

STS/EACTS Latin America Cardiovascular Surgery Conference

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How to Develop a Comprehensive Ventricular Assist Device Program

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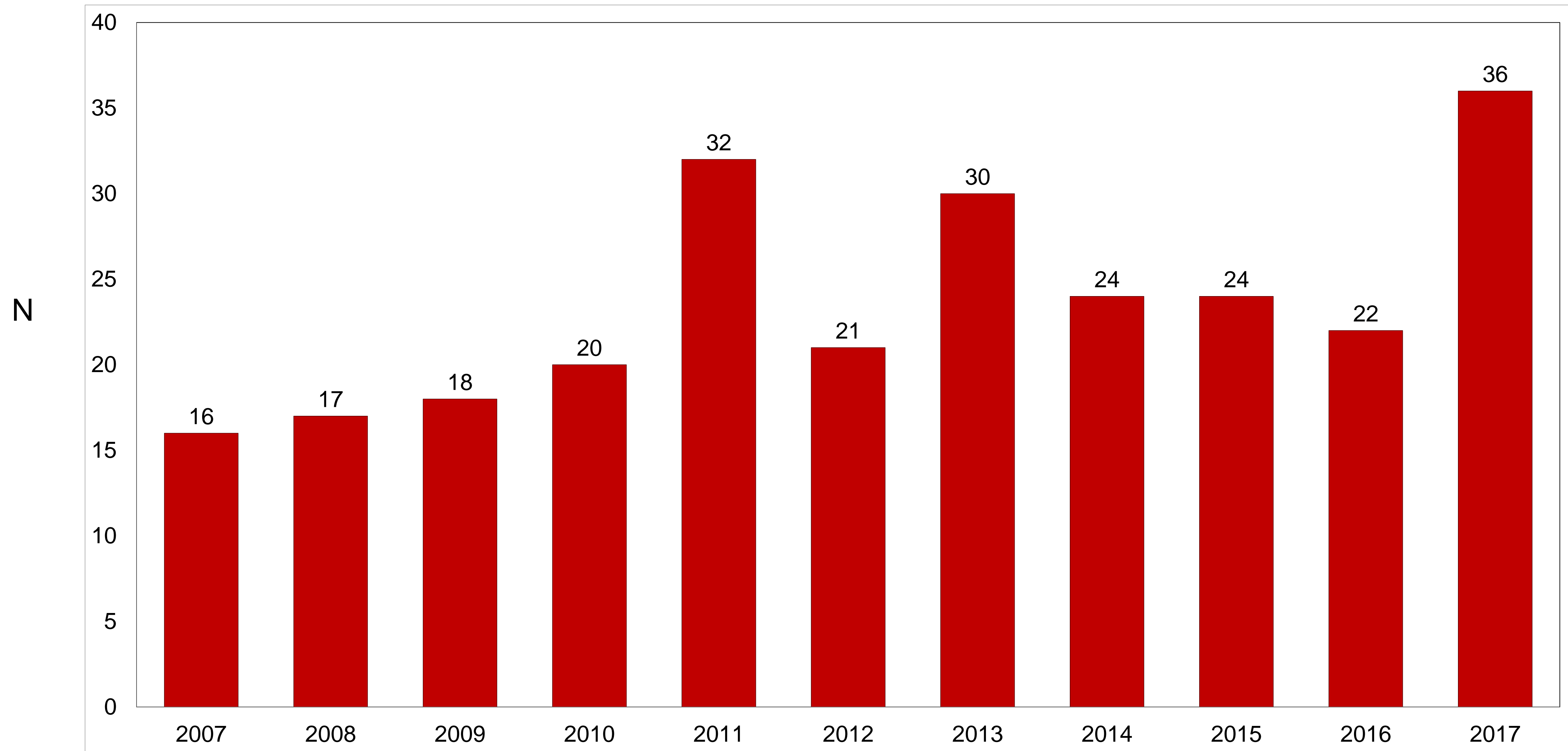


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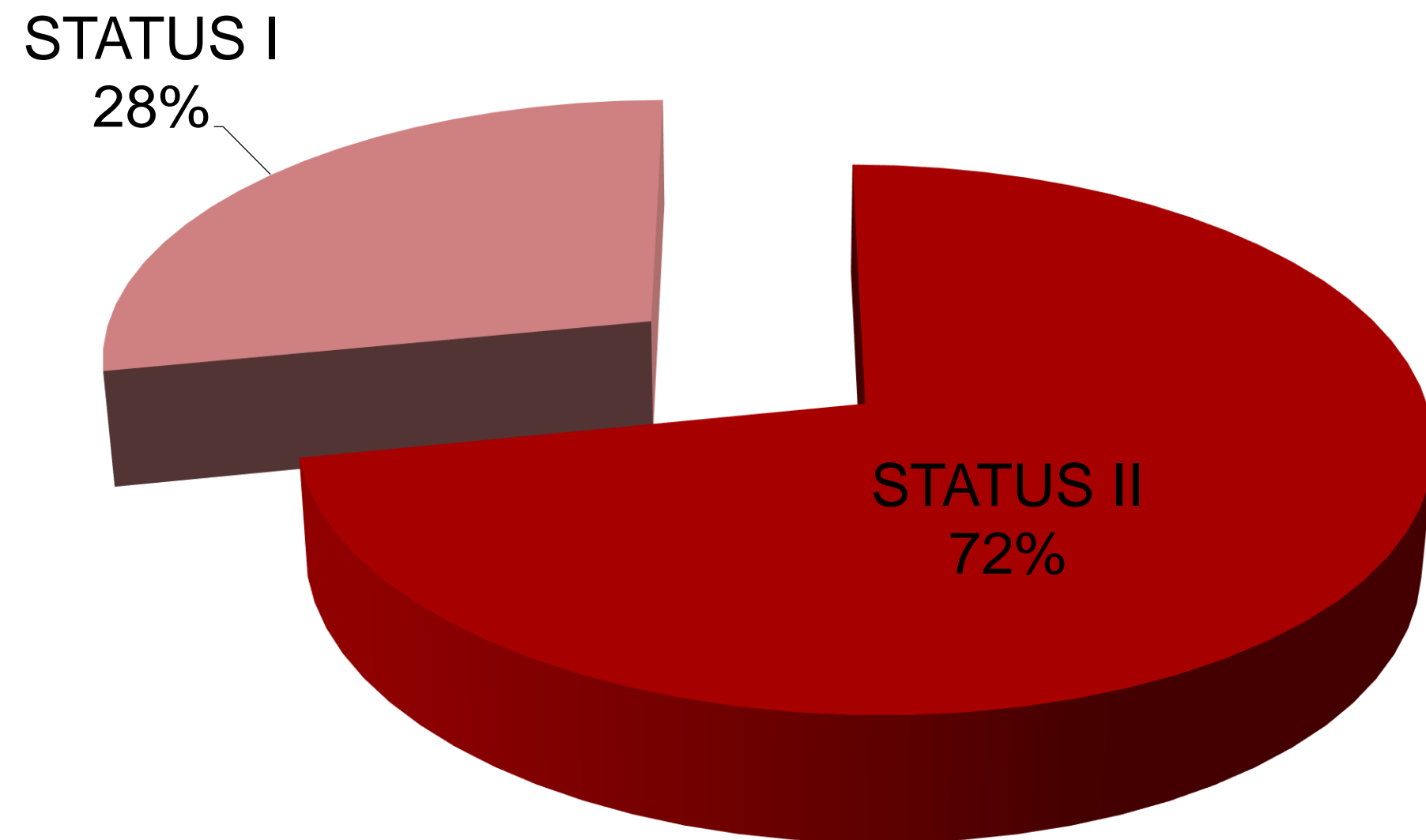
No conflict of interest

HEART TRANSPLANT IN CHILE 2007-2017

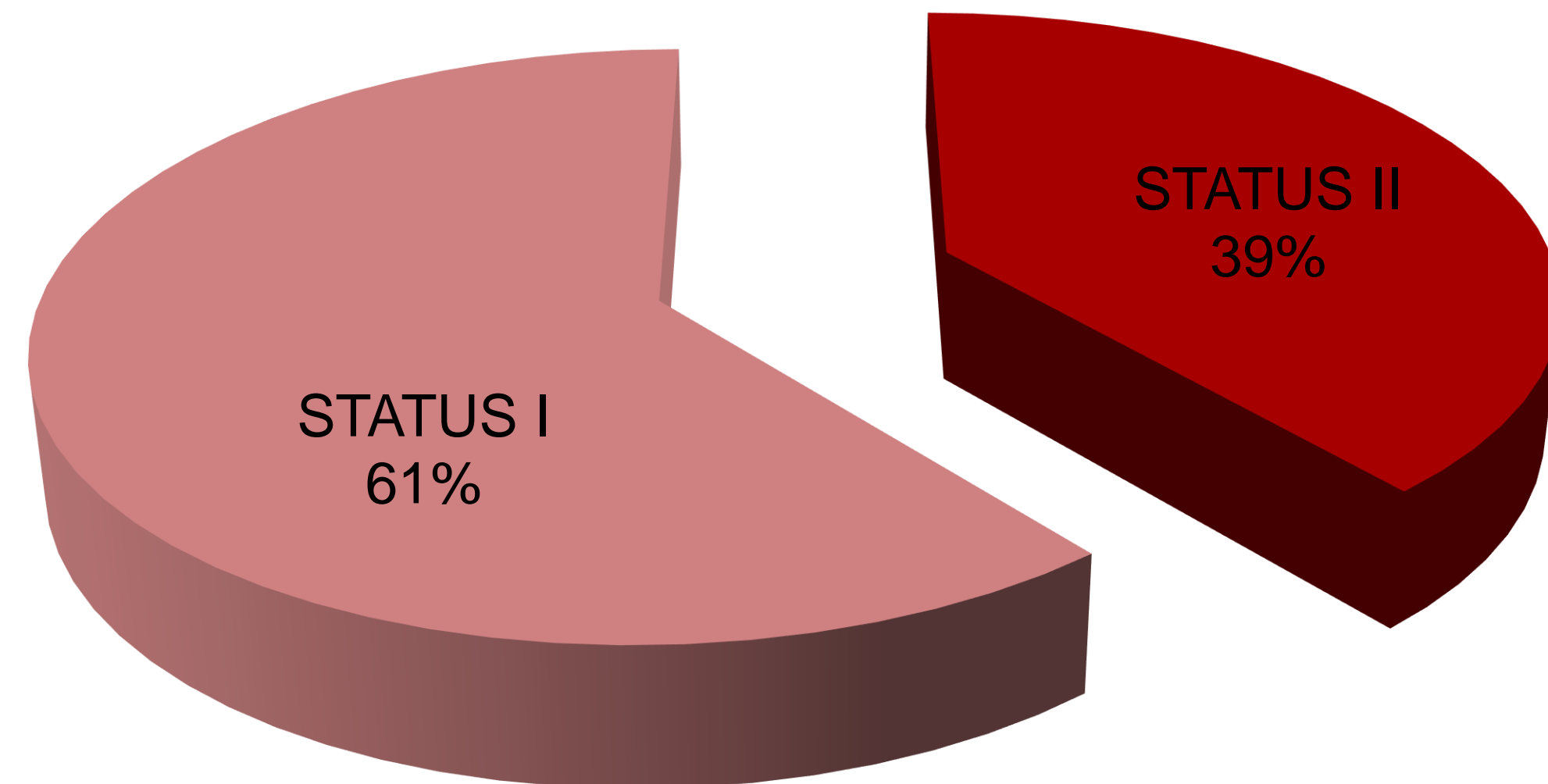


UNOS STATUS AT THE TIME OF HTx CHILE 2011 and 2017

HTx in Chile 2011

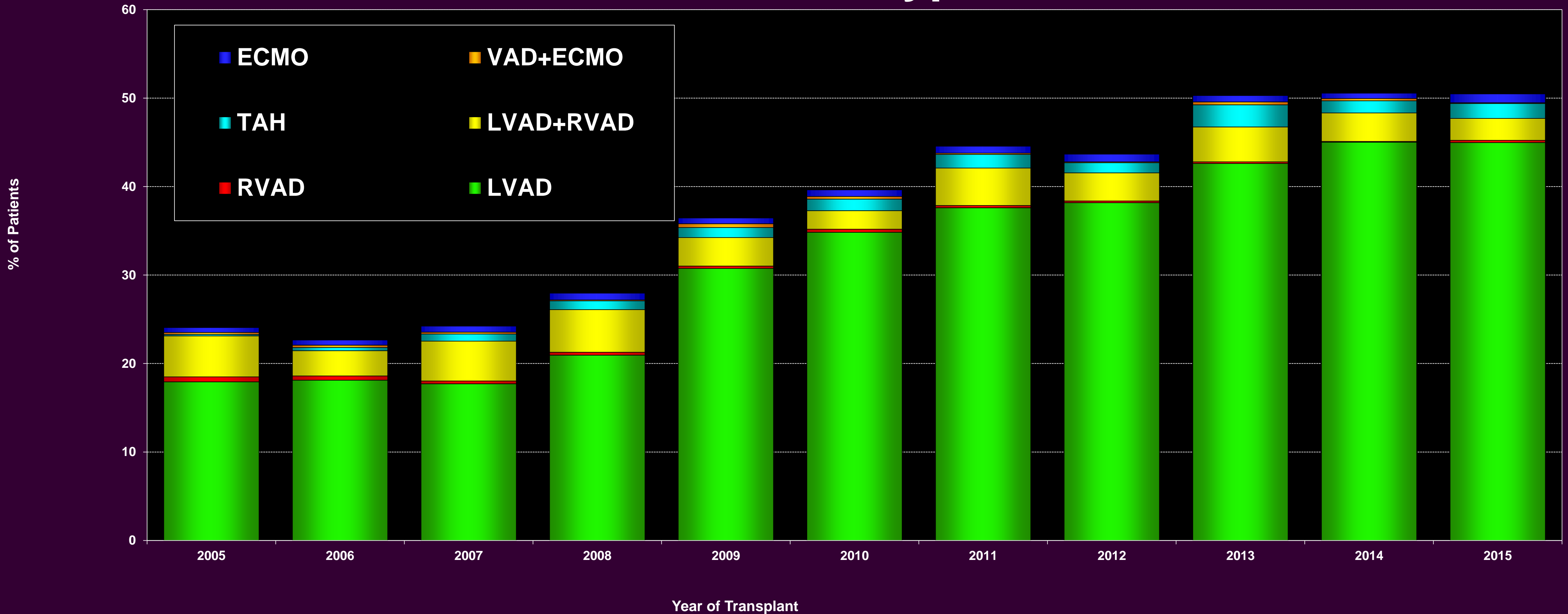


HTx in Chile 2017



Adult Heart Transplants

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



* LVAD, RVAD, TAH, ECMO

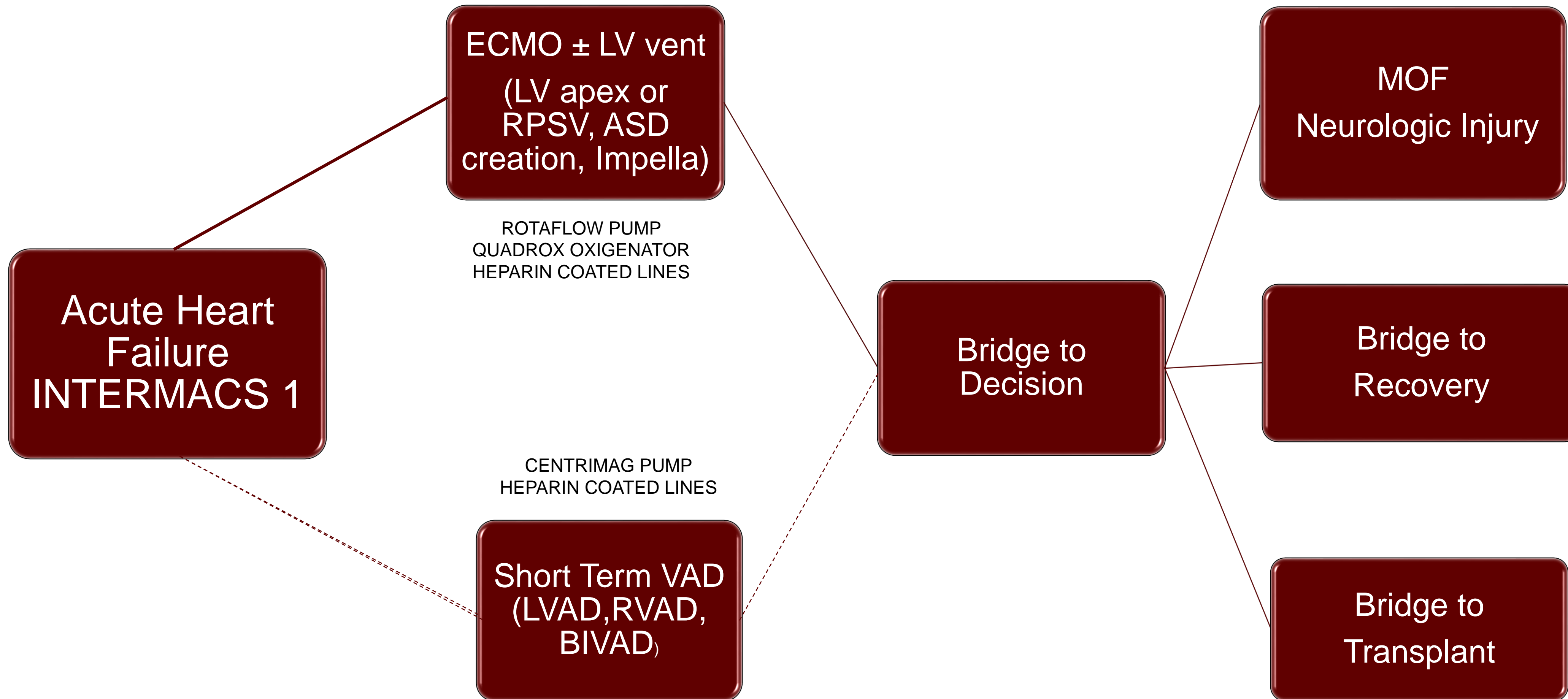


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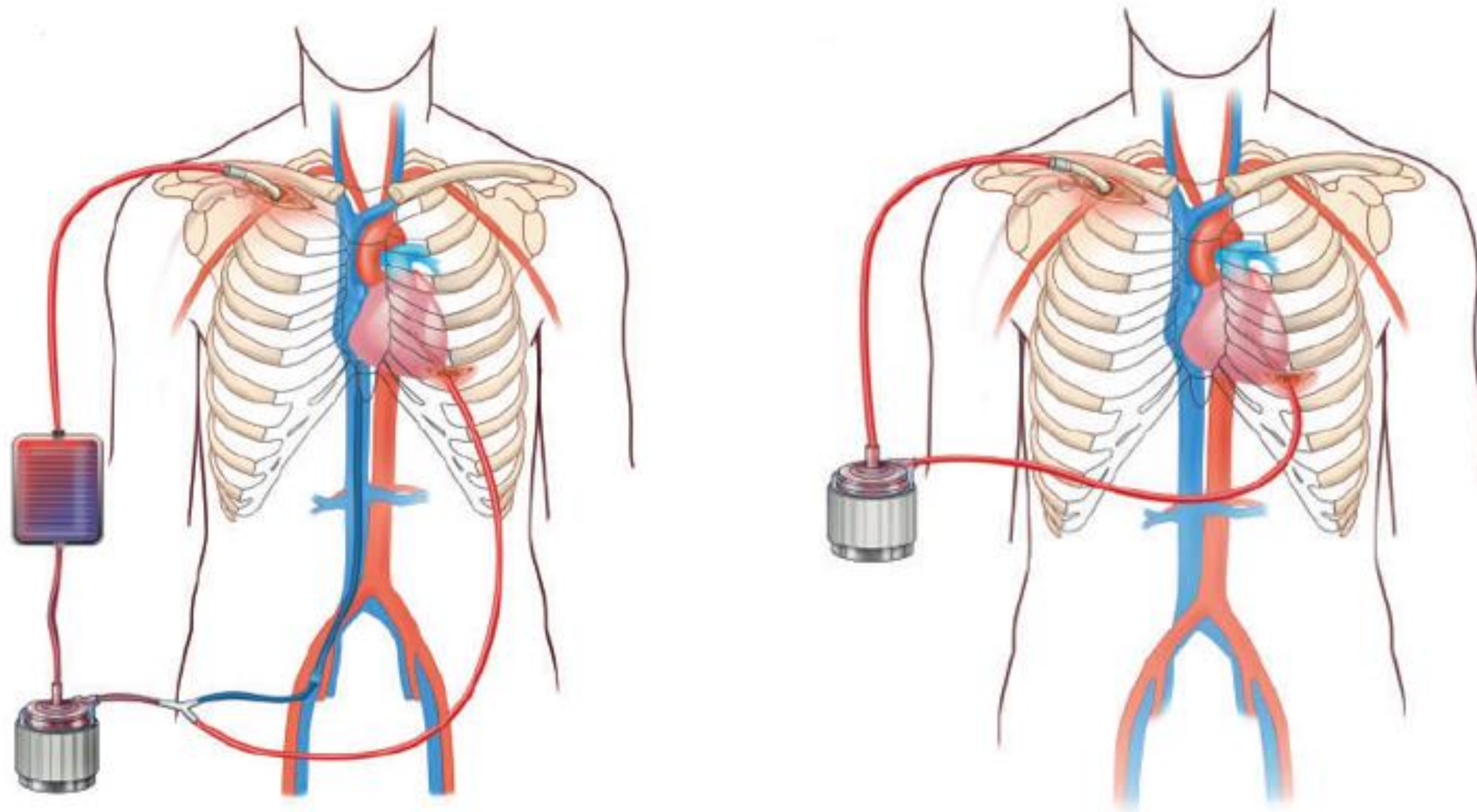


SHORT TERM VADS

MANAGEMENT OF ACUTE HEART FAILURE (INTERMACS 1)



INTERMACS 1: ECMO TO VAD



Columbia University Medical Center, New York



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LONG TERM VADS

Left ventricular assist device (LVAD) program in Chile: first successful experience in South America.

Pedemonte O et al. J Thorac Dis 2018;10(Suppl 15):S1751-S1757

- Long Term LVAD used: HVAD (HeartWare)
- Institution: Hospital Gustavo Fricke, Viña del Mar, Chile
- N : 9 patients (7 males, 2 females); Age : 39 ± 15 (range 15-57)
- Implantation Period: 2013-2017
- Diagnosis: Ischemic CM 4, DCM 3, dHOCM 1, Chemo Induced CM 1
- Indications:
 - Bridge to TX : 8
 - Destination Therapy : 1
- Financing: Kaplan Foundation (private)
- Preoperative support: ECMO 1 (DCM)
 - IABP 1 (Ischemic CM)
- Surgical Technique: Left Anterolateral Thoracotomy + Partial Sternotomy 8
 - Full sternotomy 1

INTERMACS	n
1	1
2	1
3	2
4	5

Left ventricular assist device (LVAD) program in Chile: first successful experience in South America.

Pedemonte O et al. J Thorac Dis 2018;10(Suppl 15):S1751-S1757

- Operative mortality: 1/9 (11,1%) MOF (Intermacs 1 patient)
- ICUS (days): 8,7 ± 5,5 (range 5-23)
- HLOS (days): 17,2 ± 3,8 (range 12-23)
- Follow up (8 patients)
 - 1 patient died 11 months after implantation stroke
 - 1 patient Htx after 16 month
 - 6 patients remain on LVAD mean 846 days (range 23-1481)
- Survival rate: 89%, 78% and 78% at 6, 12 and 18 month

Left ventricular assist device (LVAD) program in Chile: first successful experience in South America.

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ADVERSE EVENTS

Adverse events	<90 days	90–180 days	>180 days	Total
Reexploration for bleeding (n)	2	0	0	2
Renal dysfunction (n)	1	0	0	1
Hepatic dysfunction (n)	1	0	0	1
Sepsis (n)	0	0	1	1
Driveline infection (n)	0	0	2	2
Cerebrovascular accident (n)	1	1	0	2
Digestive bleeding (n)	1	1	2	4
Arrhythmias (n)	3	0	0	3
LVAD thrombosis (n)	0	0	1	1
Outflow stenosis (n)	0	0	1	1

VAD CASES AT HOSPITAL CLINICO UNIVERSIDAD CATOLICA DE CHILE (PEDIATRICS)

Patient n	Age (y)	INTERMACS	Date of Insertion	Pre-VAD Support	VAD System	VAD Type	Days in Device	Actual State	Observation
1	11	2	Apr/2009		Berlin Heart	BIVAD	14	Dead	Pulmonary haemorrhage
2	4	1	Dec/2015	ECMO	Berlin Heart	BIVAD	123	Dead	RVAD pump failure, brain damage
3	12	2	Mar/2011		Centrimag	BIVAD	31	HTX Alive	
4	14	2	Jan/2014		Centrimag	BIVAD	102	HTX Alive	
5	11	2	Dec/2014		Centrimag	BIVAD	103	HTX Alive	2 cerebral haemorrhages, required neurosurgical drainage. No sequelae
6	7	2	Aug2015		Heart Ware	LVAD	1008	HTX Alive	Moya-Moya disease, stroke, driveline infection
7	10	2	Jan/2017		Heart Ware	LVAD	397	HTX Alive	
8	10	2	Jun/2018		Heart Mate 3	LVAD	144	LVAD	
9	11	2	Sep/2018	Centrimag	Heart Mate 3	LVAD	27	LVAD	Severely malnourished, mechanical ventilation
Mean	10	1,89					216,5		

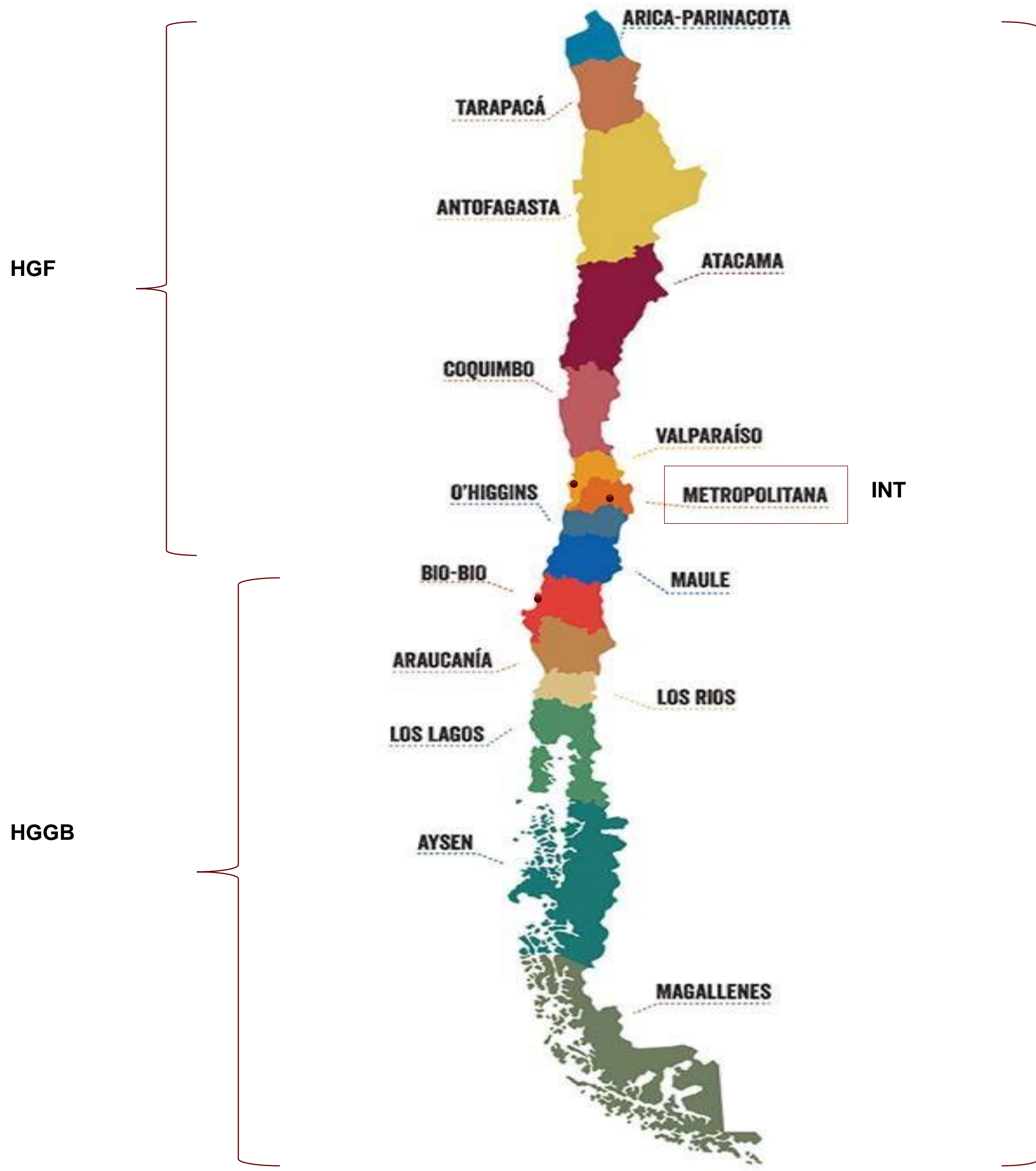
Heart Transplant Centers in Chile Public Health System

- ADULTS

- Instituto Nacional del Tórax, Santiago (Metropolitan Region)
- Hospital Gustavo Fricke, Viña del Mar (North)
- Hospital Guillermo Grant Benavente, Concepción (South)

- PEDIATRICS

- Hospital Clínico Universidad Católica de Chile (whole country)



CHILE (4300 km North-South)

TOTAL POPULATION (2017)
17.574.003
 (F 51,1% M 48,9%)

PUBLIC HEALTH SYSTEM 75-80% population

INT (Santiago)
 Metropolitan Region
 7.112.808
 ≥ 20 years 5.178.124
4.142.499

HGF (Viña del Mar)
 5.983.321
 ≥ 20 years 4.355.858
3.484.686

HGGB (Concepción)
 4.477.874
 ≥ 20 years 3.259.892
2.607.914

HCUC (PEDIATRIC Santiago)
 Population < 20 years
 4.768.447 (27.2%)
3.814.757

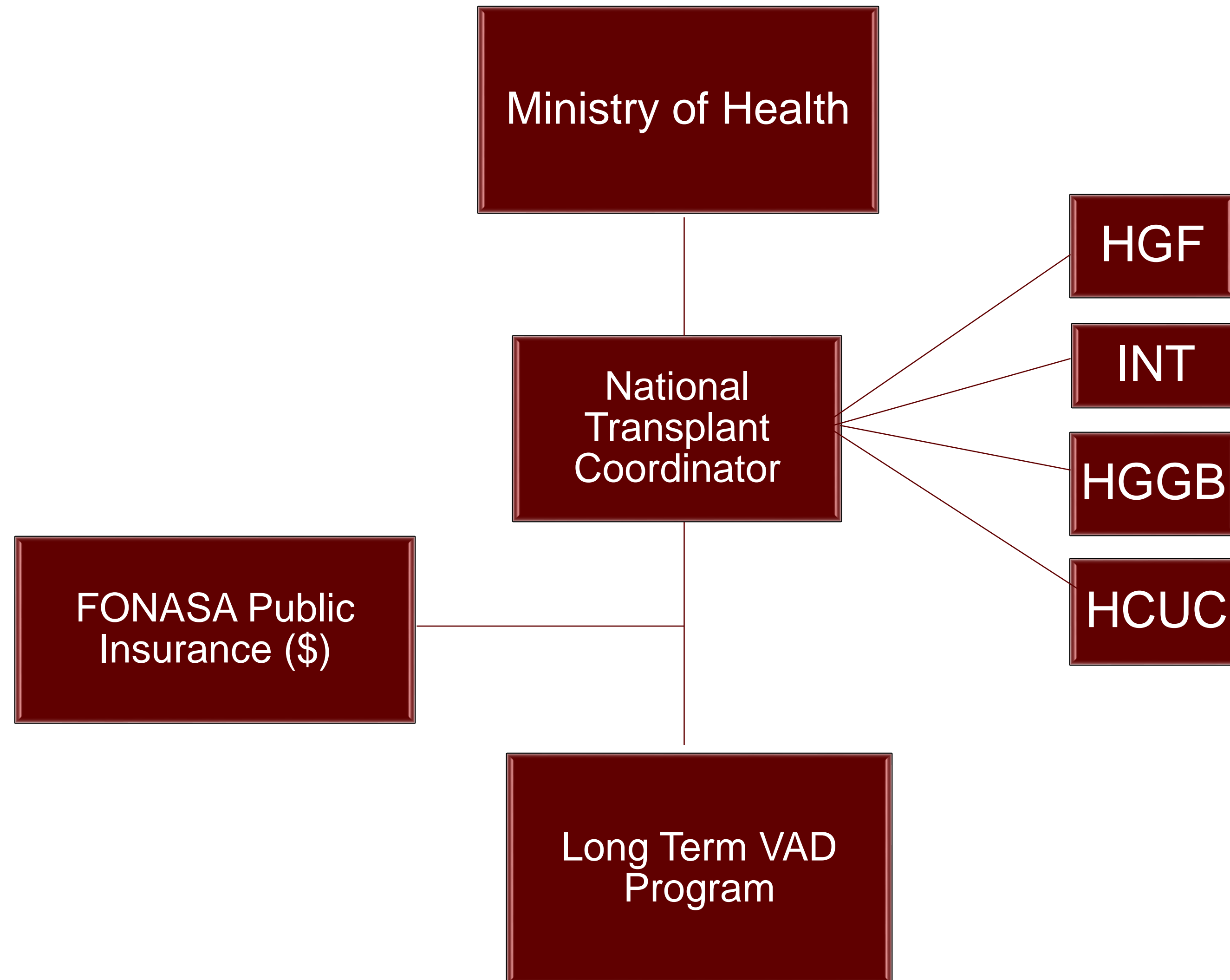
HCUC

INT

HGF

HGGB

Long Term VAD Program in Chile



Long term VAD program in Chile

- The public insurance (FONASA) will provide the financial support
- Includes 10-15 3rd generation pumps per year, with continuous flow and magnetic levitation:
 - Heart Ware
 - Heart Mate 3
- The devices will be **used only as a bridge to transplant**, in patients already in the national waiting list for heart transplantation

Long term VAD program in Chile

- **Inclusion Criteria:**

- **Age ≤ 60 years**
- **INTERMACS profile 2 or 3**
- **Only UNIVENTRICULAR assistance (LVAD or RVAD)**
- **Estimated time in the waiting list for HTx > 45 days**
(estimated time < 45 days, Centrimag VAD will be considered)

Long term VAD program in Chile

- Patients in INTERMACS 1 connected to ECMO, will be considered if:
 - No CNS damage
 - No evidence of heart recovery
 - Evidence of recovery of all other organs
 - Meets all inclusion criteria

Long term VAD Program in Chile

- **Exclusion criteria**
 - **Biventricular failure**
 - **High probability of Right Ventricular failure**

Table 6: Pre-implant Predictors of Acute Right Ventricle Failure

		Comment
Echocardiographic findings	RVEDV > 200 ml RVESV > 177 ml RV free wall strain RV fractional area change RV volumes assessed by 3D	
Laboratory	Bilirubin > 2mg/dl AST >80 IU, Creatinine > 2.3mg/dl WBC > 10.4X10 ³ /mL Haematocrit <31 %	
Haemodynamics	PVR >4 woods unit TPG >15 mmHg CVP >15 mmHg RVSWI < 300 mmHg.ml/m ² CVP / PCWP ratio >0.63	RVSWI < 600 – 38 % risk of RV failure RVSWI > 900 – 3 % risk for RV failure.
Clinical	On vassopressors Pre-op mechanical ventilation	Need for vassopressors

RVEDV = Right ventricle end diastolic volume; RVESV = Right ventricle end systolic volume; RV = right ventricle; AST = aspartate aminotransferase; WBC = white blood count; PVR = pulmonary vascular resistance; TPG = trans-pulmonary gradient; CVP = central venous pressure; RVSWI = Right ventricle stroke work index. Equal to the stroke volume index multiplied by the difference between the mean pulmonary artery pressure and the mean right pressure.³⁰⁻³⁶

Long term VAD program in Chile

- Relative Exclusion Criteria
 - Previous cardiac surgery
 - Complex congenital heart disease

Each case should be discussed individually

Long term VAD program in Chile

- Any potential receptor of a long term VAD:
 - Will be presented and discussed in an expert committee, with at least one representative of each of the other centers and the National Coordinator of the National Transplant Program
 - They will decide if the patient can receive the device for implantation
- A registry will be kept of the results of the implants and its complications
- If better VAD systems reach the market in the future, the expert committee will evaluate its incorporation to the program

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