

Special article

Spanish Heart Transplant Registry. 32nd Official Report of the Heart Failure Association of the Spanish Society of Cardiology



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Article history:

Received 3 June 2021

Accepted 16 June 2021

Available online 9 September 2021

Keywords:

Heart transplant

Registry

Survival

ABSTRACT

Introduction and objectives: The present report updates the main characteristics and outcomes of heart transplants in Spain to 2020.

Methods: We describe the main features of recipients, donors, surgical procedure, and immunosuppression in 2020. We also analyze the temporal trends of these characteristics and outcomes (survival) for the period 2011 to 2019.

Results: In 2020, 278 heart transplants were performed (7.3% decrease vs 2019). The findings in 2020 confirmed previous observations of an increase in pretransplant sternotomy, a slight decrease in urgent transplants carried out with ventricular assist devices, a slight decrease in donor age, an increase in the use of allografts with previous arrest, and a decrease in ischemia time. Survival continued to improve in recent triennia, reaching 82.0% at 1 year in the period 2017 to 2019.

Conclusions: The slight decrease in the number of heart transplants performed in 2020 in Spain, most likely due to the SARS-CoV-2 pandemic, did not change the main characteristics of the procedure. No change was observed in the tendency to improved survival.

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Registro Español de Trasplante Cardíaco. XXXII Informe Oficial de la Asociación de Insuficiencia Cardíaca de la Sociedad Española de Cardiología

RESUMEN

Introducción y objetivos: Se actualizan las características y los resultados del trasplante cardíaco en España con los hallazgos de los procedimientos realizados en 2020.

Métodos: Se describen las características de receptores, donantes, procedimiento quirúrgico e inmunosupresión en el año 2020. Se analizan las tendencias de estas características y los resultados (supervivencia) en el último periodo 2011-2019.

Resultados: En 2020 se han realizado 278 trasplantes cardíacos (un 7,3% menos que el año anterior). Los hallazgos de 2020 confirman las tendencias previas a un aumento de la esternotomía previa, una discreta disminución del trasplante urgente realizado sobre todo con dispositivos de asistencia ventricular, una ligera disminución de la edad del donante con aumento del uso de donantes con parada cardíaca previa y una disminución del tiempo de isquemia. La supervivencia continúa mejorando en los últimos trienios y alcanza el 82,0% al primer año en el trienio 2017-2019.

Palabras clave:

Trasplante cardíaco

Registro

Supervivencia

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◇ The affiliations of the collaborators are listed in [Appendix 1](#).

Conclusiones: La ligera disminución en la actividad del trasplante cardiaco en España en 2020, en relación con la pandemia por SARS-CoV-2, no ha cambiado las principales características del procedimiento. No se detectan cambios en la tendencia a la mejora de la supervivencia de los pacientes trasplantados.

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INTRODUCTION

The Spanish Heart Transplant Registry (*Registro Español de Trasplante Cardíaco*) has published an annual report every year since 1991 on heart transplant activity and outcomes in Spain. This document includes all heart transplants performed in Spain since transplant activity began here in 1984. The report is hugely valuable for detecting problems and opportunities in transplant patient care and has established itself as a driver of clinical research.^{1–3}

The present article provides an update on the data from previous years, including the procedures performed in 2020, paying particular attention to the results obtained in the last decade.

METHODS

Patients and procedures

Data related to the characteristics of recipients, donors, surgical procedures, immunosuppression, and outcomes of all procedures are collected in a pre-established, Excel-based electronic database that can be accessed online. Updating this registry at least once per year is mandatory for participating centers. The Spanish Heart Transplant Registry is anonymized for patients, has been approved by an ethics committee, and is registered by the Spanish Society of Cardiology with the Spanish Ministry of Health as outlined in the Organic Law on Data Protection. The database is the property of the Spanish Society of Cardiology. Database maintenance, quality assurance, and statistical analysis are performed by an external contract research organization. The only significant change to the current database is related to the cutoff age for defining pediatric transplants, which is now 18 years, in line with the change made by the Spanish National Transplant Organization and is aimed at standardizing our data with those of international registries.

Currently, 19 centers have an active heart transplant program (table 1). Of these, 2 perform pediatric transplants alone (which is also performed in 4 other centers with an adult program) and 2 centers are equipped to perform cardiopulmonary transplants. The types of transplants performed in 2020 and in the entire series are summarized in table 2. With 278 transplants performed in 2020 (10.4% in recipients younger than 18 years and 26.9% in those older than 60 years), the Spanish Heart Transplant Registry includes 9060 procedures (figure 1). The outcomes from 2020 are compared with those from the previous decade segmented into 3-year periods (2011–2013, 2014–2016, and 2017–2019). The changes over time in the percentages of urgent transplants, the type of pretransplant circulatory support, and donor age were analyzed by year.

Statistics

Continuous variables are expressed as mean \pm standard deviation, whereas categorical variables are expressed as percentages. Differences among time periods were analyzed using a nonparamet-

ric test for temporal trends (Kendall τ) for categorical variables and ANOVA (analysis of variance) with polynomial fit for continuous variables. Survival curves were calculated using the Kaplan-Meier test and were compared using a log-rank test. $P < .05$ was considered statistically significant.

RESULTS

Recipient characteristics

In total, 278 transplants were performed in 2020, 7.3% less than in the previous year. The fall in the number of transplants was

Table 1

Centers participating in the Spanish Heart Transplant Registry from 1984 to 2020 (by order of first transplant performed)

1.	Hospital de la Santa Creu i Sant Pau, Barcelona
2.	Clínica Universitaria de Navarra, Pamplona
3.	Clínica Puerta de Hierro-Majadahonda, Majadahonda, Madrid (adult, cardiopulmonary)
4.	Hospital Marqués de Valdecilla, Santander
5.	Hospital Reina Sofía, Córdoba (adult and pediatric)
6.	Hospital Universitario y Politécnico La Fe, Valencia (adult and pediatric, cardiopulmonary)
7.	Hospital Gregorio Marañón, Madrid (adult and pediatric)
8.	Fundación Jiménez Díaz, Madrid (1989–1994)
9.	Hospital Virgen del Rocío, Sevilla
10.	Hospital 12 de Octubre, Madrid
11.	Hospital Universitario de A Coruña, A Coruña (adult and pediatric)
12.	Hospital de Bellvitge, L'Hospitalet de Llobregat, Barcelona
13.	Hospital La Paz, Madrid (pediatrics)
14.	Hospital Central de Asturias, Oviedo
15.	Hospital Clínic, Barcelona
16.	Hospital Virgen de la Arrixaca, El Palmar, Murcia
17.	Hospital Miguel Servet, Zaragoza
18.	Hospital Clínic, Valladolid
19.	Hospital Vall d'Hebron, Barcelona (pediatrics)
20.	Hospital de Gran Canaria Doctor Negrín, Las Palmas de Gran Canaria

Table 2

Spanish Heart Transplant Registry (1984–2020). Type of procedure

Procedure	2020	1984–2020
<i>De novo heart transplant</i>	269	8678
<i>Heart retransplant alone</i>	6	204
<i>Combined heart retransplant</i>	0	7*
<i>Combined de novo heart transplant</i>	3	171
Heart-lung	2	85
Heart-kidney	1	74
Heart-liver	0	12
<i>Total</i>	278	9060

* All renal transplants.

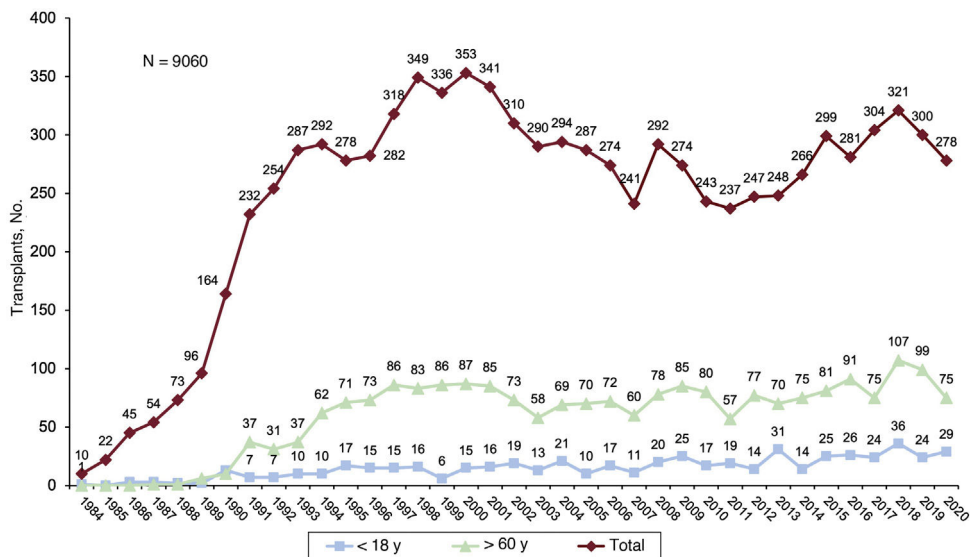


Figure 1. Annual number of transplants (1984-2020); total and by age group.

largely due to a decrease in April (figure 2). Recipient characteristics in 2020 and in the previous decade are summarized in table 3. At the time of transplantation, 10.2% of recipients were younger than 18 years and 26.9% were older than 60 years. The overall mean age was 48.7 years, similar to that of the previous decade; 33.1% were women. Almost one-third of the procedures were performed for heart diseases with etiologies other than ischemic or nonischemic dilated cardiomyopathy and in patients with previous cardiac surgery. In total, 39% of procedures were urgent (table 3); these procedures were largely performed with circulatory support via ventricular assist devices (figure 3). The percentage of urgent transplants has returned to the levels recorded at the start of the decade (about 38%), after a period (2013 and 2018) when it almost reached 50% (figure 4). In the last decade, there were no significant changes in the main characteristics of recipients, except an increase in the percentage of patients with previous cardiac

surgery and a change in the type of pretransplant circulatory support, with the almost complete disappearance of the balloon pump and an increase in ventricular assist devices, mainly continuous flow (figure 3).

Donor and surgical procedure characteristics

The characteristics of the donors and surgical procedures are summarized in table 4. Once again, a high percentage of transplants involved donors older than 45 years, which represented almost half of the patients. Nonetheless, after a peak in 2017, the subsequent years showed a slight decreasing tendency in the percentage of older donors (figure 5). As in previous years, the trends show a high percentage of transplants involving donors who had a preprocedural cardiac arrest or who died of stroke.

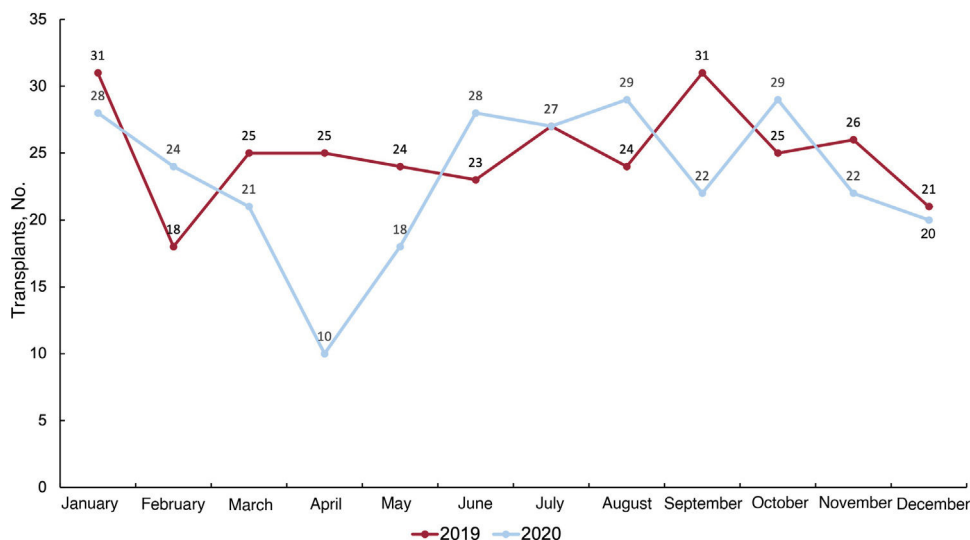


Figure 2. Number of transplants per month in 2019 and 2020.

Table 3
Recipient characteristics in the Spanish Heart Transplant Registry (2011-2020)

	2011-2013 (n = 732)	2014-2016 (n = 846)	2017-2019 (n = 925)	P for trend	2020 (n = 278)
Age, y	49.1 ± 17.1	49.7 ± 17.1	49.2 ± 17.7	.44	48.7 ± 17.9
< 18 y, %	8.7	7.7	9.1	.77	10.4
> 60 y, %	27.7	29.2	30.4	.58	27.0
Male sex	74.3	75.4	71.8	.17	66.9
BMI	24.6 ± 4.8	24.6 ± 4.5	24.8 ± 4.9	.27	24.7 ± 5.0
Underlying etiology, %				.99	
Nonischemic dilated	35.1	36.4	36.9		38.1
Ischemic	35.4	36.9	31.6		29.1
Other	29.5	26.7	31.6		32.7
PVR, UW	2.1 ± 1.2	2.2 ± 1.4	2.1 ± 1.3	.70	2.0 ± 1.2
Glomerular filtration rate, mL/min/1.73 m²	78.1 ± 36.2	79.4 ± 35.7	80.2 ± 37.8	.32	80.1 ± 41.0
Bilirubin > 2 mg/dL	16.2	17.1	15.2	.83	10.4
Insulin-dependent diabetes	19.3	22.8	20.1	.98	18.3
Moderate-severe COPD	8.7	11.5	10.4	.42	7.5
Previous infection	14.8	15.6	13.3	.96	14.8
Previous cardiac surgery	32.4	32.1	37.5	<.001	32.1
Type of transplant, %				.72	
Isolated transplant	95.8	96.3	96.7		96.8
Heart retransplant	2.2	1.8	2.2		2.2
Combined	1.9	1.9	1.1		1.0
Heart-lung	1.2	0.9	1.0		0.7
Heart-kidney	0.7	0.7	0.7		0.3
Heart-liver	0.1	—	0.3		-
Pretransplant mechanical ventilation	15.8	14.5	15.4	.55	12.2
Urgent transplant	41.4	46.3	43.0	.42	38.9
Pretransplant circulatory support				<.001	
No	65.6	61.0	59.3		68.4
Balloon pump	15.5	11.3	1.9		0.7
ECMO	6.4	10.8	10.1		7.3
Ventricular support	9.3	17.2	28.8		23.6

BMI, body mass index; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; PVR, pulmonary vascular resistance. Values are expressed as percentage or mean ± standard deviation.

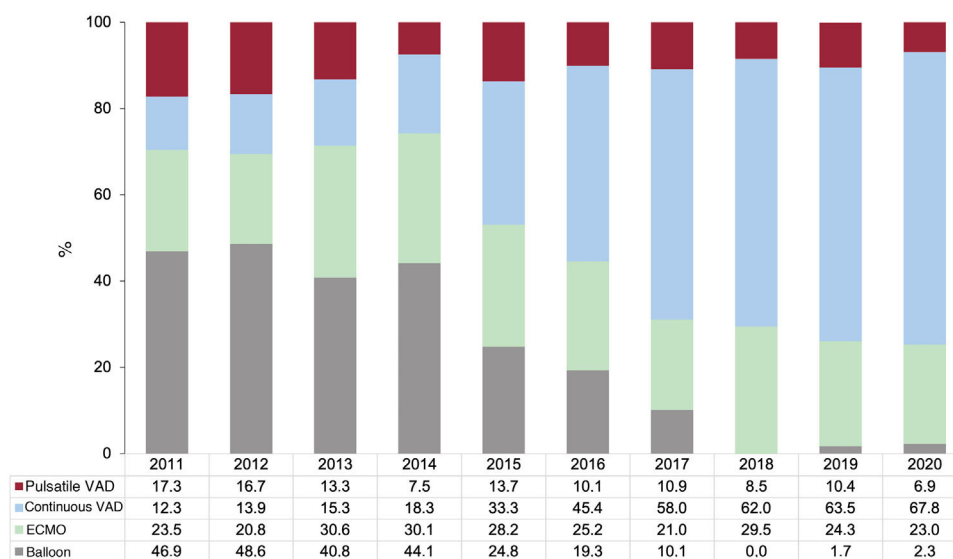


Figure 3. Distribution of the type of pretransplant circulatory support by year (2011-2020). ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device.

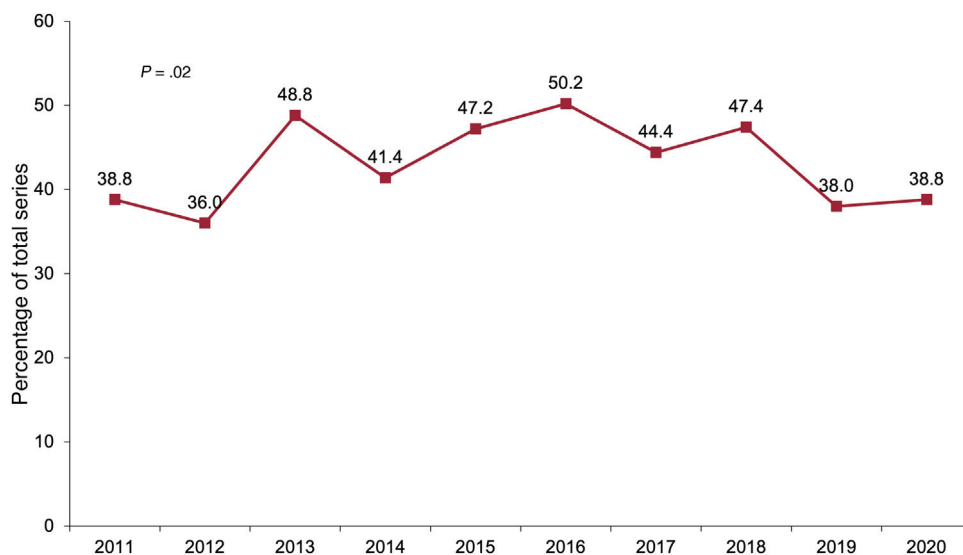


Figure 4. Annual percentage of urgent transplants in the total population (2011-2020).

Table 4

Donor characteristics and procedure times in the Spanish Heart Transplant Registry (2011-2020)

	2011-2013 (n=732)	2014-2016 (n=846)	2017-2019 (n=925)	P for trend	2020 (n=278)
Age, y	39.7 ± 14.6	43.4 ± 14.3	43.2 ± 15.4	< .001	42.2 ± 14.9
Age > 45 y	41.8	54.3	56.5	< .001	48.9
Male sex	61.2	58.9	62.0	.92	56.5
Female donor-male recipient	23.4	24.9	21.4	.47	19.8
Weight, kg	72.6 ± 18.6	74.7 ± 17.9	74.5 ± 19.8	.04	73.1 ± 19.1
Recipient/donor weight	0.94 ± 0.20	0.93 ± 0.19	0.93 ± 0.20	.68	0.93 ± 0.20
Recipient/donor weight > 1.2	9.4	6.9	8.4	.09	8.3
Recipient/donor weight < 0.8	21.0	22.0	23.9	.12	24.1
Cause of death				< .001	
Trauma	30.8	23.3	19.7		20.9
Stroke	57.0	63.0	64.8		66.9
Other	12.2	13.7	15.6		12.2
Pretransplant cardiac arrest ^a	12.4	16.6	18.7	< .001	20.9
Predonation echocardiogram ^b				.16	
Not performed	2.9	1.0	1.7		0.0
Normal	94.3	96.5	95.7		100.0
Mild generalized dysfunction	2.8	2.5	2.6		0.0
Ischemia time, min	210.9 ± 60.0	197.7 ± 72.2	197.0 ± 72.8	< .001	193.5 ± 70.8
≤ 120 min	8.9	12.5	17.9	< .001	16.2
120-180 min	19.4	22.5	19.8		22.3
180-240 min	42.9	38.3	34.7		40.6
> 240 min	28.8	26.7	27.7		220.9
Bicaval surgical technique	68.5	70.1	71.6	.77	79.7

Values are expressed as percentage or mean ± standard deviation.

^a Of 2725 transplants.

^b Of 2468 transplants.

The mean ischemia time has tended to fall in the last decade due to an increase in procedures with short ischemia times (≤ 120 minutes) and a decrease in interventions with moderately long times (180-240 minutes). In 2020, 4 of every 5 transplants were performed with a bicaval technique.

Immunosuppression

Induction immunosuppression in 2020 was in line with that observed in the previous 3-year period (2017-2019; table 5). The use of cyclosporin was very low (about 5%) and almost entirely

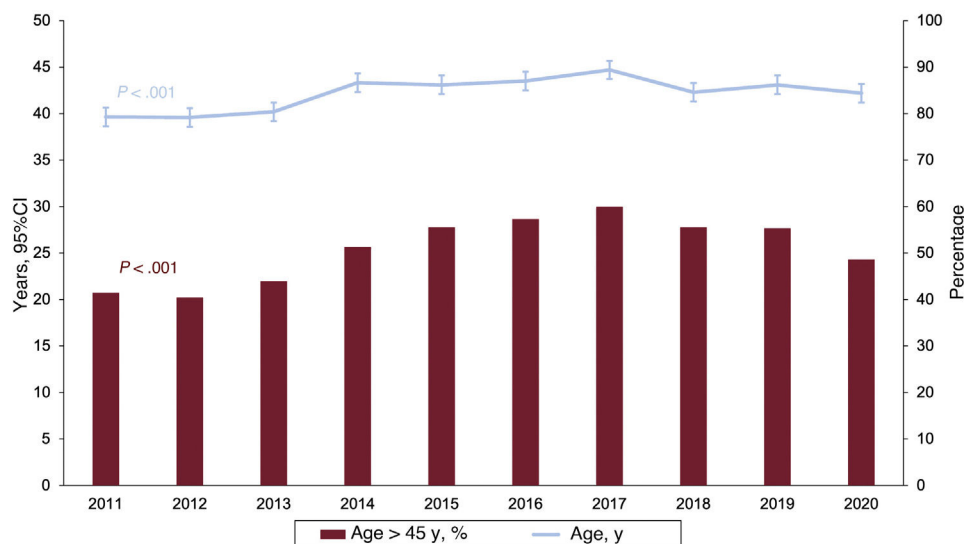


Figure 5. Annual changes in donor age and in the percentages of donors older than 45 years (2011-2020). 95%CI, 95% confidence interval.

Table 5

Induction immunosuppressive in the Spanish Heart Transplant Registry (2011-2020)

	2011-2013 (n = 732)	2014-2016 (n = 846)	2017-2019 (n = 925)	P for trend	2020 (n = 278)
<i>Calcineurin inhibitors</i>					
Cyclosporin	22.6	7.8	4.7	< .001	5.9
Tacrolimus	77.4	92.2	95.3	< .001	94.1
<i>Antiproliferative agents</i>					
Mycophenolate/mycophenolic acid	99.7	99.1	99.2	.95	98.9
Azathioprine	0.3	0.9	0.8	.95	1.1
<i>mTOR inhibitors</i>					
Sirolimus	0.4	0.3	0.4	.19	0.4
Everolimus	1.5	1.6	1.4	.41	0.4
<i>Corticoids</i>	98.6	98.5	98.5	.60	98.1
<i>Induction</i>					
No	10.6	12.6	15.1		15.9
ALG/ATG	2.5	3.3	4.3		2.3
Anti-CD25	86.4	83.7	79.3		81.8
Other	0.4	0.4	1.3		0.0

ALG, antilymphocyte globulin; anti-CD25, basiliximab, daclizumab; ATG, antithymocyte globulin. Values are expressed as percentages.

limited to patients with adverse reactions to tacrolimus. Likewise, the use of azathioprine was barely recorded in the last decade. More than 80% of patients received antibody-based pretransplant induction therapy, mainly basiliximab.

Survival

In the last decade, survival was about 80% in the first posttransplant year and was more than 70% at 5 years, which was significantly higher than that recorded in the entire previous

series (figure 6A). From the last decade, the most recent 3-year period (2017-2019) showed significantly higher survival vs the 2011 to 2013 period and nonsignificantly higher survival vs the 2014 to 2016 period (figure 6B). The 1-year survival rates in the 2011 to 2013, 2014 to 2016, and 2017 to 2019 periods were 77.7%, 78.9%, and 82.0%, respectively. As in previous years, the main univariable predictors of mortality were recipient age and urgent transplant, largely due to the higher mortality of recipients who received circulatory support with extracorporeal membrane oxygenation (table 6).

Table 6

Univariate analysis of survival by the baseline characteristics of the recipient, donor, and procedure (2011-2020)

	Hazard ratio (95%CI)	P
<i>Recipient age</i>		
< 18 y	1	
19-60 y	1.8 (0.9-1.8)	.07
> 60 y	1.9 (1.4-2.6)	< .001
<i>Type of transplant</i>		
Isolated transplant	1	
Combined transplant	1.4 (0.9-2.3)	.18
Retransplant	1.3 (0.8-2.1)	.27
<i>Donor age</i>		
≤ 45 y	1	
> 45 y	1.1 (0.9-1.2)	.27
<i>Transplant urgency</i>		
Elective	1	
Urgent	1.2 (1.0-1.4)	.03
<i>Type of support</i>		
No support	1	
Balloon pump	0.9 (0.7-1.2)	.47
ECMO	1.6 (1.3-2.0)	< .001
Ventricular support	1.2 (0.9-1.4)	.10

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

Causes of death

In the first 5 posttransplant years, almost half of deaths were due to primary graft failure or infection (figure 7), with primary graft failure concentrated in the first posttransplant month and infection in the remainder of the first year. Acute graft rejection was a major cause of death between the first and fifth post-transplant year (16.4%), only surpassed by combined sudden cardiac death/graft vascular disease (25.4%) and cancer (20.0%). These trends are similar to those recorded in the most recent registry analyses.

The trends in the posttransplant causes of death were analyzed only for those occurring in the first year, because complete information was available from this period for all patients (figure 8). The last decade showed a nonsignificant tendency for a decrease in primary graft failure as the cause of death, particularly since 2013, with infection and rejection maintained. Death due to rejection fell by almost half in the 2017 to 2019 period vs the previous 3-year period, although the difference was not significant due to the small number of events.

DISCUSSION

In all settings and particularly in the health care field, 2020 has been heavily affected by the impact of the SARS-CoV-2 pandemic. Heart transplant activity has been no exception, with the number of procedures falling in 2020 vs 2019. Nonetheless, it must be highlighted that this decrease can be considered slight and, furthermore, generally limited to April and May (the latter month with less intensity), given that the activity recovered in the following months. We believe these data to be highly valuable, particularly given that transplant activity greatly depends on the activity of intensive care units, and to undoubtedly reflect the efficacy of a mature system with a very strong involvement of all of its participants.

The clinically most relevant trends in the last 10 years regarding recipient characteristics, which seem to be confirmed by the data from 2020, are related to the increased percentage of patients with previous sternotomy, a factor with prognostic implications,⁴ and the increased percentage of transplants performed with ventricular assist devices, which specifically require sternotomy. The latter has been accompanied by the almost complete disappearance of the balloon pump as a pretransplant circulatory support device. In addition, the percentage of transplants performed under urgent conditions has shown a biphasic behavior in the last decade, with a growing tendency until 2016 and a decrease since then, particularly since 2018. Undoubtedly, these trends have been influenced by the modification of the inclusion criteria for the urgent transplant list from the middle of 2017. A similar biphasic behavior with a less obvious explanation was observed for donor age, with a peak in 2017 and a slow progressive decrease until 2020. This finding may have a positive impact on the prognosis of our patients, particularly in the mid- and long-term.² A variable related to donor age is cause of death, with stroke being the leading cause of death. However, this variable has exhibited a tendency for stabilization in the last two 3-year periods, which is clearly related to the variations in donor age. Finally, the last decade has shown an increase in the number of procedures performed with very short ischemia times (≤ 120 minutes), due to decreases in those with moderately long times (180-240 minutes), which can at least partly explain the improved survival outcomes found in our analysis.¹

As in previous reports,^{5,6} we once again observed a significant trend for improved survival, which, in the last 3-year period analyzed, exceeded 80% in the first year. This improvement must

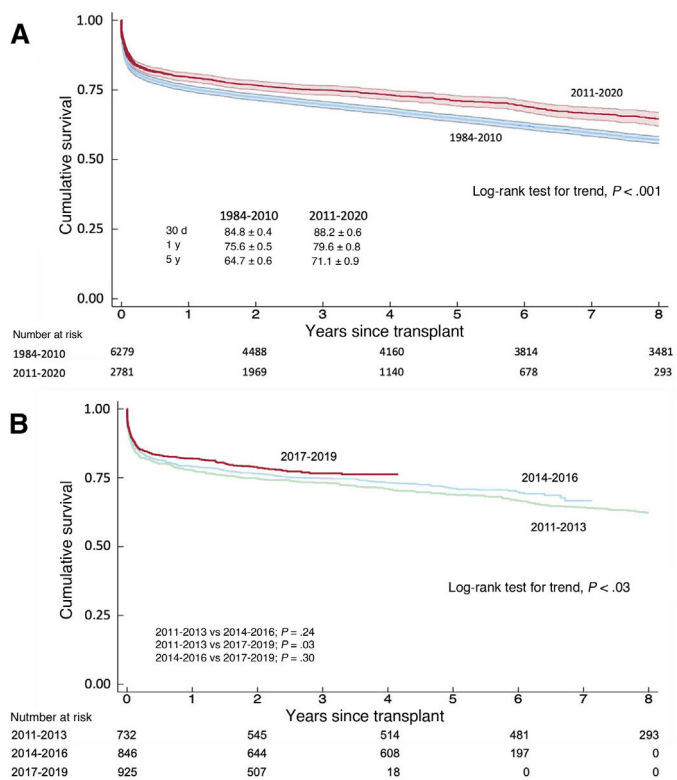


Figure 6. A: comparison of survival curves between the 2011 to 2020 and 1984 to 2010 periods. B: comparison of survival curves in the 2011 to 2019 period by 3-year period.

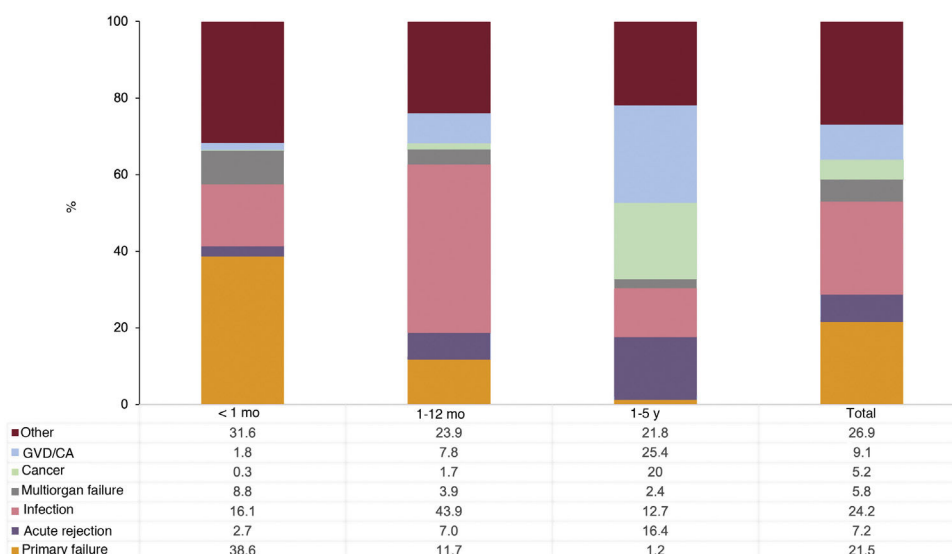


Figure 7. Main causes of death according to time since transplantation in the 2011 to 2020 period.

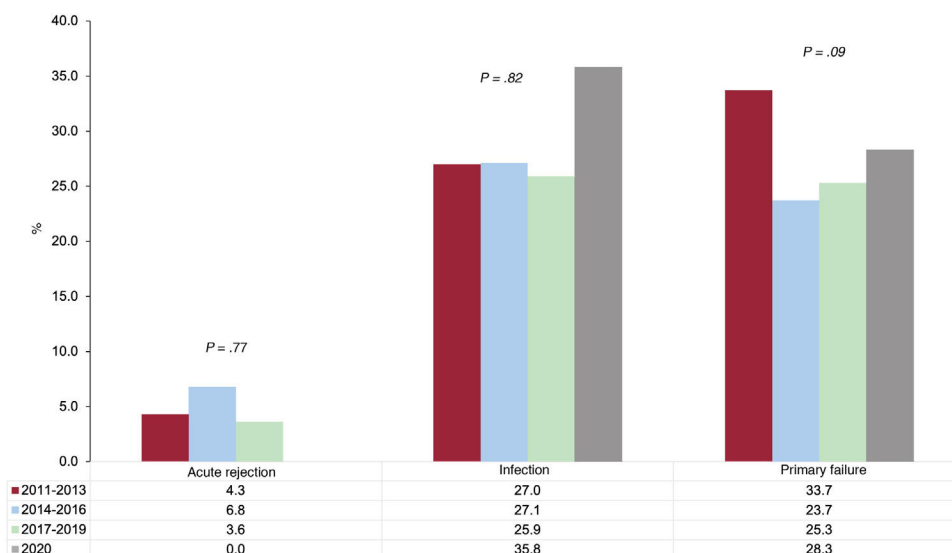


Figure 8. Changes over time in the main causes of death in the first post-transplant year in the 2011 to 2020 period by 3-year period.

be attributed to the slow progressive change in donor, recipient, and surgical procedure characteristics, as well as, highly probably, the familiarization of transplant teams with the increasingly complex clinical environment of contemporary heart transplantation. Nonetheless, a deeper investigation of this topic is impeded by the nature of the present report. Finally, in future reports, it will be possible to evaluate the possible impact of the SARS-CoV-2 pandemic on our results.

CONCLUSIONS

Heart transplant activity fell slightly in 2020 due to the SARS-CoV-2 pandemic. Nonetheless, the clinical results continue to show a tendency for progressive improvement.

FUNDING

The present article did not receive funding.

AUTHORS' CONTRIBUTIONS

All authors have contributed to the data collection, have critically revised the manuscript, and have approved its publication in the current form. F. González-Vílchez was responsible for the preparation of the manuscript.

CONFLICTS OF INTEREST

None.

APPENDIX 1. COLLABORATORS IN THE SPANISH HEART TRANSPLANT REGISTRY 1984-2020

Center	Collaborators
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Hospital Universitario Virgen del Rocío, Sevilla	Diego Rangel-Sousa, Antonio Grande-Trillo
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Hospital Clínic Universitari, Barcelona	María Ángeles Castel, Marta Ferrero
Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona	Nicolás Manito, Carles Díez, Elena García-Romero, Josep Roca
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Hospital Universitario Puerta de Hierro-Majadahonda, Majadahonda, Madrid	Javier Segovia-Cubero, Francisco Hernández-Pérez, Cristina Mitroi, Mercedes Rivas-Lasarte
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