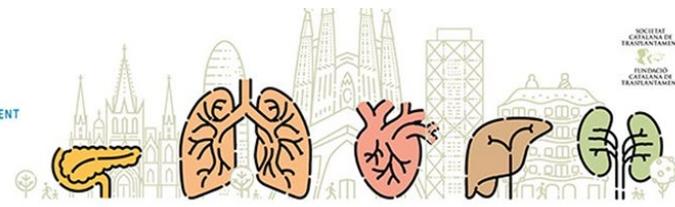


Actualización en sistemas de priorización para el trasplante cardiaco

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Introducción

- El trasplante cardiaco es la terapia de elección para la insuficiencia cardiaca terminal.
- El número anual de trasplantes queda limitado por la disponibilidad de órganos aptos para el trasplante.
- Es fundamental asegurar unos criterios de distribución que permitan:
 - Equidad en el acceso al trasplante.
 - Priorización de los pacientes más críticos.
 - Evitar la futilidad.

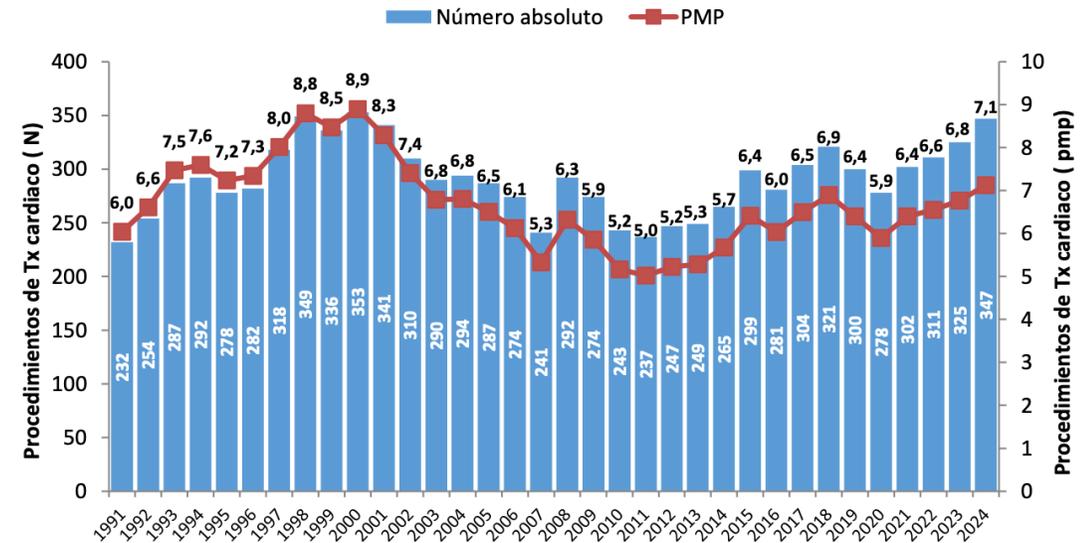
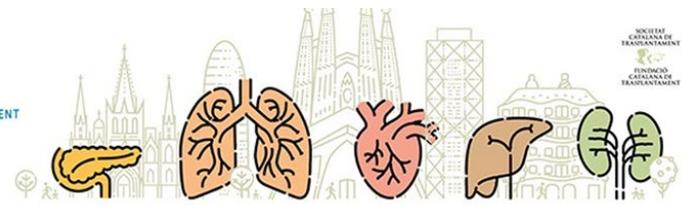
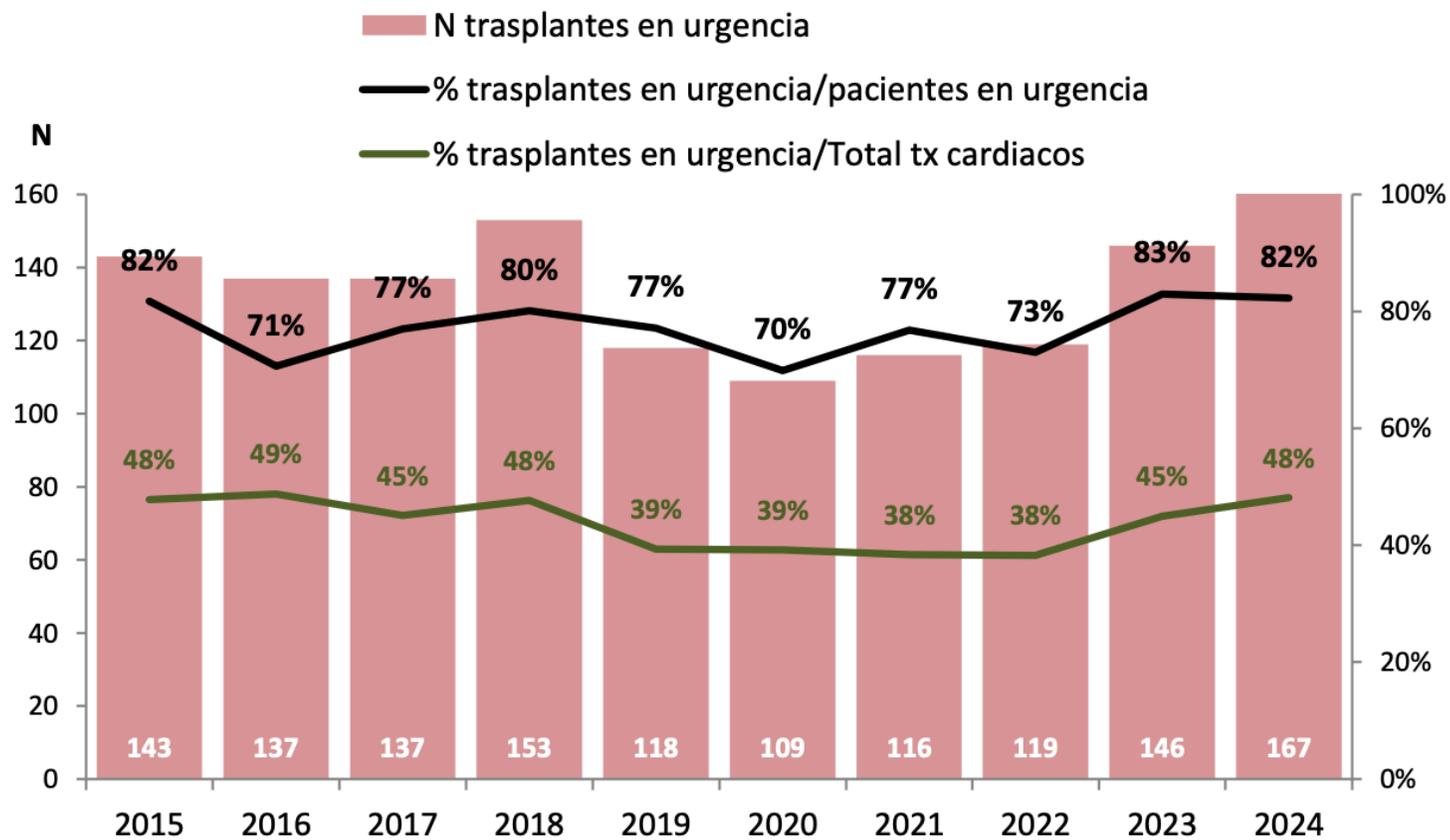
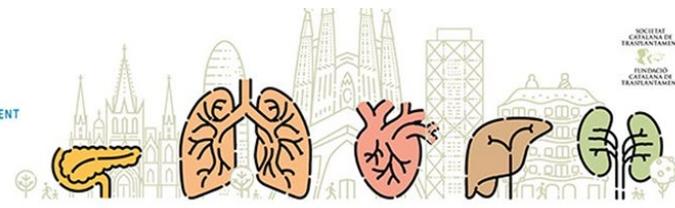


Figura 1. Procedimientos de trasplante cardiaco. España 1991-2024.



Introducción





Introducción

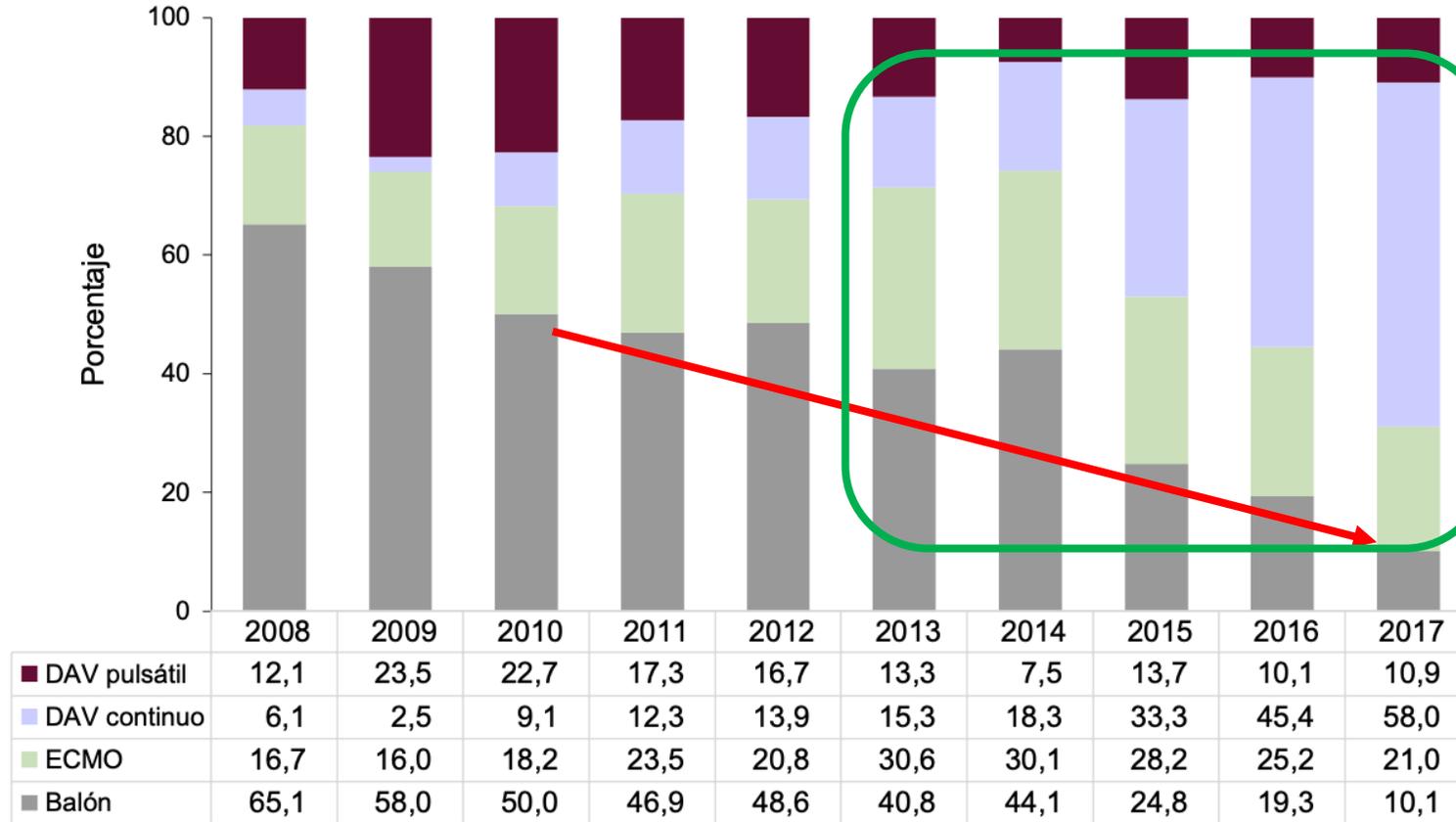


TABLE 1 Specific clinical criteria used to define waiting list priority levels in adult heart transplant candidates in the Spanish organ donor allocation system: changes over the period 2010-2020

Waitlist priority status	Era 1 (Jan 2010-May 2014)		Era 2 (June 2014-May 2017)		Era 3 (June 2017-December 2017)	
	Qualifying criteria		Specifications		Qualifying criteria	
Specifications Status 0 (High urgency)	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> ECMO Percutaneous VAD Surgically implanted non-dischargeable VAD 	National priority ^c	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> ECMO Percutaneous VAD Surgically implanted non-dischargeable VAD 	National priority ^c	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> ECMO Percutaneous VAD Surgically implanted non-dischargeable VAD 	National priority ^c Specific additional conditions are defined for candidates listed with ECMO or percutaneous VAD ^e
	Durable devices (dischargeable) <ul style="list-style-type: none"> Paracorporeal VAD Intracorporeal VAD 		Durable devices (dischargeable) <ul style="list-style-type: none"> Paracorporeal VAD with device-related complications Intracorporeal VAD with device-related complications 		Durable devices (dischargeable) <ul style="list-style-type: none"> Paracorporeal VAD with major device-related complications^f Intracorporeal VAD with major device-related complications^f 	
Status 1 (Urgency)	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> IABP 	National priority ^c	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> IABP 	Regional priority ^d	Temporary devices (non-dischargeable)^a <ul style="list-style-type: none"> IABP 	Regional priority ^d
			Durable devices (dischargeable)^b <ul style="list-style-type: none"> Paracorporeal VAD without device-related complications Intracorporeal VAD without device-related complications 		Durable devices (dischargeable)^b <ul style="list-style-type: none"> Paracorporeal VAD with minor device-related complications^g Paracorporeal VAD without device-related complications Intracorporeal VAD with minor device-related complications^g 	
			Other indications <ul style="list-style-type: none"> Refractory arrhythmic storm 		Other indications <ul style="list-style-type: none"> Post-desensitization candidates 	
Status 2 (Elective)	• All other candidates	No priority	• All other candidates	No priority	• All other candidates	No priority

ECMO, Extracorporeal membrane oxygenation; VAD, ventricular assist device.

^aExamples of percutaneous devices: Impella 2.5, Impella CP, Impella 5.0, Tandemheart, or similar. Examples of surgically implanted, nondischargeable devices: Centrimag (continuous flow), Abiomed BVS5000 (pulsatile flow), Abiomed AB5000 (pulsatile flow), or similar.

^bExamples of durable, dischargeable paracorporeal VADs (pulsatile flow): Berlinheart Excor, Thoratec PVAD or similar. Examples of durable, dischargeable intracorporeal VADs (continuous flow): Heartware HVAD, Heartmate II, Heartmate III.

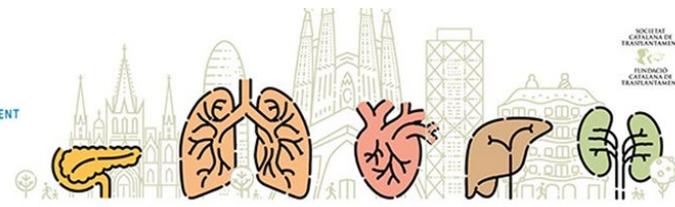
^cNational priority implies that these patients have priority over candidates listed with inferior levels for getting the first suitable donor heart which was retrieved within the whole nation of Spain.

^dRegional priority implies that these patients have priority over candidates listed in status 2 for getting the first suitable donor heart retrieved within the reference geographical area of their attending hospitals, but not for organs retrieved in other regions of Spain.

^eSpecific additional conditions defined for patients listed as status 0 with ECMO or percutaneous VAD during Era 3 are the following: a. A minimum period of 48 hours must have been elapsed since device implantation before the patient is listed for emergency HTx. b. Patients must be free of multi-organ failure at the time of emergency HTx listing. c. Patients can stay in the waiting list as status 0 for a maximum period of 7 days, which can be extended to a maximum of 10 days if they are extubated and continue to be free of multi-organ failure. Once this time period has expired, the candidate is downgraded to status 1.

^fMajor device-related complications are pump thrombosis or mechanical dysfunction.

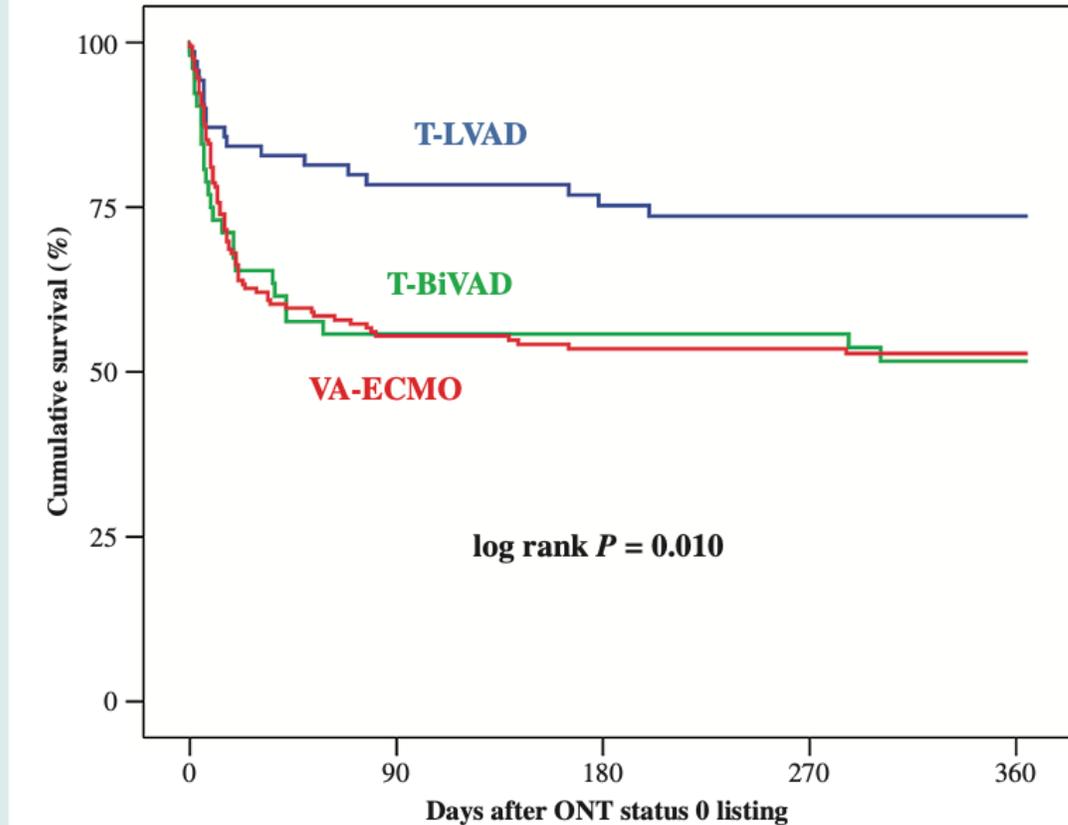
^gMinor device-related complications are driveline infection, severe right ventricular failure, or gastrointestinal bleeding.



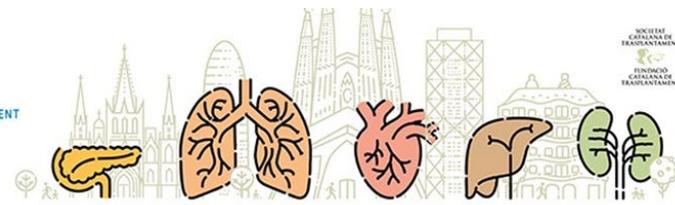
Introducción

Table 6
Univariable survival analysis by

Percentage of total series		P
Recipient age		
< 16 y		.21
16-60 y		.004
> 60 y		
Type of transplant		
Single		
Combined		.049
Retransplant		.19
Donor age		
≤ 45 y		
> 45 y		.75
Urgency code		
Elective		
Urgent		.009
Type of support		
No support		
Balloon pump		.80
ECMO		< .001
Ventricular assist device		.19



95%CI, 95% confidence interval; ECMO, extracorporeal membrane oxygenation.



Cambio de paradigma en EUA

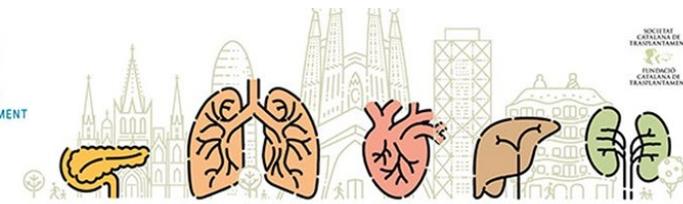


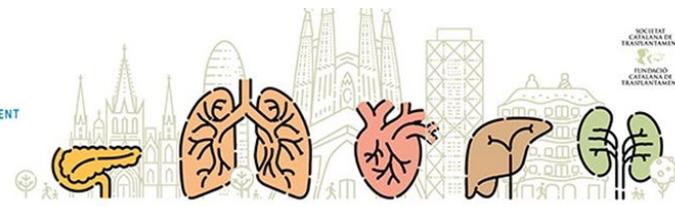
- Simultáneamente a los cambios de criterios para el trasplante en ECMO, en EUA se cambiaron los criterios de distribución de 3 niveles (status 1A, status 1B and status 2) a un sistema de 7 niveles.
- Se paso a priorizar a los pacientes en ECMO y dispositivos de corta duración, para reducir la mortalidad en lista y favorecer “compartir” órganos.

TABLE 1.

Change in heart allocation criteria resulting in a new 6-tiered system

Old allocation system	New allocation system	Listing criteria
	Status 1	<ul style="list-style-type: none"> • VA-ECMO • Nondischargeable, surgically implanted, nonendovascular biventricular support device • MCS D with life-threatening ventricular arrhythmia
Status 1A	Status 2	<ul style="list-style-type: none"> • IABP • Nondischargeable, surgically implanted, nonendovascular LVAD • VT or VF without mechanical support • MCS D with device malfunction or failure • TAH, BiVAD, RVAD, or VAD for single ventricle patients • Percutaneous endovascular MCS D
	Status 3	<ul style="list-style-type: none"> • Dischargeable LVAD for discretionary 30 d • Multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring • Single inotrope with continuous monitoring • VA-ECMO after 7 d; IABP or percutaneous endovascular circulatory support device after 14 d • Nondischargeable, surgically implanted, nonendovascular LVAD after 14 d • Mechanical support device with complication
Status 1B	Status 4	<ul style="list-style-type: none"> • Dischargeable LVAD without discretionary 30 d • Inotropes without hemodynamic monitoring • Retransplant • Diagnosis of CHD, ischemic heart disease with intractable angina, hypertrophic CM, restrictive CM, amyloidosis
Status 2	Status 5	<ul style="list-style-type: none"> • On waitlist for at least one other organ at the same hospital
	Status 6	<ul style="list-style-type: none"> • All other active candidates





Cambio de paradigma en EUA

Table 2. Comparison of Recipient, Donor, and Transplant-Related Characteristics at the Time of Transplant Before and After the Change in Heart Allocation Policy*

Characteristic	Before change (n = 6078)	After change (n = 2801)	P value
Recipients			
Age, mean (SD), y	53.9 (12.7)	52.8 (13.1)	<.001
Pretransplant mechanical ventilatory support	63 (1.0)	80 (2.9)	<.001
Pretransplant intensive care unit	1907 (31.4)	1543 (55.1)	<.001
Intra-aortic balloon pump	534 (8.8)	887 (31.7)	<.001
Extracorporeal membrane oxygenation	71 (1.2)	172 (6.1)	<.001
Bridge with ventricular assist device			
None	3381 (55.6)	1823 (71.5)	<.001
Left ventricular assist device	2549 (41.9)	651 (25.5)	
Right ventricular assist device	9 (0.2)	10 (0.4)	
Total artificial heart	50 (0.8)	14 (0.6)	
Biventricular assist device	89 (1.5)	51 (2.0)	
Type of left ventricular assist device			
HeartMate 2	1168 (19.2)	107 (3.8)	<.001
HeartWare	966 (15.9)	203 (7.3)	<.001
HeartMate 3	68 (1.1)	239 (8.5)	<.001
Other durable device	399 (6.6)	124 (4.4)	<.001
Temporary device	62 (1.0)	105 (4.2)	<.001

Left ventricular assist device	2549 (41.9)	651 (25.5)	
Right ventricular assist device	9 (0.2)	10 (0.4)	
Total artificial heart	50 (0.8)	14 (0.6)	
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A Competing risk of death or clinical deterioration

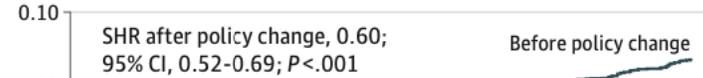
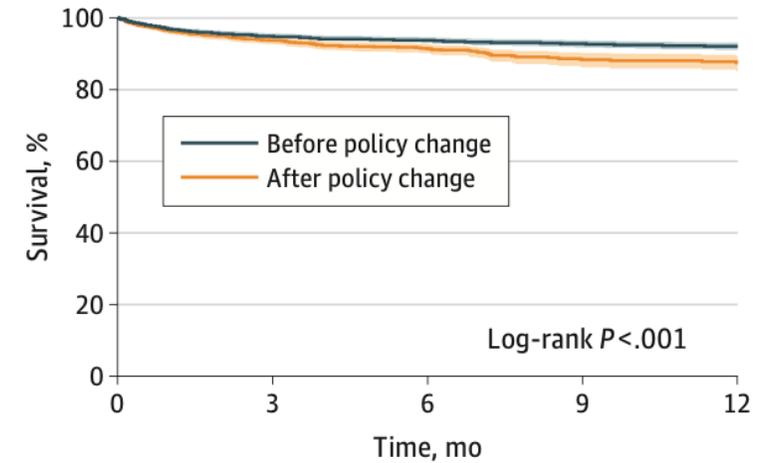
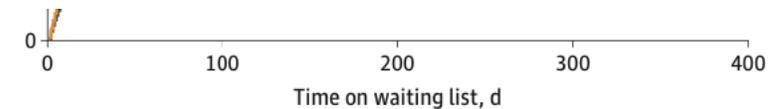


Figure 2. Kaplan-Meier Curve



No. at risk	0	3	6	9	12
Before policy change	6068	5737	5654	5573	5152
After policy change	2455	1443	976	343	242

The 1-year survival after heart transplant following the policy change decreased. Shaded areas indicate 95% CIs.



Spain (2022 criteria)

Urgency status 0 (national)

- Total ST-VAD support, without multiorgan failure
- VA-ECMO or partial ST-VAD support, more than 2 days after implantation and less than 7 days on the waiting list, extendable to 10 days if the patient is extubated
- Patients with malfunctioning dVAD due to mechanical dysfunction or thrombosis
Pediatric patients: any type of circulatory support (including VA-ECMO)

Urgency status 1 (regional)

- Patients with a properly functioning external dVAD
- Patients with a malfunctioning implanted dVAD due to driveline infection, gastrointestinal bleeding, or severe right ventricular failure
- Hyperimmunized patients responding to desensitization therapy

Pediatric patients:

- Patients requiring intravenous inotropic support
- Fontan circulation with severe protein-losing enteropathy
- Restrictive cardiomyopathy with a pulmonary vascular resistance index ≥ 6 WU/m²

Regional priority (after urgency status 1)

- Patients with a cPRA $\geq 50\%$ and possibility of virtual crossmatch

Eurotransplant

International priority

- Signs of hypoperfusion with inotropic dependence or temporary MCS
- Intractable ventricular arrhythmias
- Amyloidosis or restrictive cardiomyopathy
- Severe congenital heart disease
- Severe primary graft failure
- dVAD with complications: dVAD dysfunction, thromboembolism, intractable bleeding, aortic regurgitation, systemic infection, chronic right heart failure

National priority (own national criteria)

France

Individual score including:

1. Recipient risk score based on VA-ECMO presence and duration of support, natriuretic peptides, glomerular filtration rate, and bilirubin
2. Exception (additional points):
 - Complications from dVAD (thrombosis, bleeding, infection, dysfunction)
 - Arrhythmic storm
 - TAH and BVS without complications
 - Contraindication to MCS
3. Transplant risk score: based on 7 recipient variables (age, indication, previous cardiac surgery, diabetes mellitus, mechanical ventilation, glomerular filtration rate, and bilirubin) and 2 donor variables (age and sex). This criterion is Yes/No and means that a heart is not offered if the mortality risk is $\geq 50\%$
4. The total score is adjusted to the predicted travel time

United Kingdom

Superurgent:

- VA-ECMO
- Temporary MCS
- Accepted by a panel of experts and 1 of the following: IABP, imminent risk of death and/or complications without possibility of MCS implantation, pediatric patients on VA-ECMO

Urgent:

- Inotropic agent/IABP dependency
- TAH or dVAD with RV failure and inotropic agent dependency or recurrent infection or thrombosis
- High risk of death or irreversible complications
- Refractory arrhythmia
- Not candidate for MCS or inotropic agents and 1 MOF criterion*

Pediatric patients:

- Short-term MCS or Berlin Heart
- dVAD with complications
- > 15 kg with high-dose inotropic agents
- < 15 kg, ventilated with inotropic agents
- Exception

United States

Status 1

- VA-ECMO
- Unstable surgically implanted biventricular MCS
- Ventricular arrhythmia with MCS

Status 2

- Nondischargeable MCS, surgically implanted, not endovascular
- IABP
- Ventricular arrhythmias without MCS
- MCS dysfunction
- Endovascular MCS
- TAH, BVS, univentricular support in patients with a single ventricle

Status 3

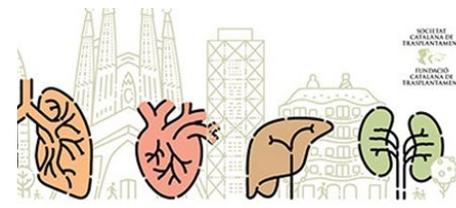
- Dischargeable dVAD, less than 30 days
- High-dose inotropic agents with hemodynamic monitoring
- VA-ECMO after 7 days, percutaneous ventricular support or IABP > 14 days
- dVAD with a complication: infection, hemolysis, thrombosis, RV failure, mucosal bleeding, aortic regurgitation

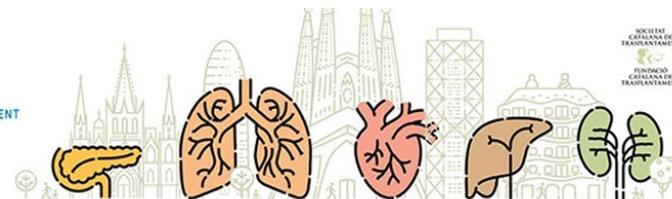
Status 4

- Dischargeable dVAD, after 30 days
- Inotropic agents without hemodynamic monitoring
- Retransplantation
- Congenital heart disease
- Intractable angina
- Hypertrophic or restrictive cardiomyopathy/amyloidosis

Status 5

On the waiting list for another organ in the same hospital





Criteria actuales

New allocation criteria for heart transplant in Spain (2023)

Urgency status 0: national priority

Status 0 A: maximum priority

Patients with 1 of the following:

- MCS without multiorgan failure criteria^a:
- VA-ECMO or total biventricular ST-VAD support^b
- Implanted or external dVAD with severe mechanical dysfunction or

cardioembolic complication

For pediatric recipients:

- Patients with any MCS (including VA-ECMO)
- Patients with congenital heart disease and need for MV and inotropic

agents not a candidate for MCS implantation

Status 0 B: national priority but after 0 A

Patients with multiorgan failure criteria^a and 1 of the following:

- Patients with total univentricular ST-VAD support^b
- Patients with refractory arrhythmic storm,^c without MCS

Urgency status 1: regional transplant priority, except for pediatric recipients, who also have priority over national elective transplants

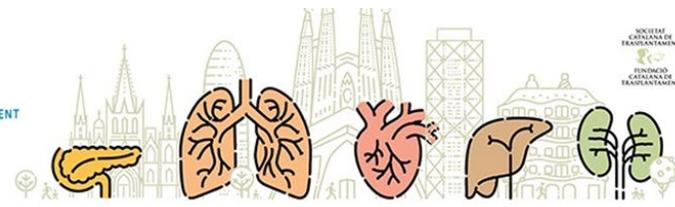
- dVAD complicated with severe device infection, recurrent gastrointestinal bleeding, severe aortic regurgitation, or severe right heart failure (inotropic support for at least 14 days)
- Properly functioning external dVAD
- Univentricular physiology in hospitalized adults whose stabilization requires continuous intravenous pharmacological therapy
- Fontan circulation in an adult with severe protein-losing enteropathy^d
- Hospitalized patients with hypertrophic or restrictive cardiomyopathies who are not candidates for MCS and whose stabilization requires continuous intravenous pharmacological therapy

For pediatric recipients:

- Patients with inotropic support with or without IMV who require hospital admission
- Fontan circulation with severe protein-losing enteropathy^d
- Restrictive cardiomyopathy with a PVRI > 6 WU/m²
- Patients who have spent more than 2 years on the elective waiting list after assessment by an advisory committee

Regional priority: priority after urgency status 1

- Hyperimmunized patients, with or without need for desensitization therapy and without a time limit who have a cPRA > 80% in 2 consecutive measurements at least 1 month apart, considering only a MFI > 5000 in those who can undergo virtual crossmatch testing



Evolución de la asistencia ventricular corta duración



Urgencia 0- Nacional



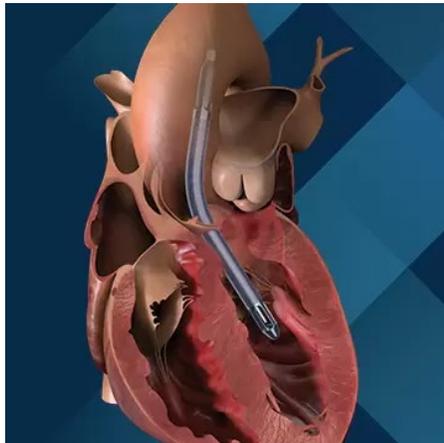
Urgencia 0- Nacional

2-7 días soporte.
10 d si paciente extubado



Urgencia 0A-0B Nacional

- Extubados si >7d soporte
- No fallo renal
- No miopatía.



Urgencia 0- Nacional



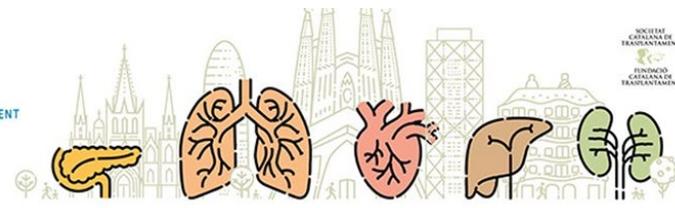
Urgencia 0- Nacional

Si no hay fallo multiorgánico.



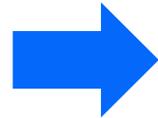
Evolución de la asistencia ventricular de larga duración





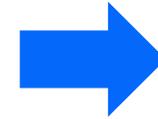
Evolución de la asistencia ventricular de larga duración

Urgencia 0
Dispositivos intracorpóreos con complicaciones.



Urgencia 1- Regional
Dispositivos intracorpóreos sin complicaciones.

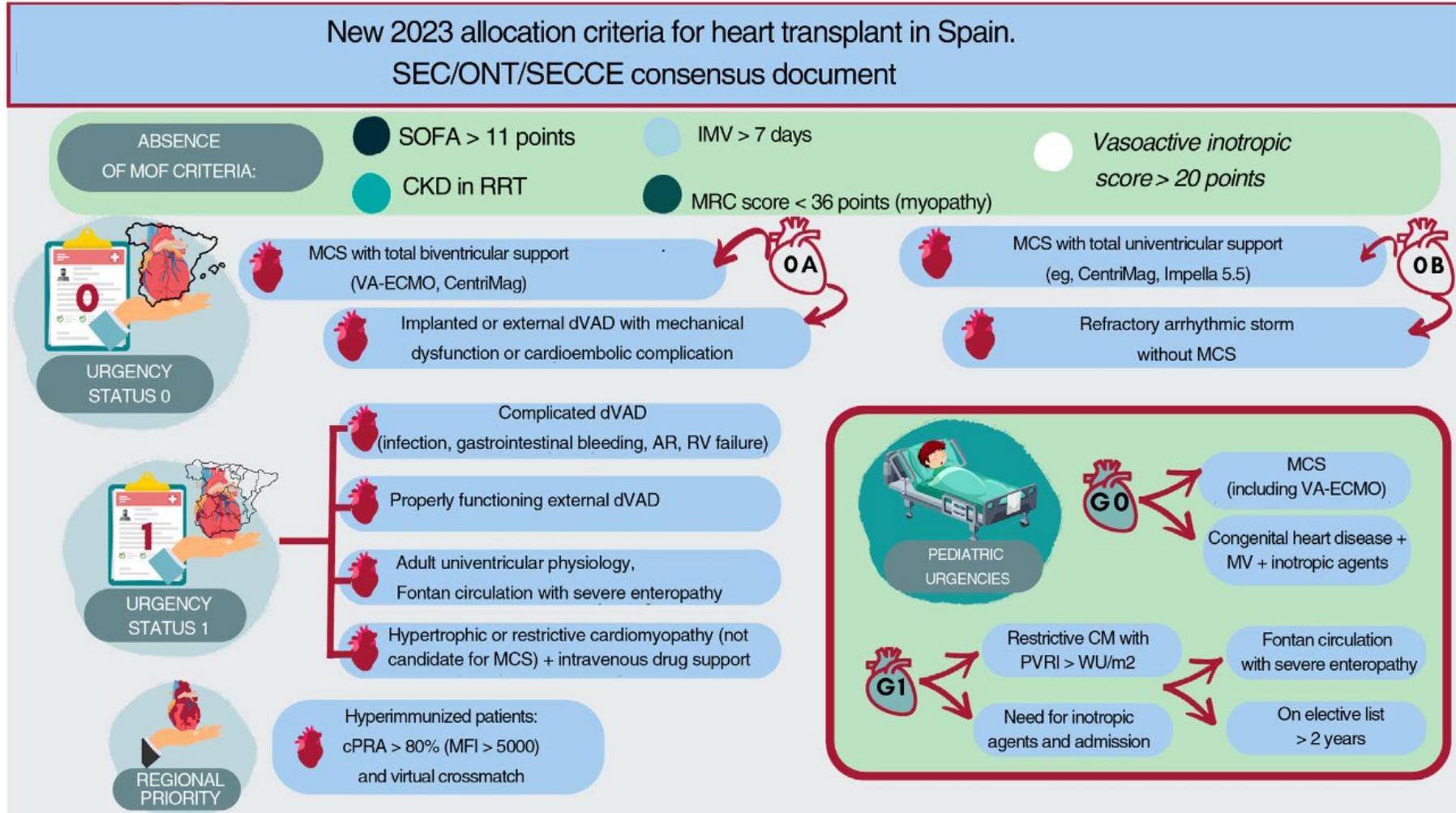
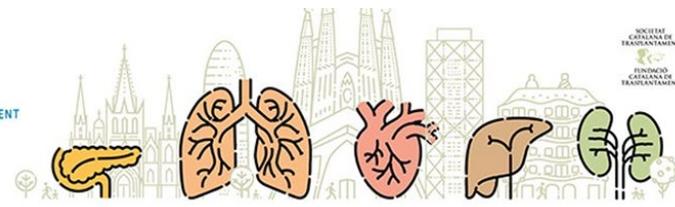
Urgencia 0
Dispositivos intracorpóreos con complicaciones graves (Trombosis o disfunción mecánica).

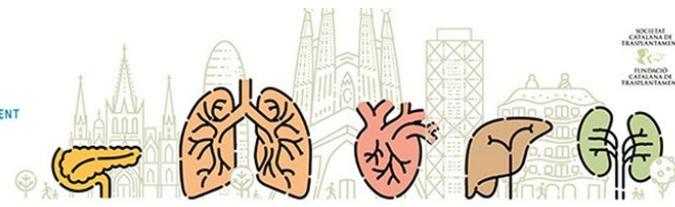


Urgencia 0A
Disfunción mecánica grave del dispositivo de larga duración.

Urgencia 1-Regional
Dispositivos intracorpóreos con complicaciones menores (Infección, sangrado digestivo, fallo VD).

Urgencia 1-Regional
Dispositivo de larga duración con complicaciones como sangrado digestivo, infección, insuficiencia aórtica, fallo VD.



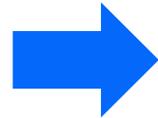


Poblaciones especiales

Urgencia 0

Pacientes pediátricos:

- Dependientes de inotrópicos
- Circulación de Fontan con enteropatía pierde-proteínas
- Cardiopatía restrictiva con >6UW

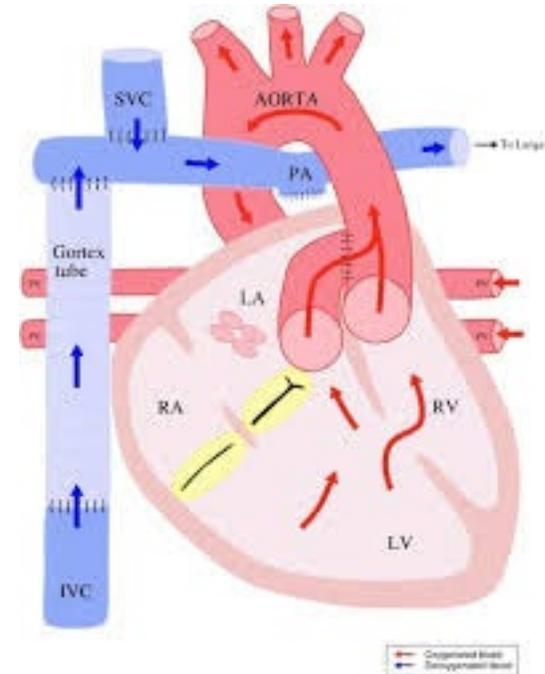


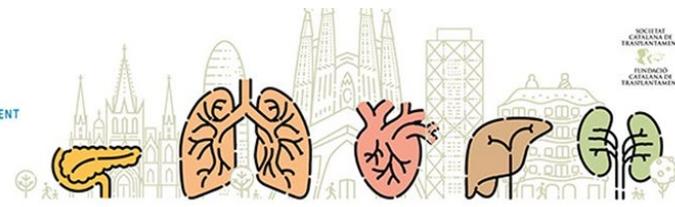
Urgencia 0

- Pacientes pediátricos bajo soporte circulatorio.
- Pacientes pediátricos con cardiopatía congénita bajo ventilación mecánica e inotrópicos.

Urgencia 1-Regional

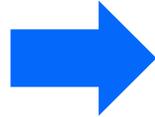
- Pacientes pediátricos ingresados dependientes de inotrópicos.
- Circulación de Fontan con enteropatía pierde- proteínas
- Miocardiopatía restrictiva >6UW.
- Pacientes con >2a en LE.



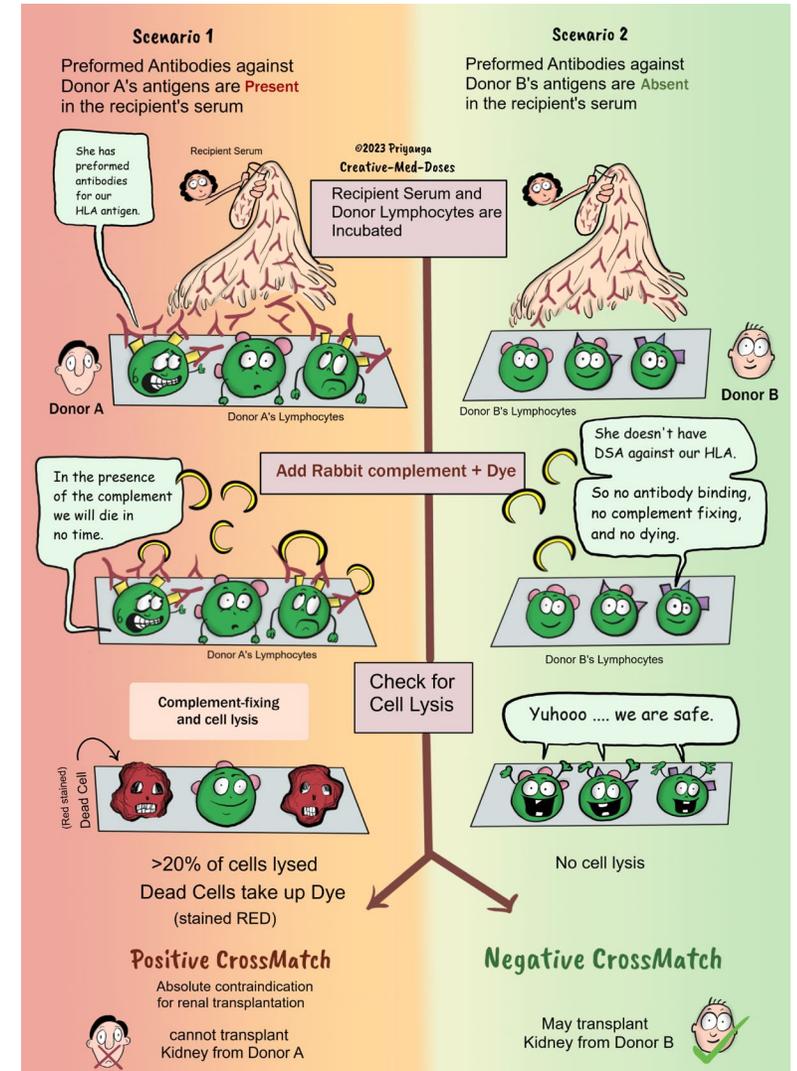


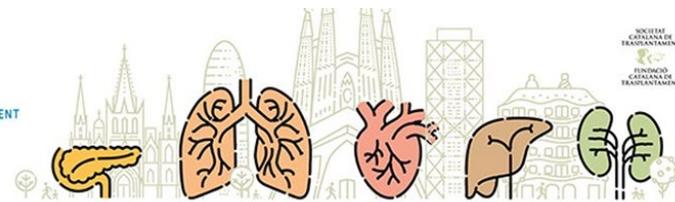
Poblaciones especiales

Urgencia 1- Regional
Pacientes con cPRA>50% y
posibilidad de cross-match.



Urgencia 1-Regional
Pacientes hipersensibilizados con o sin
tratamiento desensibilizador y con mas
de 2 determinaciones de cPRA>80%
(separadas 1 mes), considerando con
MFI >5000 a los que puedan tener
"cross-match" virtual.

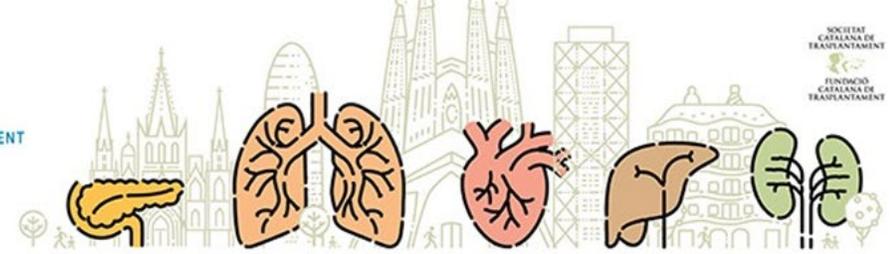




Conclusiones

- Los criterios de priorización buscan la equidad en la distribución de los órganos disponibles.
- Es fundamental buscar el equilibrio entre priorizar a los pacientes más críticos, evitando la futilidad.
- En el caso del corazón, los criterios de distribución se han ido modificando para mejorar los resultados, sobre todo, de los pacientes en soporte de corta duración.

18º CONGRESO
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UNIVERSITAT POMPEU FABRA
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Gracias

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