

SUPPLEMENTARY DATA

Specific definitions of adverse clinical events associated with mechanical circulatory support.

Infection: any culture-proven infection or empiric intravenous antibiotic therapy due to a high clinical suspicion of infection during temporary mechanical circulatory support (MCS).

Bleeding: any hemorrhagic event requiring transfusion of 4 or more packed red blood cell units, or leading to hemodynamic instability requiring vasopressors or an invasive intervention –eg, surgical exploration, percutaneous drainage, endoscopic therapy, or any intracranial bleeding, during temporary MCS.

Stroke: new onset of a permanent or transient neurologic deficit, which is presumably caused by cerebral ischemia or intracranial bleeding.

Non-CNS thromboembolism: any arterial embolic or thrombotic event, excluding acute stroke or cerebral transient ischemic attack, during temporary MCS, eg, limb ischemia, bowel infarction.

Venous thromboembolism: any episode of deep venous thrombosis or pulmonary embolism during temporary MCS.

Device dysfunction: failure of any component of the MCS device leading or potentially might lead to insufficient circulatory support or death or requiring device explantation or replacement.

Renal failure: acute renal dysfunction requiring dialysis, hemofiltration or ultrafiltration at any time during temporary MCS.

Open-chest cardiac surgery: in patients with surgically implanted devices, any cardiac surgical intervention requiring redo sternotomy during temporary MCS. This definition includes redo cardiac surgery in patients with surgically implanted devices.

Pleural effusion: any pleural effusion requiring thoracentesis or surgical drainage during temporary MCS.

Pericardial effusion: any pericardial effusion requiring pericardiocentesis or surgical drainage during temporary MCS.

Wound dehiscence: in patients with surgically implanted devices, persistent tissue separation at the surgical incision, with or without infection, that requires surgical correction.

Hemolysis: persistent laboratory findings of hemolysis, ie, unexplained anemia, high levels of lactate dehydrogenase and plasma-free hemoglobin, schistocytes, requiring transfusion of packed blood red cells, or a substantial reduction in device parameters, or device exchange, relocation or replacement.

Major adverse clinical event: first occurrence of stroke, device dysfunction, infection, or bleeding event.

Specific definitions of in-hospital postoperative outcomes following heart transplantation

Postoperative infection: any culture-proven infection or empiric intravenous antibiotic therapy due to a high clinical suspicion of infection after heart transplantation and before hospital discharge.

Postoperative renal failure: acute renal dysfunction requiring dialysis, hemofiltration, or ultrafiltration at any time after heart transplantation and before hospital discharge.

Open-chest cardiac reoperation: any cardiac surgical intervention requiring sternotomy after heart transplantation and before hospital discharge.

Excessive postoperative bleeding: postoperative bleeding after heart transplantation that requires transfusion of 10 or more packed red blood cells units or surgical exploration, or that causes hemodynamic instability requiring intravenous vasopressors.

Postoperative graft failure (left ventricular or biventricular): contractile dysfunction of the graft that occurs during the first 24 hours after transplantation, which is defined by current International Society for Heart and Lung Transplantation criteria as moderate or severe left ventricular (or biventricular) primary graft failure—left ventricular ejection fraction < 40% and/or a hemodynamic pattern with mean arterial pressure > 70 mm Hg lasting more than 1 hour, right atrial pressure > 15 mm Hg, cardiac index < 2 L/min/m² and pulmonary wedge pressure > 20 mm Hg, requiring high-dose vasoactive drugs (vasoactive-inotropic score > 10), intra-aortic balloon pump, or mechanical circulatory support.

Postoperative graft failure (right ventricular): contractile dysfunction of the graft that occurs during the first 24 hours after transplantation and is characterized by the presence of a preserved left ventricular ejection fraction (> 40%), together with a typical hemodynamic pattern with right atrial pressure > 15 mm Hg, cardiac index < 2 L/min/m² and pulmonary wedge pressure < 15 mm Hg, or the need for a RVAD.

Postoperative mechanical circulatory support: insertion of a temporary MCS device—ECMO, surgically implanted LVAD or BIVAD, or percutaneous LVAD—at any time after transplantation and before hospital discharge. This definition does not include intra-aortic balloon pump.

Table 1 of the supplementary data. Specific clinical criteria used to define waiting list priority levels in adult heart transplant candidates in the Spanish organ donor allocation system: changes from 2010 to 2020.

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

ECMO, extracorporeal membrane oxygenation. VAD, ventricular assist device. Adapted from data from Barge-Caballero E, Gonzalez-Vilchez F, Almenar-Bonet L, et al. Temporal trends in the use and outcomes of temporary mechanical circulatory support as a bridge to cardiac transplantation in Spain. Final report of the ASIS-TC study. *J Heart Lung Transplant*. 2022: S1053-2498(22)02202-1. doi: 10.1016/j.healun.2022.10.020.

^a Examples 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.

^b Examples 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.

^c *National priority* implies that these patients have priority over candidates listed with lower levels for being allocated the first suitable donor heart which was retrieved within the whole nation of Spain.

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

^e Specific 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 elapsed since device implantation before the patient is listed for emergency HTx.
- b. Patients must be free of multiorgan 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 free of multiorgan failure. Once this period has expired, the candidate is downgraded to *status 1*.

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

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

Table 2 of the supplementary data. Cumulative incidence of adverse clinical events associated with mechanical circulatory support in the study population according to the surgical approach used

	Full median sternotomy (n = 277)	Less invasive approach (n = 81)	P
<i>Need for blood transfusions</i>	231 (83.4)	35 (43.2)	<.001
<i>Infection</i>	129 (46.6)	29 (35.8)	.086
<i>Bleeding event</i>	110 (39.7)	2 (24.7)	.013
Thoracic	92 (33.2)	12 (14.8)	
Related to vascular access site	20 (7.2)	12 (14.8)	
Intracranial	4 (1.4)	0	
Gastrointestinal	9 (3.2)	4 (4.9)	
Other	21 (7.6)	4 (4.9)	
<i>Thromboembolic event</i>	42 (15.2)	14 (17.3)	.644
Cerebral transient ischemic attack	8 (2.9)	0	
Ischemic stroke	25 (9)	9 (11.1)	
Noncerebral arterial thromboembolism	5 (1.8)	1 (1.2)	
Venous thromboembolism	1 (0.3)	3 (3.7)	
Device thrombosis	7 (2.5)	3 (3.7)	
Intracardiac thrombosis	5 (1.8)	0	
<i>Cerebrovascular event</i>	33 (11.9)	9 (11.1)	.844
<i>Renal failure requiring dialysis</i>	63 (22.6)	13 (16)	.195
<i>Cardiac reoperation</i>	73 (26.4)	9 (11.1)	.004
<i>Surgical wound complication</i>	6 (2.2)	5 (6.2)	.066

<i>Hemolysis</i>	11 (4)	4 (4.9)	.702
<i>Pleural effusion or pneumothorax</i>	45 (16.2)	17 (21)	.321
<i>Pericardial effusion</i>	47 (17)	8 (9.9)	.120
<i>Device malfunction</i>	10 (3.6)	8 (9.9)	.023
Related to the pump	1 (0.4)	2 (2.5)	
Related to cannulae	9 (3.2)	6 (7.4)	

The data are expressed as No. (%).

Table 3 of the supplementary data. Characterization of episodes of device malfunction registered in the study

Institution code	Patient code	Type of support	Type of device failure	Clinical consequences	Treatment	Outcome of support
#3	#38	Left ventricular	Insufficient blood drainage through the inflow cannula placed in left atrium	Hemodynamic instability	Insertion of a second inflow cannula in left ventricle	Transplant
#4	#49	Biventricular	Massive thrombosis of inflow cannulae placed in right atrium and left atrium	Cardiac arrest	Replacement of both atrial cannulae	Death
#11	#9	Left ventricular	Thombosis of the inflow cannula placed in left atrium	Hemodynamic instability	Replacement of left atrial cannula	Transplant
#11	#55	Left ventricular	Insufficient blood drainage by the inflow cannula placed in left atrium	Refractory pulmonary congestion and hemodynamic instability	Insertion of a second inflow cannula in left ventricle	Transplant
#13	#35	Left ventricular	Thrombosis of the inflow cannula placed in left atrium and the outflow cannula placed in thoracic aorta	Hemodynamic instability	Replacement of left atrial and aortic cannulae	Transplant
#13	#48	Biventricular	Insufficient blood drainage by the inflow cannula placed in left ventricle	Refractory pulmonary congestion and hemodynamic instability	Insertion of a second inflow cannula in left atrium	Death
#13	#50	Left ventricular	Thrombosis of the inflow cannula placed in left atrium	Hemodynamic instability and cerebral embolism	Replacement of left atrial cannula	Death
#14	#80	Left ventricular	Thrombosis of the outflow cannula placed in femoral artery	Hemodynamic instability	Thrombectomy	Transplant
#14	#89	Left ventricular	Displacement of the outflow cannula placed in the axillary artery	Hemodynamic instability + bleeding	Re-insertion of the outflow cannula and transition to biventricular support	Death
#14	#91	Left ventricular	Thrombosis of the inflow cannula placed in left ventricle	Hemodynamic instability and cerebral embolism	Thrombolysis	Death

#14	#93	Biventricular	Thrombosis of the outflow cannula placed in axillary artery	Hemodynamic instability and visceral embolism	Thrombectomy (failed) and subsequent insertion of a new outflow cannula in femoral artery	Death
#14	#94	Left ventricular	Mechanical pump failure	Low flow (well tolerated)	Pump replacement	Transplant
#14	#109	Left ventricular	Migration of the inflow cannula placed in the left atrium (transeptal) to the right atrium	Hemodynamic instability and respiratory failure	Transition to CentriMag veno-arterial ECMO	Death
#17	#37	Left ventricular	Thrombosis of the inflow cannula placed in left atrium	Cardiac arrest	None	Death
#18	#46	Left ventricular	Electrical pump failure	Low flow (well tolerated)	Pump replacement	Transplant
#18	#69	Left ventricular	Displacement of the inflow cannula placed in left ventricle	Hemodynamic instability + bleeding	Re-insertion of the inflow cannula	Transplant
#18	#111	Biventricular	Thrombosis of the inflow cannula placed in left ventricle	Hemodynamic instability	Replacement of left ventricular cannula	Transplant
#20	#64	Left ventricular	Mechanical pump failure	Severe hemolysis leading to acute renal failure	Pump replacement	Transplant

Table 4 of the supplementary data. Postoperative outcomes during the in-hospital period following heart transplantation, according to the surgical approach used for preoperative device implantation

	Full median sternotomy (n = 236)	Less invasive approach (n = 67)	P
Postoperative infection	100 (42.4)	26 (38.8)	.601
Postoperative renal failure	65 (27.5)	16 (23.9)	.550
Postoperative graft failure	49 (19.5)	13 (19.4)	.987
Postoperative isolated right ventricular failure	35 (14.8)	5 (7.5)	.116
Postoperative mechanical circulatory support	37 (15.7)	11 (16.4)	.884
Excessive surgical bleeding	63 (26.7)	13 (19.4)	.224
Cardiac reoperation	33 (14)	10 (14.9)	.845
Duration of postoperative mechanical ventilation, ^a d	3 [9]	2.5 [6.25]	.371
Duration of postoperative ICU stay, ^a d	12 [19]	7 [10.25]	.012
Total duration of postoperative hospital stay, ^a d	32 [32]	25 [33.25]	.271
Postoperative 90-day mortality	38 (16.1)	14 (20.9)	.358
Postoperative 1-year mortality	50 (21.2)	18 (26.9)	.325

ICU, intensive care unit.

The data are expressed as No. (%) or median [interquartile range].

^aMissing values: length of postoperative mechanical ventilation (n = 14), length of postoperative ICU stay (n = 14), total length of postoperative stay (n = 14).