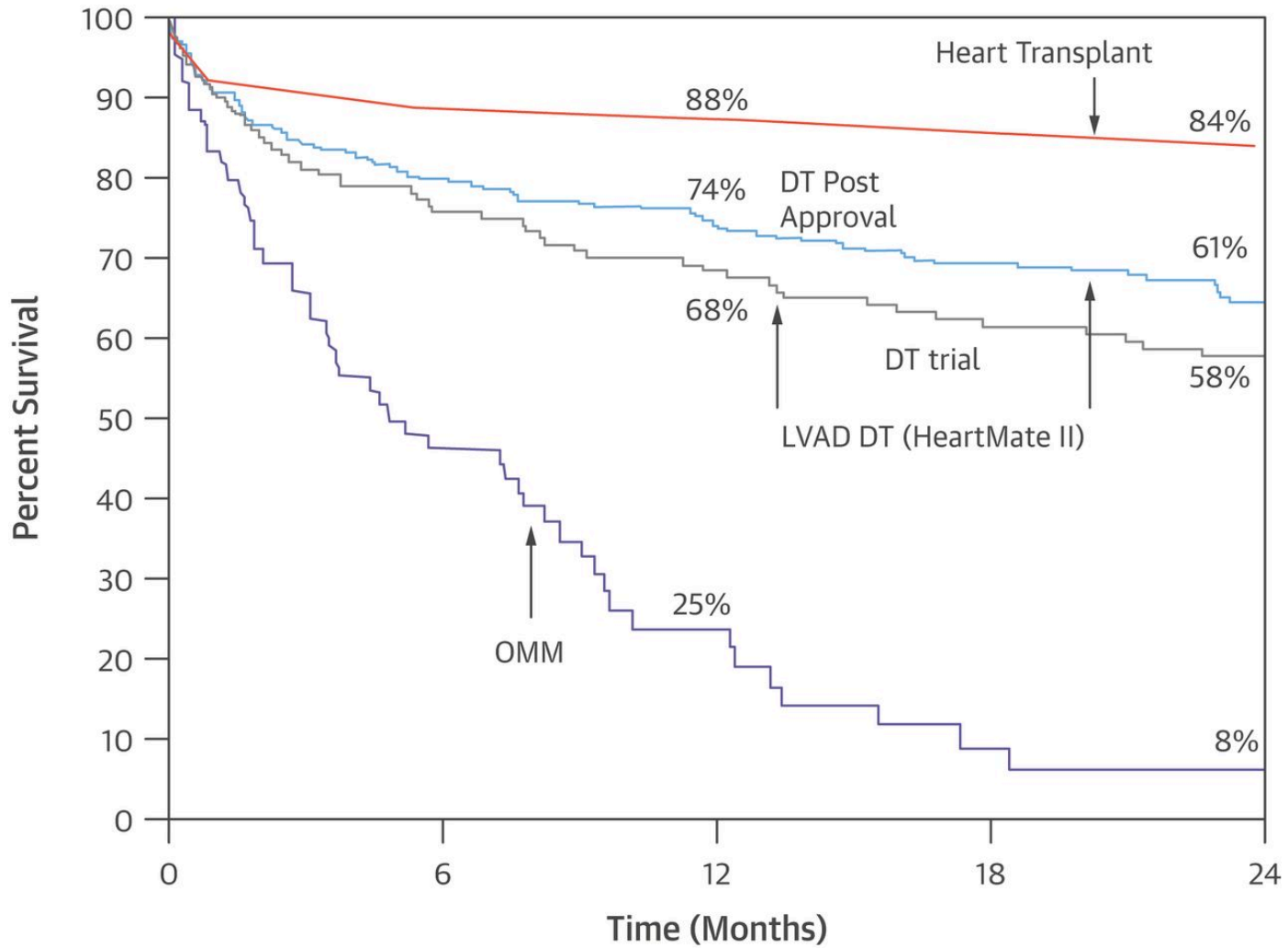


TCI HeartMate II®

Pompa Assiale



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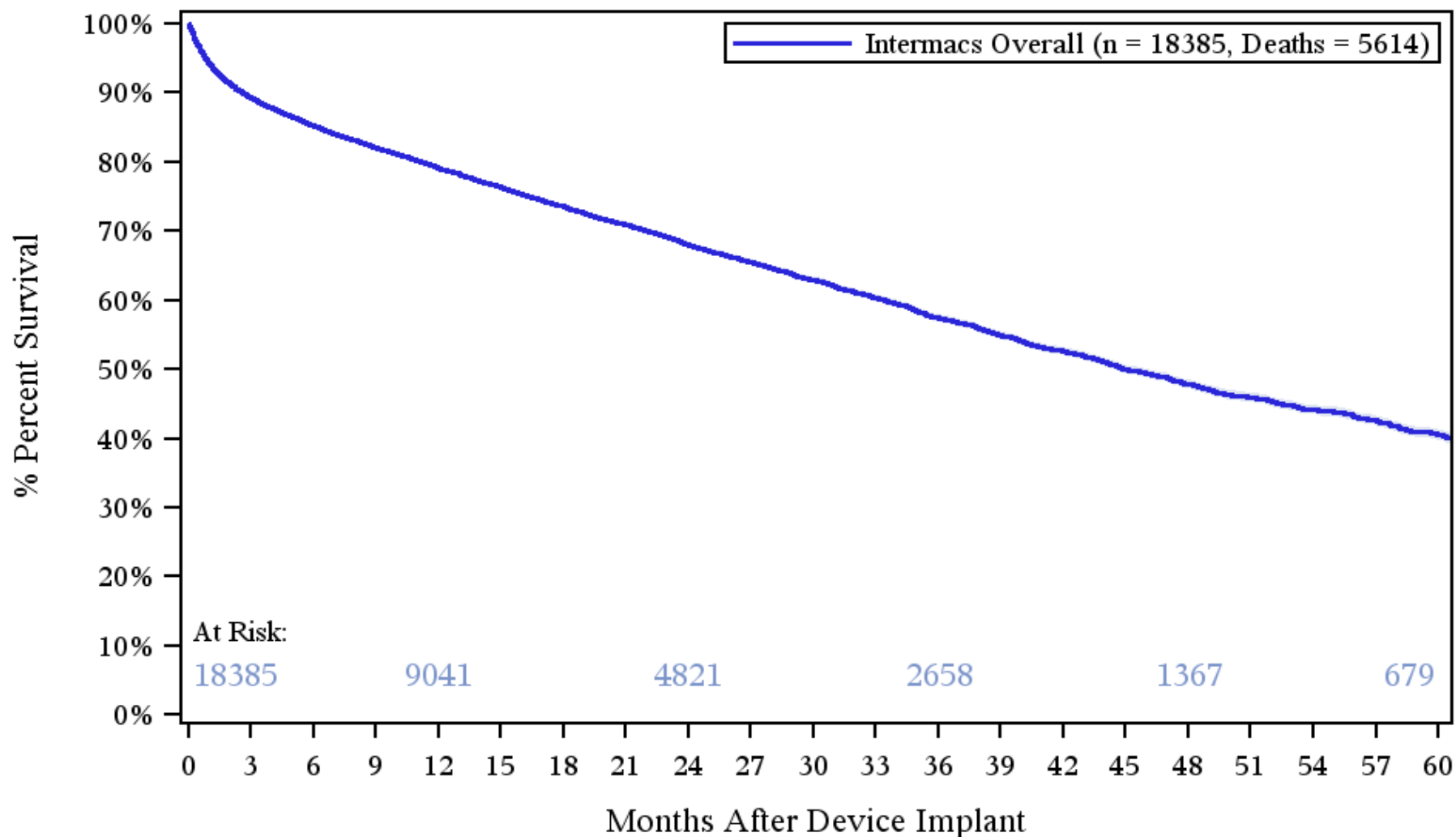
Donna Mancini, and Paolo C. Colombo JACC 2015;65:2542-2555

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Intermacs - Kaplan-Meier Survival for Intermacs Overall

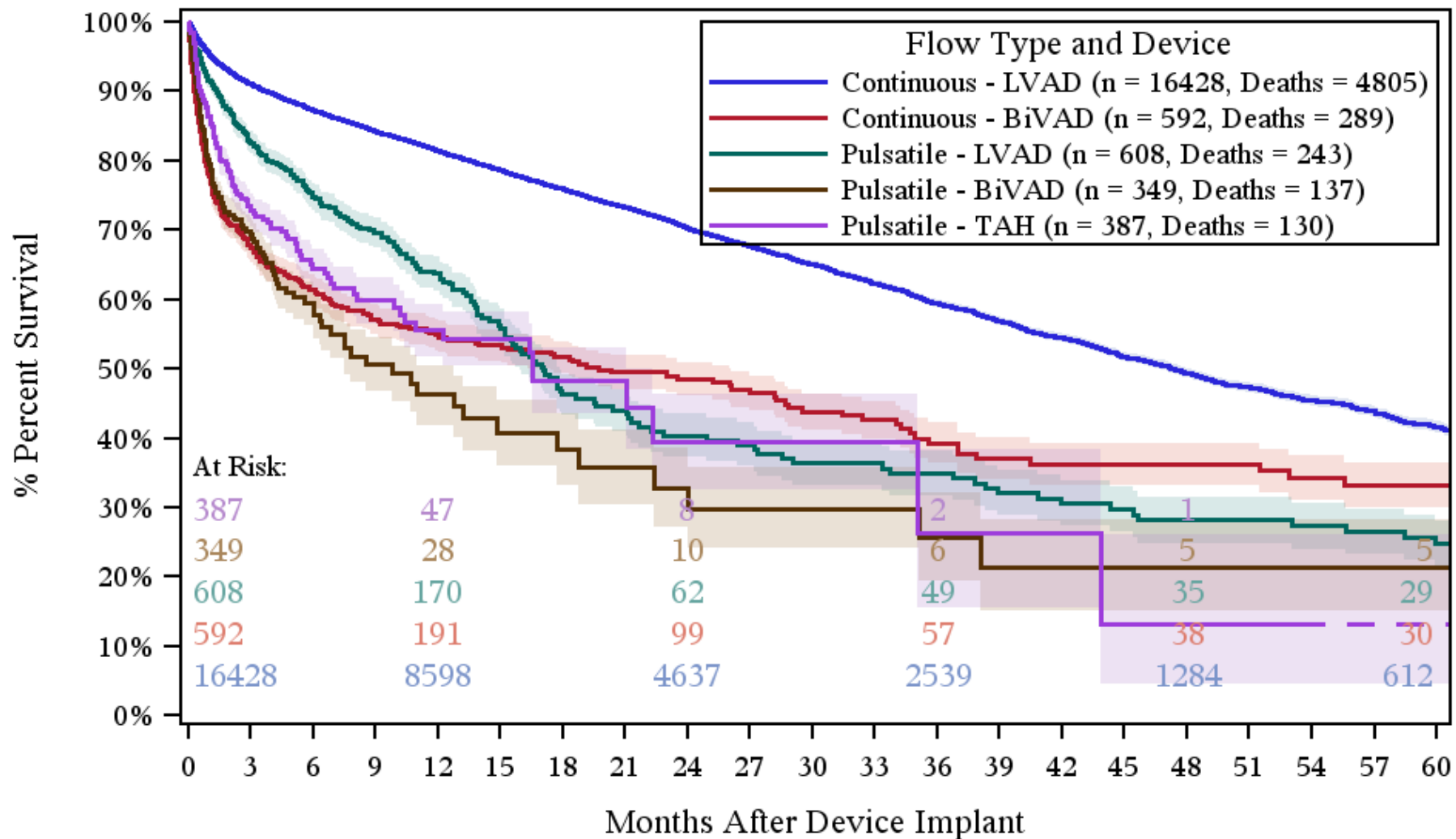
Primary Prospective Implants: June 23, 2006 to September 30, 2016



Shaded areas indicate 70% confidence limits
p (log-rank) = N/A
Event: Death (censored at transplant or recovery)

Intermacs

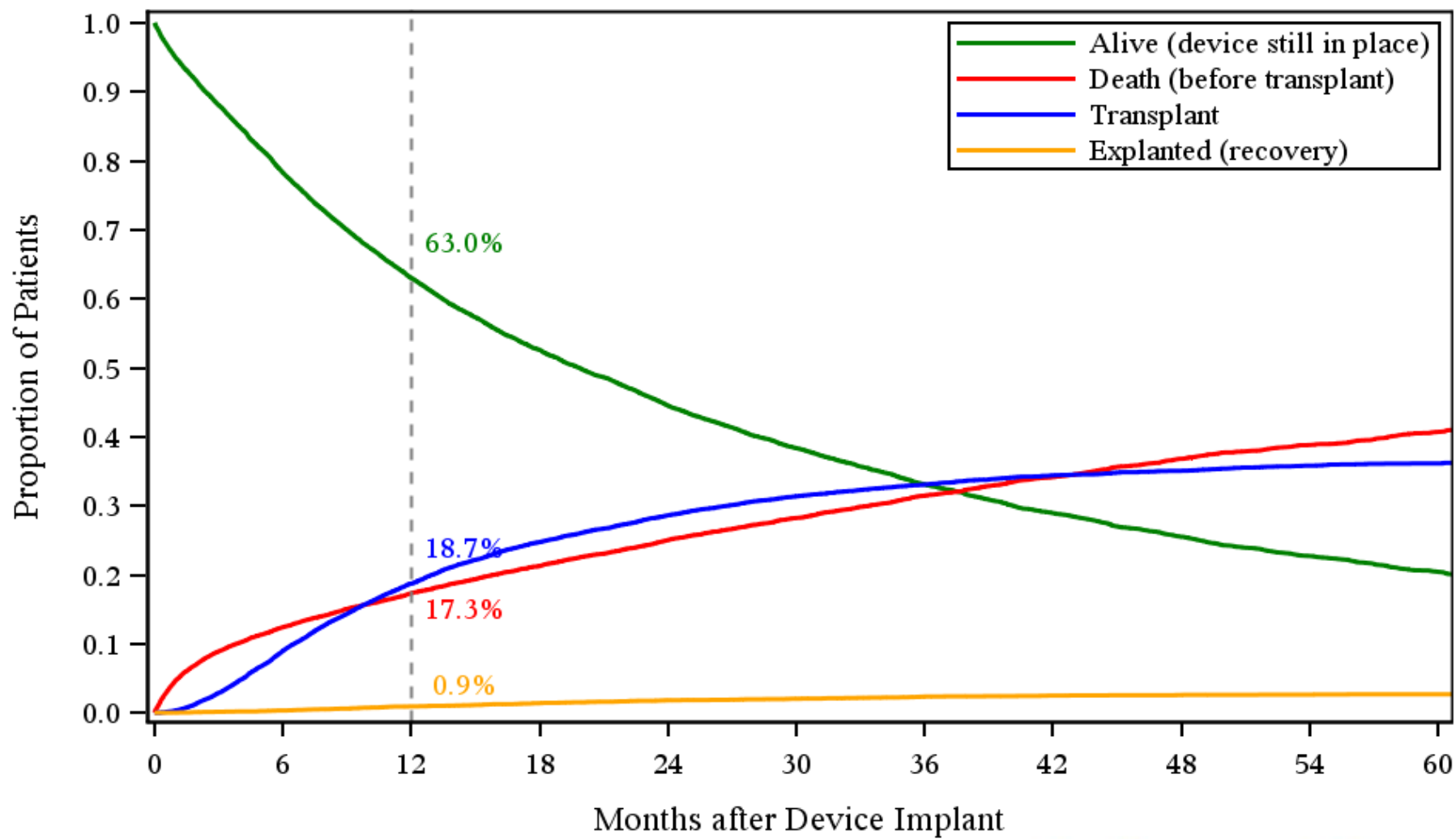
Intermacs - Kaplan-Meier Survival by Flow Type and Device Primary Prospective Implants: June 23, 2006 to September 30, 2016



Shaded areas indicate 70% confidence limits
 p (log-rank) = <.0001
 Event: Death (censored at transplant or recovery)

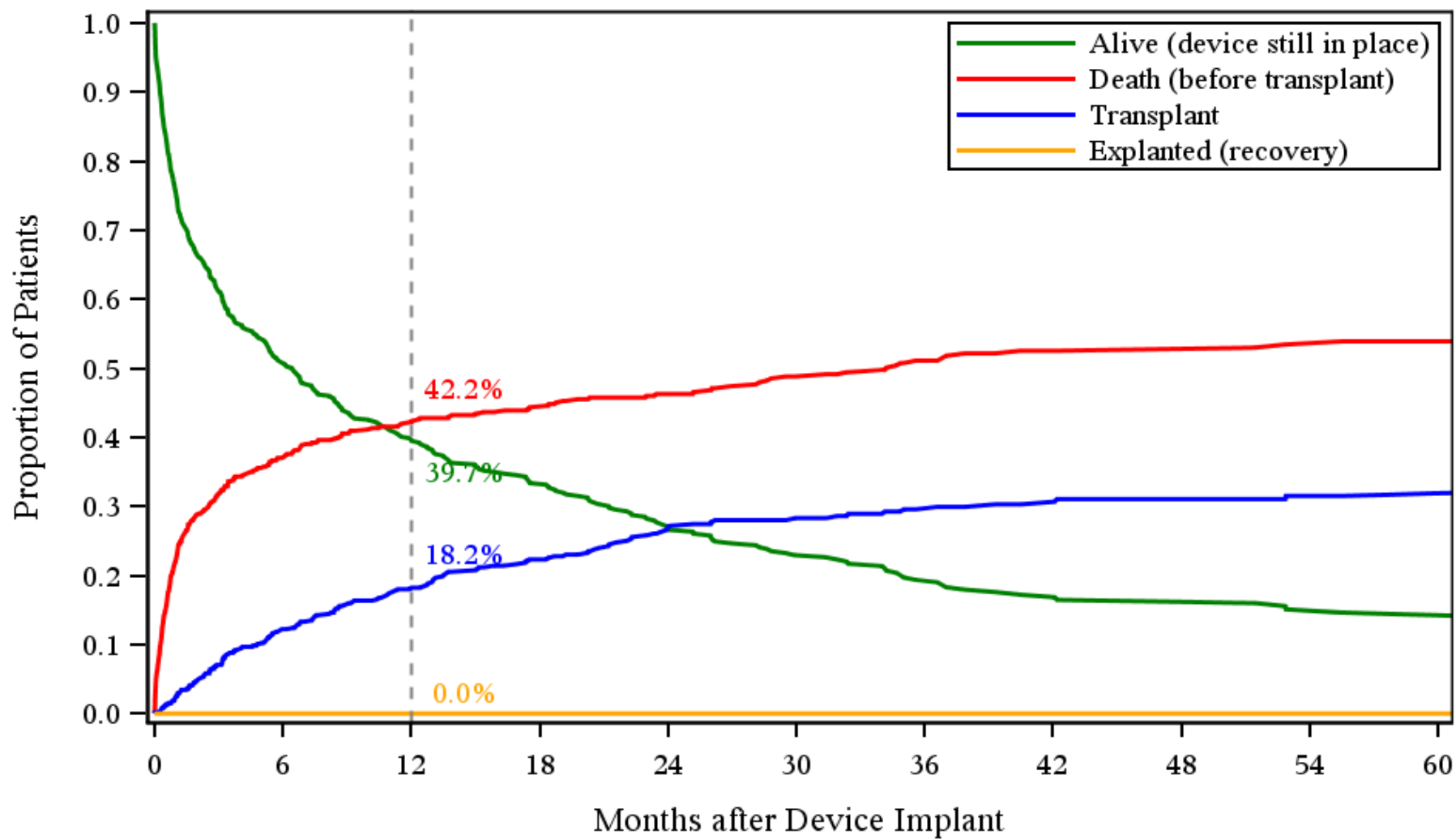
Intermacs - Competing Outcomes for Continuous Flow LVADs (without RVAD implant at time of LVAD operation)

Primary Prospective Implants: June 23, 2006 to September 30, 2016



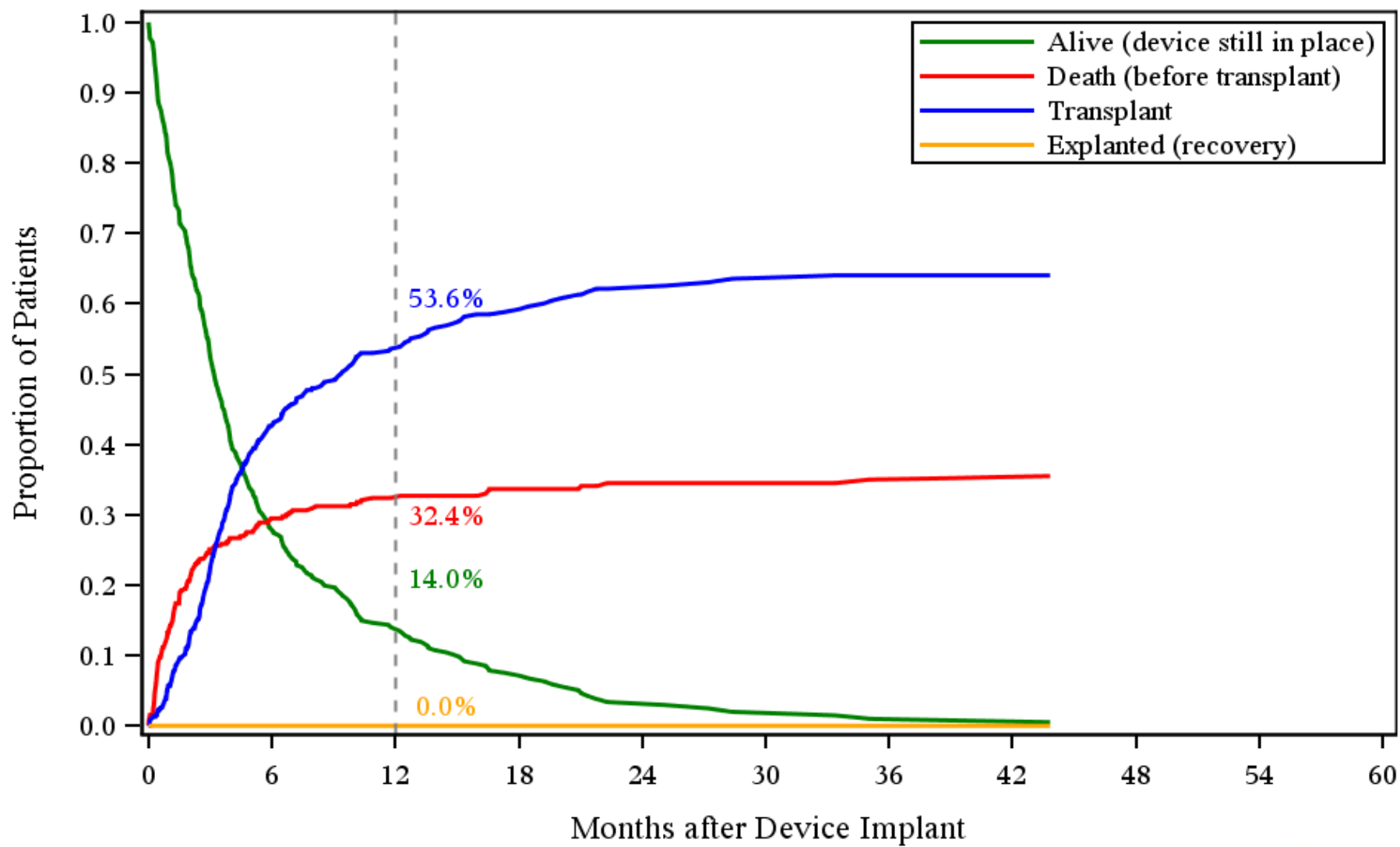
Intermacs - Competing Outcomes for Continuous Flow LVADs (with RVAD implant at time of LVAD operation)

Primary Prospective Implants: June 23, 2006 to September 30, 2016



Intermacs - Competing Outcomes for TAHs

Primary Prospective Implants: June 23, 2006 to September 30, 2016

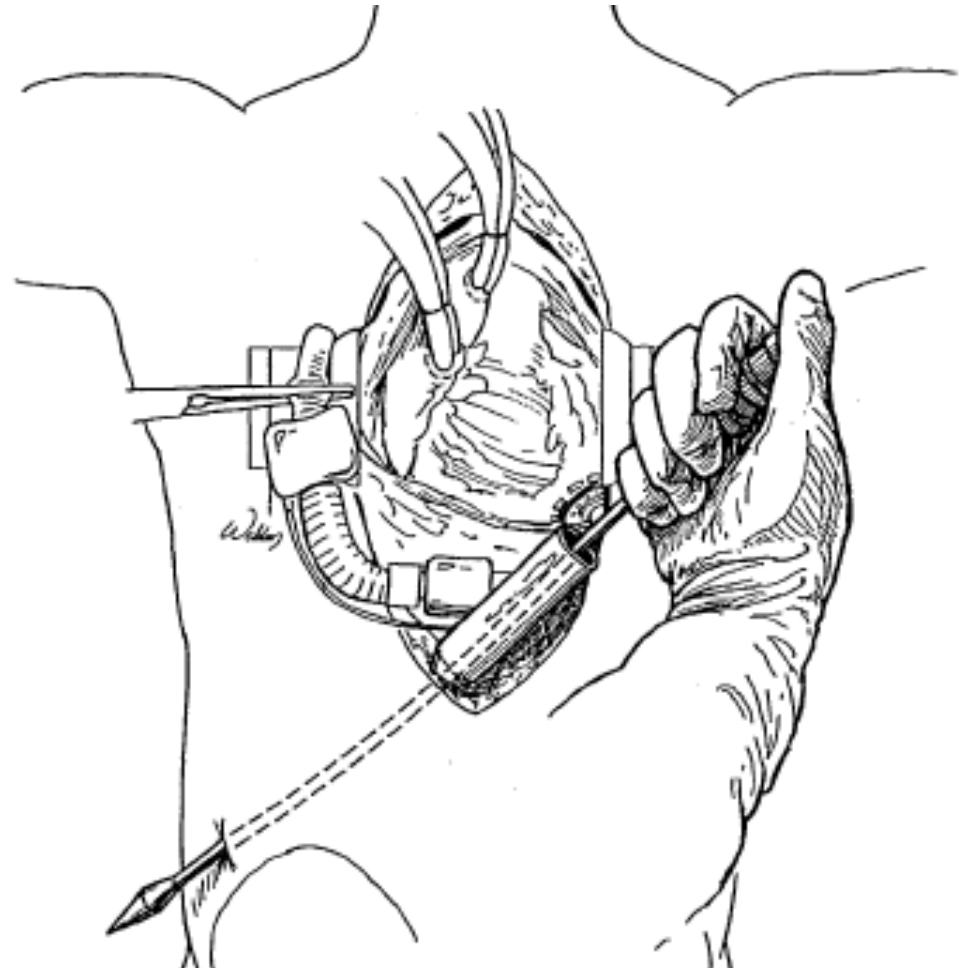


Controller and Battery Pack



Driveline

Il Tallone di Achille dei sistemi di assistenza meccanica al circolo



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TABLE 6 Adverse Events

| | OMM (n = 103) | LVAD (n = 94) | DT Trial§ (EPPY) |
|------------------------|-----------------------------|------------------------------|-----------------------------|
| Bleeding | 1 (1) [0.02] | 44 (47) [1.22]‡ | 1.13 |
| GI bleeding | 1 (1) [0.02] | 29 (31) [0.76]‡ | — |
| Driveline infection | — | 9 (9.6) [0.14]‡ | 0.22 |
| Pump thrombus | — | 6 (6.4) [0.08]† | 0.07¶ |
| Within 90 days | — | 1 (1.1) | — |
| Pump exchange yr 1 | — | 4 (4.3) | 2.1% |
| Stroke | 2 (2) [0.02] | 8 (8.5) [0.09]* | 0.08 |
| Ischemic | 1 (1) [0.01] | 5 (5.3) [0.06]* | 0.05 |
| Hemorrhagic | 1 (1) [0.01] | 4 (4.3) [0.03] ^{NS} | 0.03 |
| Arrhythmias VT/VF | 6 (5.8) [0.12] | 17 (18.1) [0.23]* | 0.46 |
| Worsening HF# | 36 (35) [0.68] | 10 (10.6) [0.12]‡ | — |
| Rehospitalizations | 64 (62) [1.43] | 75 (79.8) [2.49]‡ | 2.64** |
| Composite event rate†† | 39 (38) [0.83] | 62 (66) [1.89]‡ | 2.09 |
| Relative risk (95% CI) | OMM/LVAD: 0.44 (0.35-0.56)‡ | | — |

Values are n (%) for prevalence of patients within 1 year and events/patient-year [EPPY] on all data, unless otherwise indicated. p values OMM vs. LVAD: *p < 0.05. †p < 0.01. ‡p < 0.001. §Park et al. (16). ||4 patients had 50% of all gastrointestinal bleeding events. ¶Thrombus plus hemolysis. #HF symptoms resulting in unexpected hospitalization, emergency department visit, or urgent clinic visit requiring intravenous therapy. **Slaughter et al. (3). ††Sum of bleeding, infection, thrombus, stroke, arrhythmias, and worsening HF.

CI = confidence interval; DT = destination therapy; EPPY = events per patient-year; GI = gastrointestinal; NS = not significant; VF = ventricular fibrillation; VT = ventricular tachycardia; other abbreviations as in Table 1.

TABLE 7 Reasons for Rehospitalizations

| | OMM Rehospitalizations (n = 160) | LVAD Rehospitalizations (n = 328) |
|---|---|--|
| Adverse events | 97 (61) | 207 (63) |
| Bleeding | 1 (1) | 79 (24)† |
| Worsening HF | 72 (45)* | 16 (5) |
| Elective procedure | 10 (6) | 22 (7) |
| Comorbidity management | 13 (8) | 16 (5) |
| Blood pressure/volume management | 6 (4) | 16 (5) |
| Pain | 5 (3) | 12 (4) |
| Trauma | 0 | 9 (3) |
| LVAD alarms/driveline and controller problems | 0 | 9 (3) |
| Dizziness/syncope | 9 (6) | 8 (2) |
| LVAD implantation or exchange/ heart transplant | 11 (7) | 7 (2) |
| Anticoagulation management | 0 | 7 (2) |
| Rehabilitation/hospice | 4 (3) | 5 (2) |
| Other‡ | 5 (3) | 10 (3) |

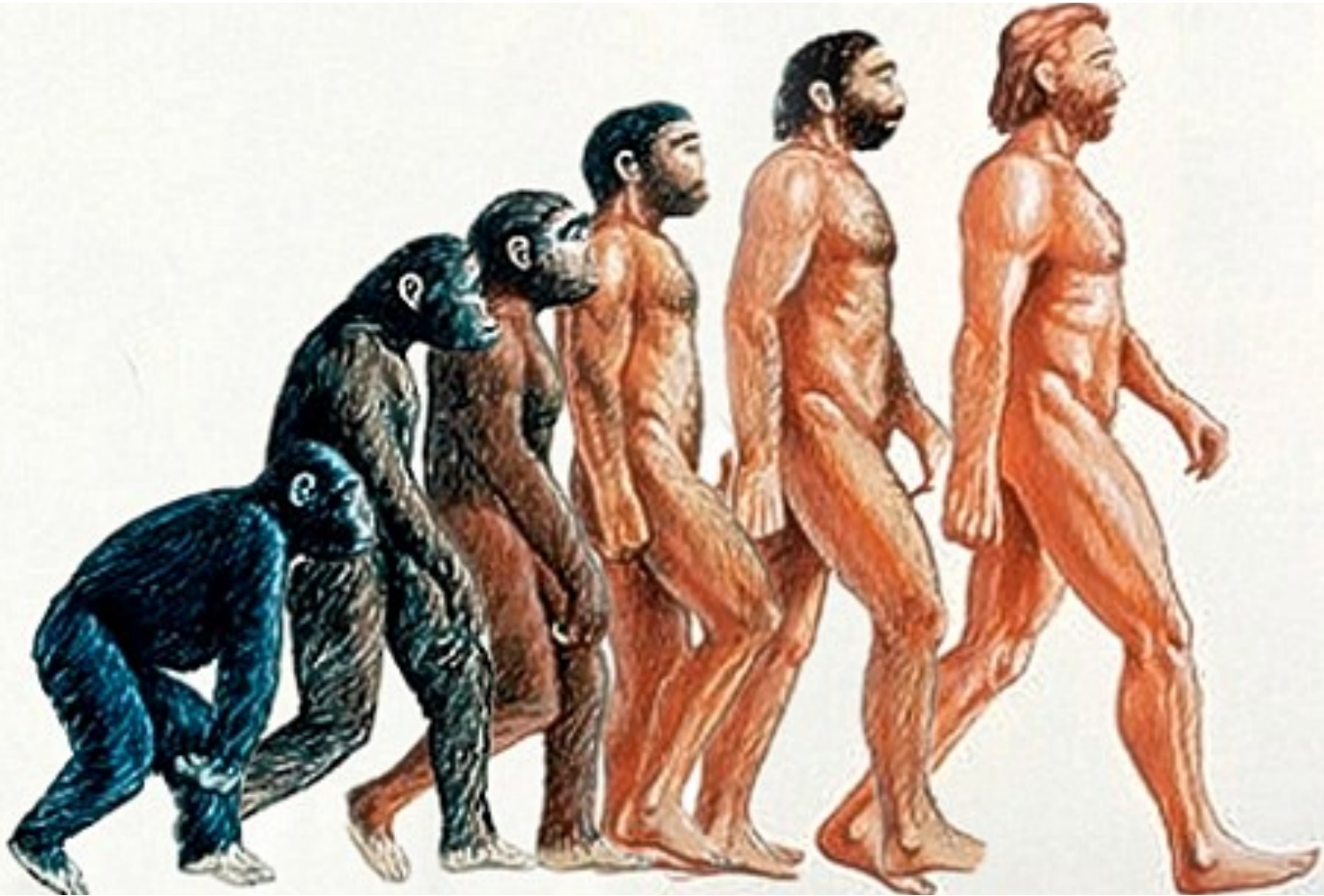
Values are n (%) of rehospitalizations. *Most frequent OMM rehospitalization reason was worsening HF, which included 9 delayed HMII and 1 total artificial heart implantation. †Most frequent LVAD rehospitalization reason was bleeding. ‡Includes thoracentesis, depression, fever, failure to thrive, peripherally inserted central catheter line pulled out, dyspnea, and cellulitis.

Abbreviations as in [Table 1](#).

Quale VAD?

- Rapidamente Disponibile
 - Facile da Gestire
 - Facile da Ottimizzare
 - Ridotta Necessità di “Aggiustamenti”
- Elevata Efficienza Emodinamica
 - Biocompatibile
 - Bassa Anticoagulazione
- Facilità di Modulazione dei Flussi per lo Svezamento

MAN and VAD EVOLUTION



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VAD Implantabile più Piccolo al Mondo

Minimally invasive

- Dimensioni Miniaturizzate per Favorire Impianto Superficiale in Tasca Sottocute (Tipo Pace Maker)

Supporto Parziale :

- Flusso > 4 L/min

Lunga Emivita Implantabile:

- Studiato per Supporto Definitivo

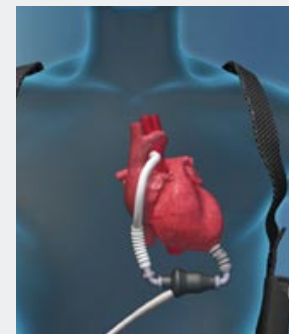
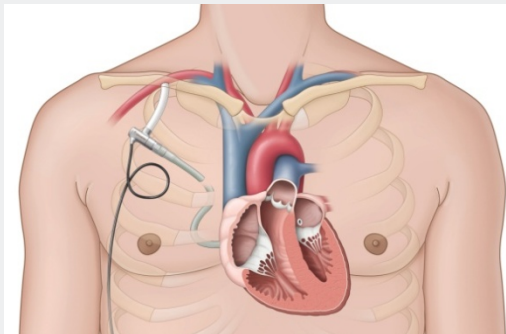


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Una Nuova Soluzione per il Trattamento Pazienti in Scompenso Cardiaco Avanzato

Synergy[®] MICS

VADs



Paziente Ideale



- Pazienti in Classe NYHA III – IV precoce
- Non allettati – Fortemente Sintomatici

- Classe IV° avanzata e Shock
- Inotropo - Dipendenti
- Ospedalizzati - Allettati

Device

- Supporto Parziale, 2-4¼L/minuto
- **Supplementa** funzione cardiaca nativa
- Peso: **25g**

- Full Support, 5-6L/minute
- **Sostituisce** la funzione nativa
- **370g** (HeartMate II) / **140g** (HVAD)

Procedura Chirurgica

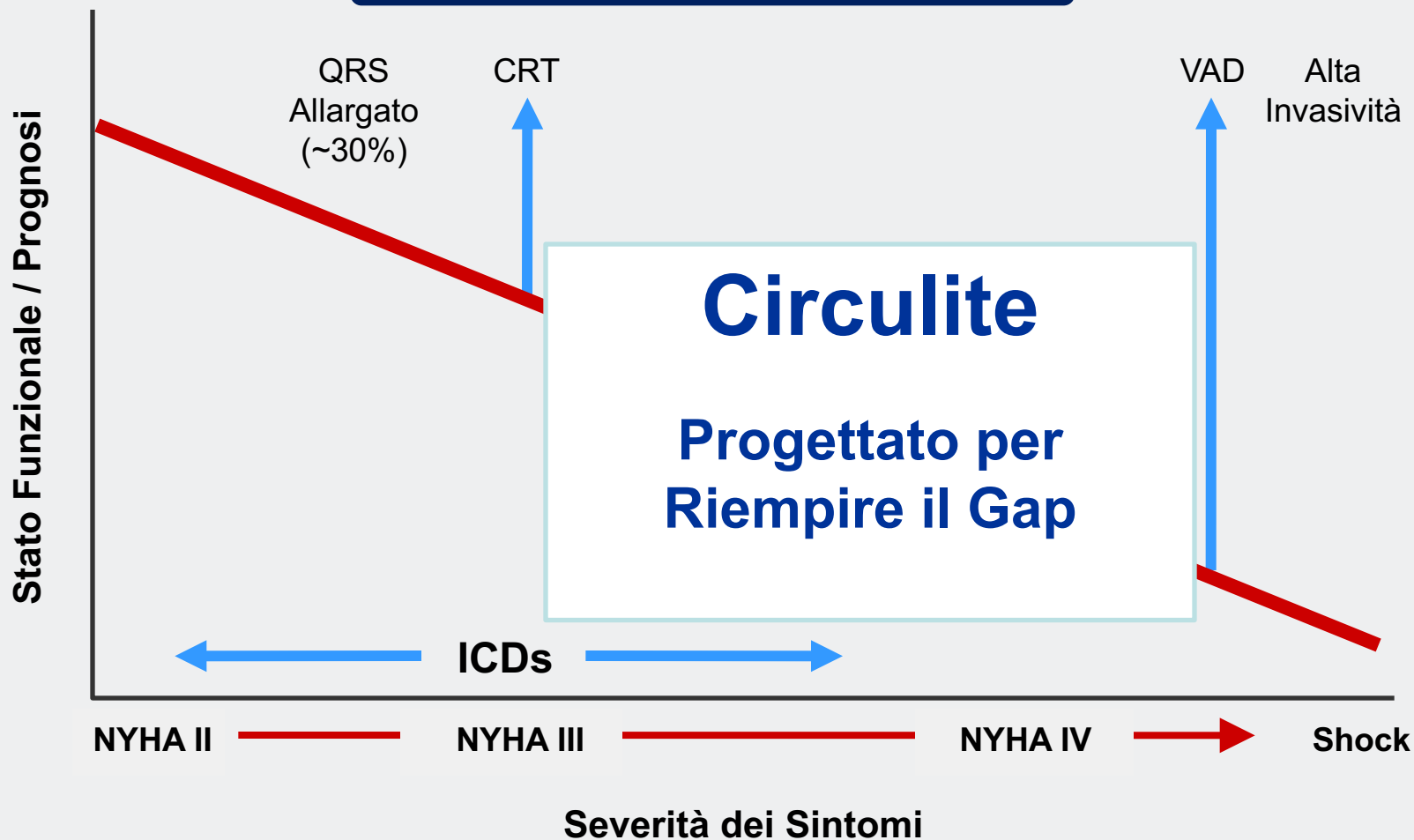
- Impianto Elettivo, Procedura **Superficiale**
- Mini-toracotomia **Off-pump**
- Procedura di 90-150 Minuti

- Urgente, Procedura a cuore aperto
- Sternotomia e **CEC**
- Procedura di 180 – 300 minuti

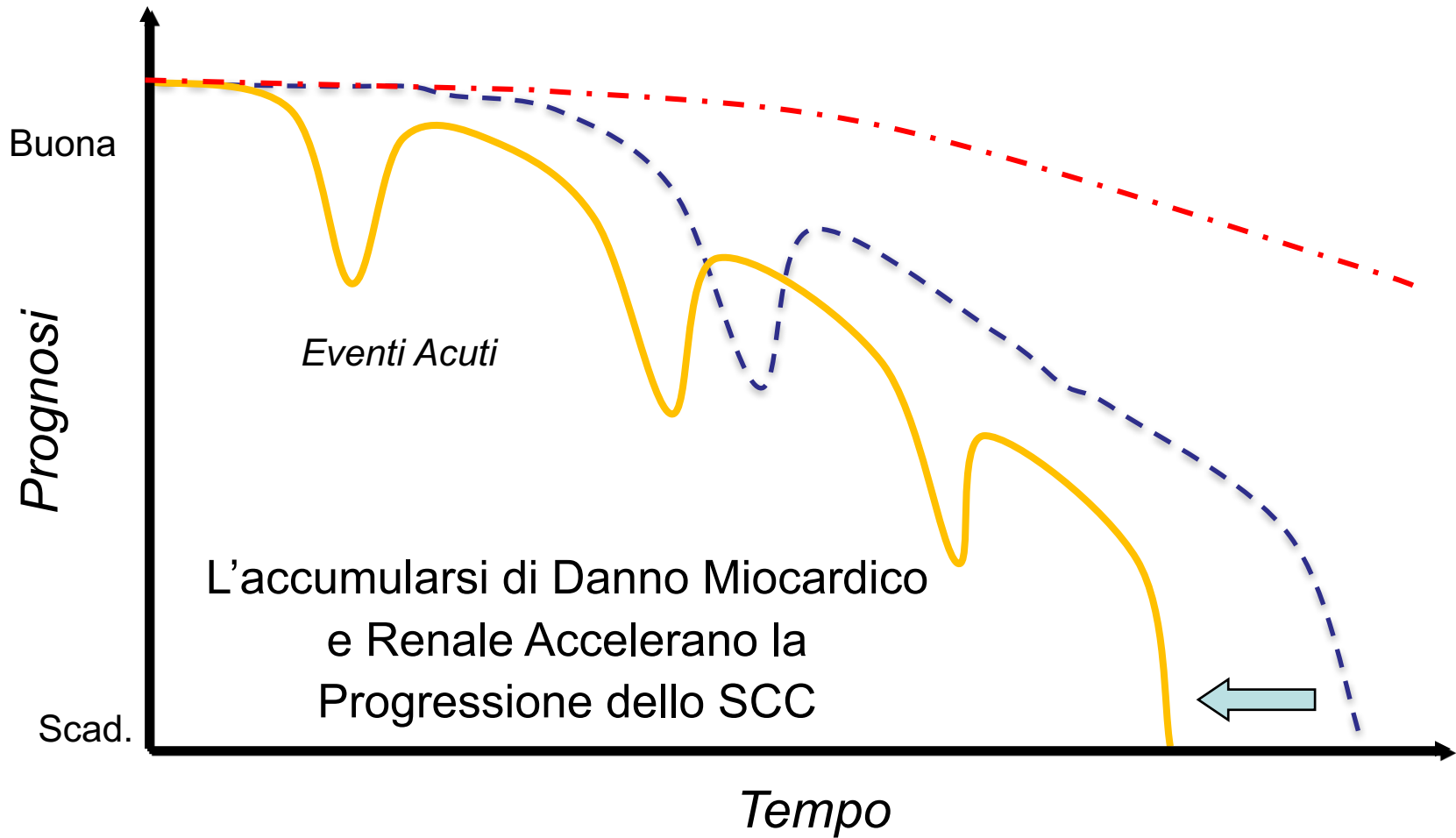


Limiti della Terapia per Scompenso Cardiaco

Attuali Limitazioni Terapeutiche



Storia Clinica Scompenso

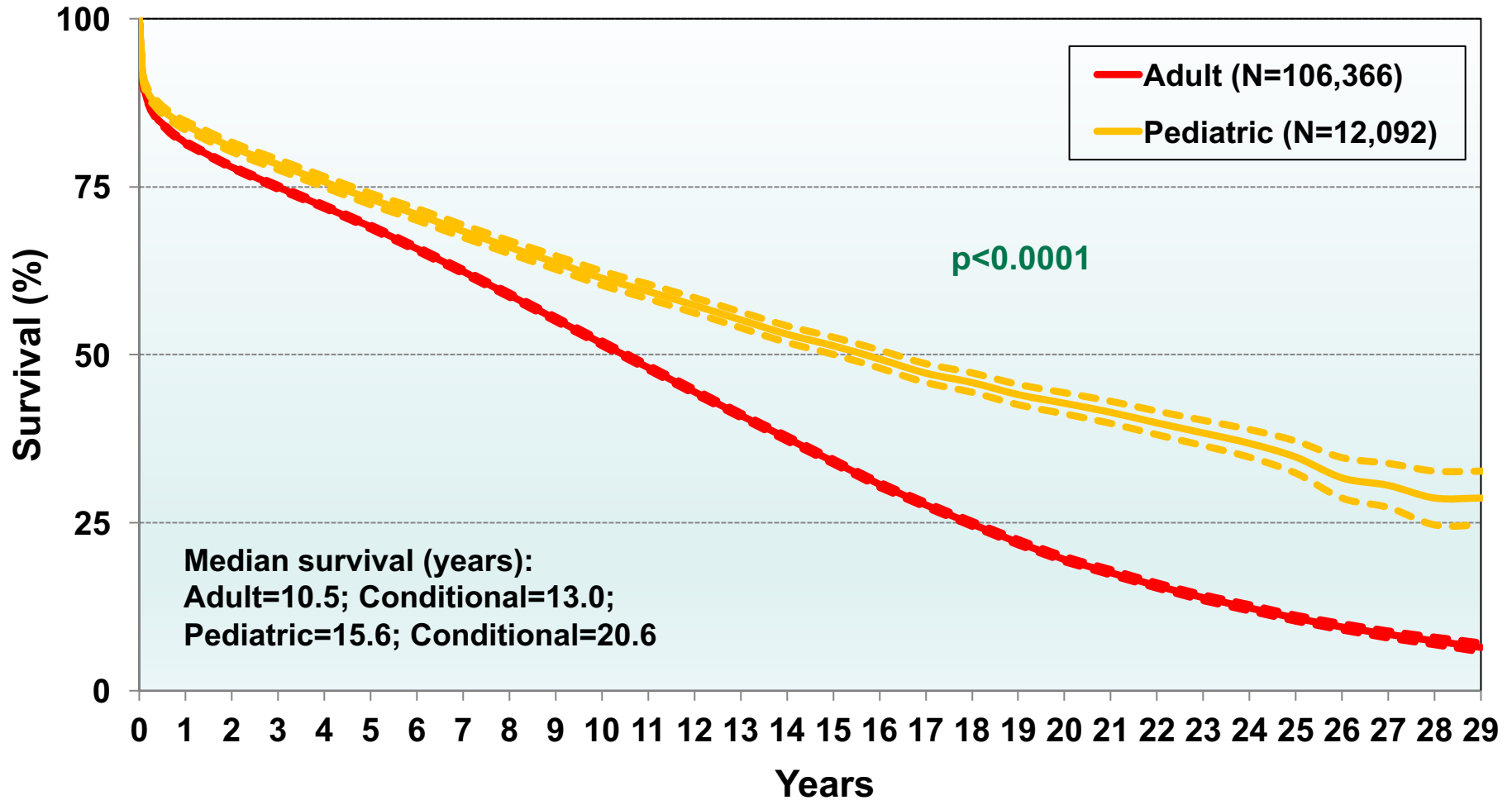


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From Gheorghide . Am J Cardiol 2005 (mod.)

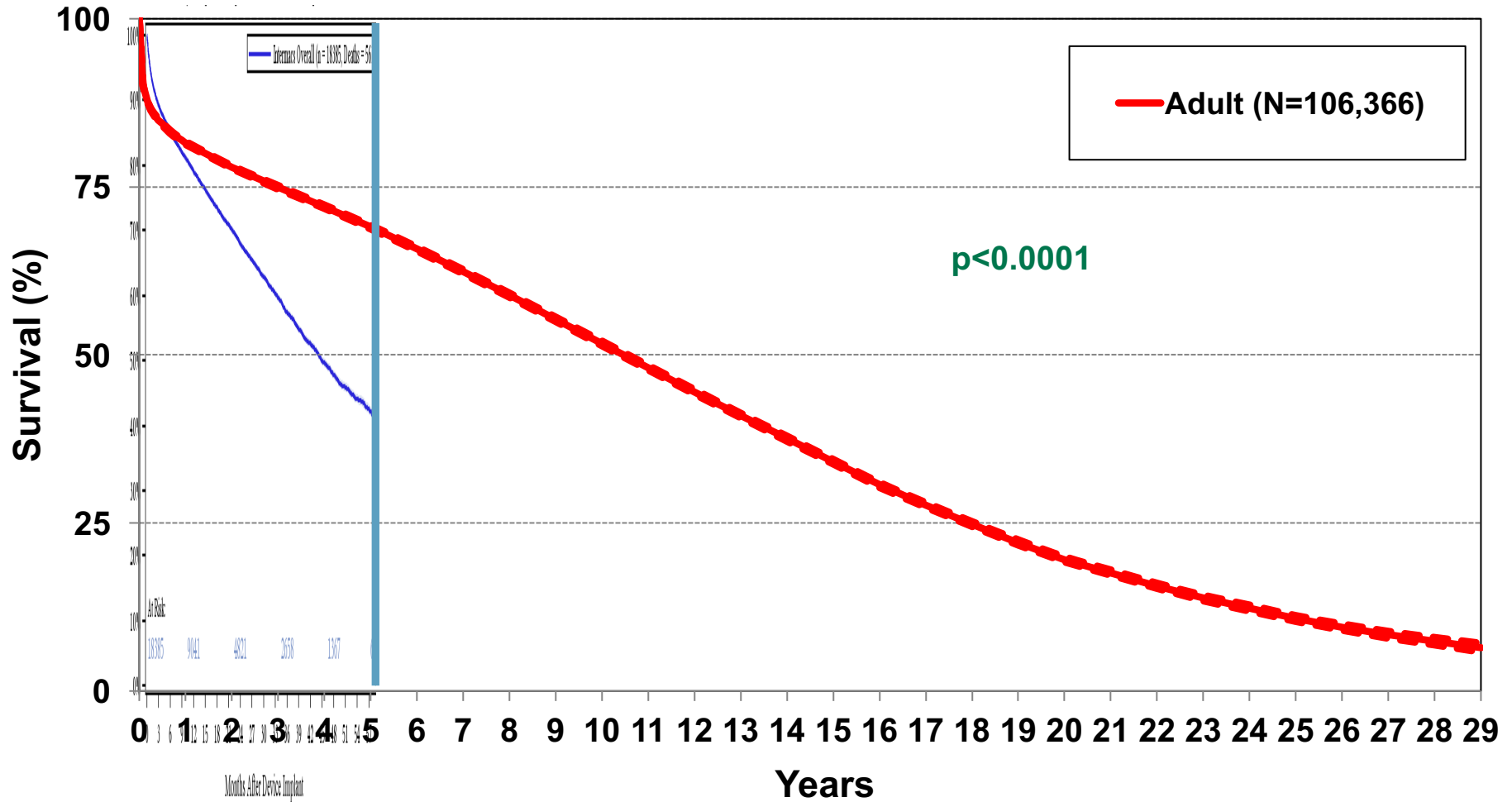
Adult and Pediatric Heart Transplants Kaplan-Meier Survival by Age Group

(Transplants: January 1982 – June 2015)



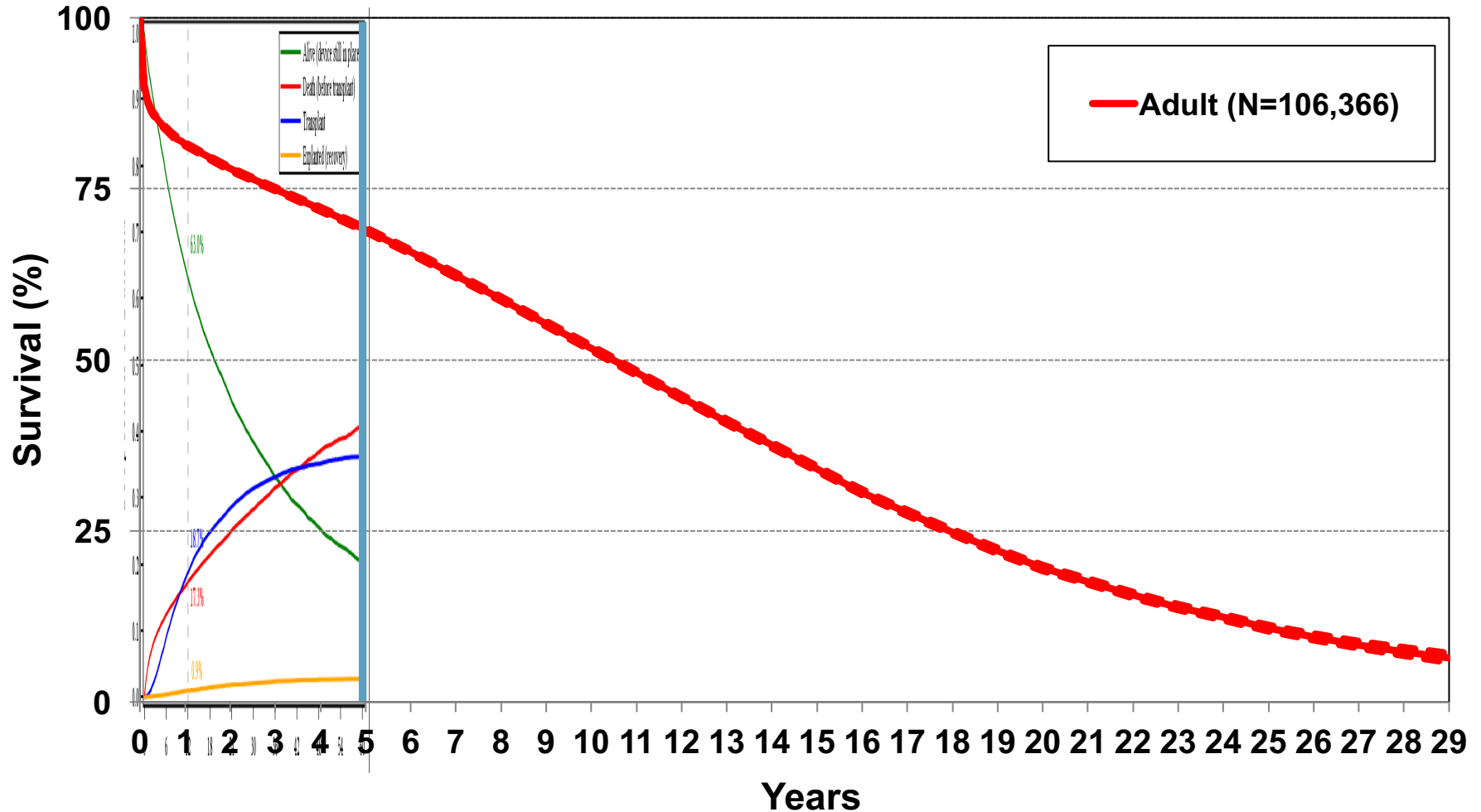
Adult and Pediatric Heart Transplants Kaplan-Meier Survival by Age Group

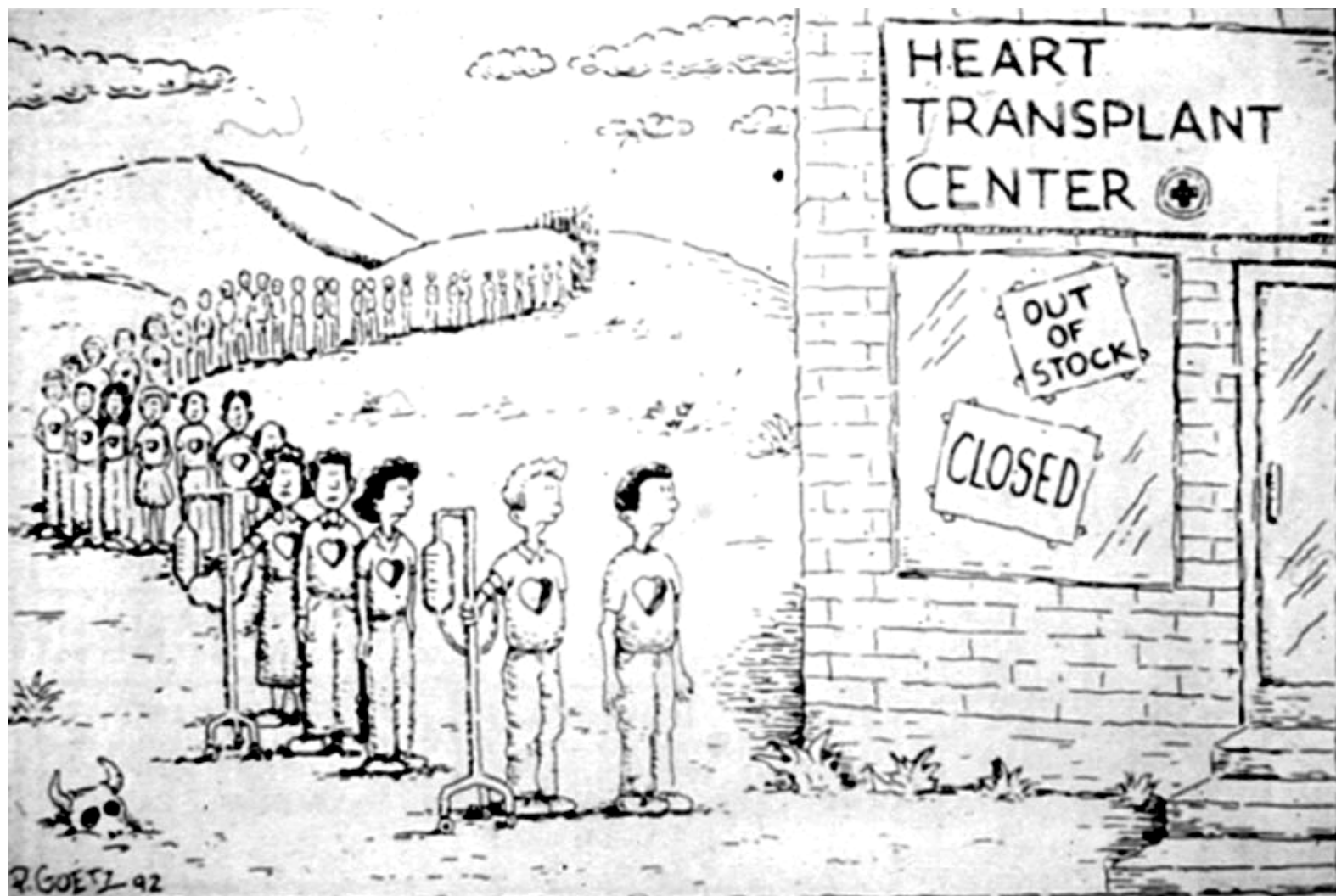
(Transplants: January 1982 – June 2015)



Adult and Pediatric Heart Transplants Kaplan-Meier Survival by Age Group

(Transplants: January 1982 – June 2015)





When is too early –too late?

| | Support Level | | | | | |
|--|---------------|-------|--------|-------|-------|----------|
| | Too Early | Lower | Higher | BIVAD | TAH | Too Late |
| LVEF (%) | 35 | 30 | 25 | 20 | 15 | <10 |
| LVEDD (mm) | 65 | 70 | 75 | 80 | 85 | >90 |
| Indice Cardiaco (l/min/m ²) 1,4 | | 2,4 | 2,2 | 2 | 1,8 | 1,6 |
| PVC | 10 | 12 | 14 | 16 | 18 | >20 |
| APACHE II | <10 | <10 | 11-15 | 11-15 | 16-20 | >20 |
| Inotropi (giorni) | 0 | 0 | 1 | 2-4 | 5-10 | >10 |
| Insufficienza Epatica (bil mg/dl) | <1 | <1.5 | <2 | <3 | <5 | >5 |
| RVF (RVFAC)% | >40 | >40 | >35 | >30 | >25 | <20 |
| Ventilazione (giorni) | 0 | 0 | <1 | 1-3 | 4-6 | >7 |
| Altro supporto meccanico (giorni) | 0 | 0 | <1 | 1-3 | 4-6 | >7 |
| MOF (organs) | 0 | 1 | 1 | 2 | 3 | >3 |

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